

NeuroMetrix, Inc.  
Form 10-K  
March 14, 2008

Use these links to rapidly review the document

[NEUROMETRIX, INC. ANNUAL REPORT ON FORM 10-K YEAR ENDED DECEMBER 31, 2007 TABLE OF CONTENTS](#)

[INDEX TO FINANCIAL STATEMENTS NeuroMetrix, Inc. Years ended December 31, 2007, 2006 and 2005](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2007

OR

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

For the transition period from \_\_\_\_\_ to  
Commission File Number 000-50856

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**04-3308180**  
(IRS Employer Identification No.)

**62 Fourth Avenue Waltham, Massachusetts**  
(Address of principal executive offices)

**02451**  
(Zip Code)

**(781) 890-9989**

(Registrant's telephone number, including area code)

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

<b>Title of each class</b>	<b>Name of exchange on which registered</b>
Common Stock, \$0.0001 par value per share	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	
Securities Registered Pursuant to Section 12(g) of the Act	

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a  
smaller reporting company)

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

As of June 30, 2007 the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$99,334,533 based on the closing sale price of the common stock as reported on the NASDAQ Global Market on June 30, 2007. For this computation, the registrant has excluded the market value of all outstanding shares beneficially owned by any director, executive officer or person known to the registrant to beneficially own 10% or more of the registrant's common stock; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of March 7, 2008, there were 13,690,134 shares of Common Stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2008 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, 2007, are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

---

---

**NEUROMETRIX, INC.  
ANNUAL REPORT ON FORM 10-K  
YEAR ENDED DECEMBER 31, 2007**

**TABLE OF CONTENTS**

		<b>Page No.</b>
<b>Part I</b>		
<u>Item 1.</u>	Business	2
<u>Item 1A.</u>	Risk Factors	28
<u>Item 1B.</u>	Unresolved Staff Comments	46
<u>Item 2.</u>	Properties	47
<u>Item 3.</u>	Legal Proceedings	47
<u>Item 4.</u>	Submission of Matters to a Vote of Security Holders	47
<b>Part II</b>		
<u>Item 5.</u>	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	48
<u>Item 6.</u>	Selected Financial Data	50
<u>Item 7.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	52
<u>Item 7A.</u>	Quantitative and Qualitative Disclosures About Market Risk	75
<u>Item 8.</u>	Financial Statements and Supplementary Data	76
<u>Item 9.</u>	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	76
<u>Item 9A.</u>	Controls and Procedures	76
<u>Item 9B.</u>	Other Information	77
<b>Part III</b>		
<u>Item 10.</u>	Directors, Executive Officers and Corporate Governance	78
<u>Item 11.</u>	Executive Compensation	78
<u>Item 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
<u>Item 13.</u>	Certain Relationships and Related Transactions, and Director Independence	78
<u>Item 14.</u>	Principal Accountant Fees and Services	78
<b>Part IV</b>		
<u>Item 15.</u>	Exhibits, Financial Statement Schedules	79
<u>SIGNATURES</u>		82

**PART I**

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

**ITEM 1: BUSINESS**

**Our Business An Overview**

We design, develop and market proprietary medical devices used to help physicians diagnose and treat diseases of the nervous system such as neuropathies, which are disorders of the peripheral nerves and parts of the spine, and neurovascular disorders such as diabetic retinopathy. We are also developing medical devices designed to be used to provide regional anesthesia and pain control. To date, our focus has been on products that help physicians with the diagnosis or detection of neuropathies and neurovascular disorders. We have two product lines cleared by the United States Food and Drug Administration, or FDA, that are currently being marketed primarily to physicians and clinics, including the NC-stat System for the assessment of neuropathies and the DigiScope for the detection of eye disorders such as diabetic retinopathy.

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, or CTS, 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. The NC-stat System has been on the market since May 1999 and is used in over 5,500 physicians' offices and clinics in the United States. Over one million patients have had nerve conduction tests performed using the NC-stat System. We are currently developing a traditional nerve conduction system, the ADVANCE System, designed to help physicians with the diagnosis of neuropathies and have filed a 510(k) application with the FDA. The ADVANCE System is expected to provide physicians with even greater clinical functionality and is expected to be marketed to specialists such as neurologists as well as primary care physicians.

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 or their clinical staff. 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 a point-of-service product offering such as the NC-stat System could 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 CTS markets in the aggregate could be greater than 9.5 million annual patient tests, estimated to be more than \$1.0 billion annually in the United States. We believe there is potentially a large market opportunity for our nerve conduction product line in the international markets and we recently launched the NC-stat System in the U.K. on a limited basis.

Diabetic retinopathy is a common neurovascular complication of diabetes and is the leading cause of blindness among working age adults. On December 26, 2007, we acquired substantially all of the assets and assumed certain liabilities of EyeTel Imaging, Inc., or EyeTel, whose product, the DigiScope, is a retinal imaging system designed for use at the point-of-service in primary diabetes care physician offices and optometry clinics for the detection of diabetic retinopathy and certain other eye disorders. Previously, we had obtained an exclusive sales and marketing license to the DigiScope from EyeTel for the primary diabetes care market. If abnormalities are detected using the DigiScope, the patient can then be referred to an ophthalmologist for treatment if deemed necessary. It is recommended by the American Diabetes Association, or ADA, that all patients with diabetes receive an annual dilated eye examination, which may be performed using the DigiScope, to determine if there are any abnormalities. There are approximately 21 million people in the United States with diabetes according to the ADA and only approximately 50% comply with the recommendation to have an annual eye examination. We believe that a product such as the DigiScope in primary diabetes care physician offices and optometry clinics could potentially lead to an increase in the level of testing and result in the earlier detection of eye disorders in patients with diabetes. Currently, there are approximately 190 physician practices and clinics in the United States using the DigiScope.

Our goal is to become the leading provider of innovative, proprietary, high gross margin medical devices that provide comprehensive solutions to help physicians with the diagnosis and treatment of patients with diseases of the nervous system, including neuropathies, and neurovascular disorders and provide solutions for regional anesthesia and pain control. We believe that our core technologies can be leveraged into additional diagnostic and therapeutic products.

One of the areas we are leveraging our core technology into is the minimally invasive delivery of commercially available drugs and other therapeutic agents using a proprietary delivery system for regional anesthesia, pain control and the treatment of neuropathies. We are currently in the clinical stage of development of a nerve localization system, which we refer to as NAVIGATOR, and expect to submit a 510(k) application to the FDA in the second half of 2008.

We are also pursuing product development efforts focused on neural repair and regeneration. We are in the early stages of developing a product for the treatment of peripheral nerve injuries by promoting nerve regeneration through electrical stimulation. We are pursuing these product development efforts through a joint venture established in February 2008 with Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics, a medical device company focused on the treatment of neurological conditions. This product is in the preclinical stage of development. In November 2007, prior to the formation of the joint venture, we entered into a strategic alliance with Cyberkinetics through an investment of \$2.5 million in shares of Cyberkinetics common stock. (See Strategic Alliance.)

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

We sell our products through a sales force of approximately fifty regional sales managers, five regional sales directors and a national sales director for sales of our products to physician offices and clinics.

Our revenues declined 19.2% to \$44.6 million in 2007, after increasing 61.1% to \$55.2 million in 2006 from \$34.3 million in 2005. The decline in revenues was primarily attributable to challenges experienced with reimbursement of nerve conduction studies performed using the NC-stat System. The American Medical Association, or AMA, CPT Editorial Panel ("the CPT Panel") has been reviewing the reimbursement coding for nerve conduction studies and recently met in February 2008 to consider various proposals set forth by a work group formed by the CPT Panel. At this meeting, we believe that the CPT Panel approved a new Category III CPT Code for nerve conduction studies performed using equipment with certain automated features such as the NC-stat System. Unless we are able to successfully challenge this decision, a new Category III CPT Code would likely be published in July 2008 and become effective in January 2009. If the CPT Panel ultimately implements a Category III CPT code, this is likely to have a material and adverse impact on our business given that it is likely to result in limited or no Medicare reimbursement since there is the potential that no specified reimbursement values would be assigned to such codes and they do not automatically appear on the Medicare physician fee schedule. This could also adversely impact reimbursement by other third party payers and could have an adverse and material impact on our revenues and results of operations.

The majority of our revenues in 2007 were derived from sales of the NC-stat System and approximately 88% of our revenues were attributable to sales of the disposable biosensors that physicians use to perform nerve conduction tests with our NC-stat System. We recorded a net loss of \$8.4 million in 2007 compared with net income of \$4.3 million in 2006 and net income of \$249,300 in 2005. Our net loss in 2007 was a result of the decline in revenues and an increase in operating expenses.

### Neuropathies

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

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

*Low back pain.* Low back pain can have many causes. When low back pain has a neurological source, it is often focal in nature and associated with pain that radiates from the lower back region into the leg, called sciatica. In some cases, the patient may also experience loss of

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

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

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

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

### **Limitations of Traditional Methods for Detecting Neuropathies**

Neuropathies have traditionally been evaluated using clinical and diagnostic methods but there are limitations to these methods. The clinical examination is qualitative rather than quantitative, it is subjective and it does not often detect pre-clinical or early stage disease. Traditional nerve conduction studies and NCS/nEMG procedures are performed under a referral to a neurologist and this referral process can result in delays and inconvenience for the patient, higher expense and loss of control of the patient's care by the referring physician. Traditional procedures are complex and are therefore only performed by a small number of physicians, such as neurologists, and the testing is therefore not generally widely available. In addition, traditional procedures may be painful if an nEMG procedure is involved since the physician will insert needles into the patient's muscles often in close proximity to the site of pain.

### **NeuroMetrix Solution/NC-stat System**

The NeuroMetrix point-of-service neurodiagnostic solution is known as the NC-stat System. The NC-stat System is comprised of: (1) disposable single use biosensors that are placed non-invasively on the patient's body, (2) the NC-stat device and related components and (3) the NC-stat docking station, an optional device that enables the physician to transmit data to our onCall Information System. The 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 provides raw data and information for the physician to consider along with the clinical examination of the patient and other information in diagnosing a patient's condition. The NC-stat System assists the physician in rapidly and accurately examining the patient in a manner that may be cost-effective for the patient and third-party payer.

*Biosensors.* The biosensors are single use, self-adhesive, nerve-specific, electrodes that are placed on the body and connected to the NC-stat device. Through the use of a specialized gel and a digital thermometer, both of which are contained within the biosensors, nerve signals are converted to electronic data that can be received and displayed by the NC-stat device. Currently, we sell biosensors for assessment of nerve function in the median and ulnar nerves in the upper extremities for the diagnosis of CTS and for assessment of the nerve function in peroneal, tibial and sural nerves in the lower extremities for the diagnosis of DPN and low back conditions.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

The biosensors are designed to be positioned according to common anatomical landmarks with a configuration that facilitates correct placement. We designed the biosensors so that they could be applied with minimal training by members of a physician's clinical staff. In a typical nerve conduction study, multiple nerves are evaluated and multiple biosensors are used according to general guidelines established by the Center for Medicaid and Medicare Services, or CMS, and physician associations.

*NC-stat device.* The NC-stat device is designed for efficient use by the physician or a member of the physician's clinical staff. The NC-stat device can only be operated with our biosensors. This instrument customizes and calibrates the test for each patient, analyzes neurophysiological signals collected from the biosensor and displays the pertinent results on an liquid crystal display, or 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 NC-stat device 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 device and the biosensors. Another device for the assessment of potential neuropathic conditions, the ADVANCE System, is under 510(k) review by the FDA.

*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 device via telephone line, such as those used by facsimile machines, to the onCall Information System that we maintain. The data is automatically processed by the onCall Information System and stored in a central database, and a detailed computer generated report is created for each patient that is then sent to the physician via facsimile or e-mail in three to four minutes on average. The report includes the raw waveform data, comparisons to an age-adjusted and height-adjusted normal range population, study reference table and text summaries of the study, which provides additional information and a convenient summary of the study to assist the physician in the diagnosis of the patient. Although the study data presented in the onCall Information System report can be generated manually by the physician using the numerical measurements displayed by the NC-stat device, the report is a convenient and fast adjunct. Whether using the information from the onCall Information System report or the NC-stat device display, the actual clinical interpretation of the NC-stat System 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 three million individual nerve tests within the onCall Information System database. We believe that this information provides us with the ability to continually improve our products and provide our customers with a very high level of customer service and value. During the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) filing relating to portions of the onCall Information System currently in use. Depending on the outcome of the FDA's review, we may be required to modify or remove the aspects of the onCall Information System that are under review, which may make the NC-stat System more difficult to use by physicians. We are currently in the process of responding to the second additional information request that we have received from the FDA relating to this filing.

Recognizing the opportunity created by what we believe are the limitations of traditional diagnostic methods coupled with the availability of current and potential new treatments for certain neuropathies,



## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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 assists physicians in performing rapid and accurate examinations that may be 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 have 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, including primary care and specialist physicians. By allowing nerve conduction studies to be performed in the primary care or specialist physician's office, the patient can avoid the expense and inconvenience of a referral visit. Additionally, the NC-stat System enables primary care and specialist 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 could potentially 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 accuracy. 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. When an nEMG procedure is also performed, the cost can be even higher.

*Requires minimal capital investment.* We sell the NC-stat System, with equivalent technical specifications to the more expensive traditional instruments, for a list price of approximately \$6,000, compared with \$15,000 to \$40,000 for the cost of traditional NCS/nEMG equipment. We believe the lower capital cost of the NC-stat System will aid in the expansion of nerve conduction studies beyond neurologist offices.

*Simple to operate.* The biosensors are designed for ease in placement, which allows a wide range of physician office personnel to administer the technical portion of the study under the supervision of a physician. The NC-stat device 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 results are accurate and reliable. We believe that, in combination, these features allow accurate and reliable nerve conduction studies to be performed in 15 to 30 minutes on average.

*Patient-friendly, non-invasive procedure.* The NC-stat System allows for reduced patient discomfort during the nerve conduction study by minimizing the magnitude of the electrical stimulus to the nerve via a proprietary patient-specific calibration procedure. We believe that 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 NCS/nEMG procedure. This saves the patient the discomfort, stress and risk of this invasive procedure.

### **Neurovascular Disease**

Diabetic retinopathy is a neurovascular disease and is one of the most serious complications of diabetes. Diabetic retinopathy is the leading cause of blindness in adults age 20 to 65. Microvascular complications caused by diabetes can lead to retinopathy and if untreated can result in vision loss and even blindness. Twenty years after diagnosis nearly all patients with Type I diabetes have some degree

of diabetic retinopathy and 60% of all patients with Type II diabetes have some degree of retinopathy, even though many may not have symptoms.

Over time, diabetes affects the circulatory system of the retina. The earliest phase of the disease is known as background diabetic retinopathy. In this phase, the arteries in the retina become weakened and leak, forming small, dot-like hemorrhages. These leaking vessels often lead to swelling or edema in the retina and decreased vision. The next stage is known as proliferative diabetic retinopathy. In this stage, circulation problems cause areas of the retina to become oxygen-deprived, or ischemic. New, fragile, vessels develop as the circulatory system attempts to maintain adequate oxygen levels within the retina. This is called neovascularization. Unfortunately, these delicate vessels hemorrhage easily. Blood may leak into the retina and vitreous, causing spots or floaters, along with decreased vision. In the later phases of the disease, continued abnormal vessel growth and scar tissue may cause serious problems such as retinal detachment and glaucoma. Ultimately, if untreated, diabetic retinopathy can lead to loss of vision or blindness.

The traditional approach to the detection of retinopathy in patients with diabetes is a referral to an eye specialist, such as an ophthalmologist, for an assessment. In spite of the recommendation by the ADA that all patients with diabetes have an annual dilated eye examination, only approximately 50% of these patients are actually complying and being tested on an annual basis. Treatments such as laser surgery are available for patients diagnosed with diabetic retinopathy and the earlier the condition is detected the more likely a favorable outcome.

### **The DigiScope**

The DigiScope was developed by EyeTel in clinical partnership with the Wilmer Ophthalmological Institute at Johns Hopkins University for the risk assessment of retinopathy. We acquired substantially all of the assets and assumed certain liabilities of EyeTel, including all rights to the DigiScope, on December 26, 2007.

The DigiScope has a fully integrated digital fundus camera which allows for the capture of high quality dilated retinal images in approximately ten minutes. The test is performed in primary care physicians' offices, optometry clinics and vision centers and the images obtained are sent electronically to the Wilmer EyeTel Reading Center and are read by retinal specialists. The results are reviewed by the physician or optometrist and a referral will be made to the eye specialist, such as an ophthalmologist, if clinically relevant abnormalities are detected. The test using the DigiScope can be easily administered by the physician's clinical staff under the supervision of the physician and requires minimal training. The DigiScope system is self-prompting, has a touch screen and audible cues for simple operation. The DigiScope examination is acceptable as an annual diabetic eye examination under the Health Plan Employer Data and Information Set, or HEDIS, 2004 technical specifications.

### **Market Opportunity**

#### *NC-stat System*

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 that the availability of point-of-service nerve conduction studies 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. The most common indication for which the NC-stat System has been used historically is CTS. CTS represented approximately 40% of total nerve conduction testing by our customers in 2007, while DPN and low back pain represented the balance of the testing performed. 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 CTS markets in the aggregate could be greater than 9.5 million annual patient tests, estimated to be more than \$1.0 billion annually for our disposable biosensors, in the United States. However, market size is difficult to predict, and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of a point-of-service product offering such as the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this potential market size. We believe a potential opportunity in the international markets exists for the NC-stat System. We recently launched the NC-stat System into the U.K. on a limited basis through a local distributor of medical device products.

#### *DigiScope*

The high level of incidence of diabetic retinopathy and its serious complications creates a market opportunity for a device that can be used by primary care physicians and endocrinologists as well as optometrists at the point-of-service for the early detection of diabetic retinopathy. There are estimated to be 21.0 million people in the United States with diabetes and this total is expected to grow. Diabetic retinopathy is the leading cause of blindness in adults age 20 to 65. Twenty years after diagnosis nearly all patients with Type I diabetes have some degree of diabetic retinopathy and 60% of all patients with Type II diabetes have some degree of retinopathy, even though many may not have symptoms. The ADA recommends an annual dilated eye examination for all patients with diabetes. In spite of this recommendation, only approximately 50% of patients with diabetes actually receive an annual eye examination. This has created an opportunity for such testing to be performed in the primary care physician or endocrinologist office and optometry clinics and vision centers since these patients with diabetes are routinely seen by these care providers.

#### **Market Size**

We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures currently performed each year in the United States. This estimate is based on (1) data from a Centers for Disease Control and Prevention, or 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. We anticipate that the advantages and increased availability of point-of-service products such as the NC-stat System could potentially increase the number of nerve conduction studies performed.

*We estimate the potential DPN market for a point-of-service product offering such as the NC-stat System could be over six million annual patient tests.* The number of individuals with diabetes in the United States was estimated to be 21.0 million, or 7.0% of the population. Among this group, approximately 6.0 million were undiagnosed. According to the CDC, there are about 26.0 million annual patient visits to office-based physicians for diabetes. We anticipate that the increasing focus on early detection and prevention of the chronic complications of diabetes will lead to increased nerve conduction studies for DPN. We believe that the estimated 50% rate of annual foot examinations in patients known to have diabetes is a reasonable estimate for the addressable testing market in diabetes. If these examinations were replaced by a nerve conduction study, or a nerve conduction study were added to the examination, the diabetes arena would represent an opportunity for over six million annual NC-stat System patient tests. The number of Americans with diabetes is projected to more than double over the next 40 to

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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 and to provide differential diagnosis. 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 do not believe there are any therapies for DPN that appear to have an opportunity for commercial launch within the next two years.

*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. 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 CTS 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 health care survey published in the Journal of the American Medical Association, approximately 14% of adults reported symptoms characteristic of CTS. It was further estimated that 2.5% of adults have true CTS, which could be confirmed by clinical examination and nerve conduction studies. This is equivalent to approximately five million individuals in the United States. Over 350,000 surgeries are performed annually for CTS. The surgical procedure is called a carpal tunnel release, or CTR. Most third-party payers require a nerve conduction study prior to authorizing CTR surgery. According to the CDC, there are more than two million annual visits to office-based physicians for which CTS is the primary diagnosis. The CDC estimates that about one third of CTS-related office visits are initial visits, at which time we believe utilization of a point-of-service nerve conduction product offering is most likely. As a result, we estimate that there may be as many as 650,000 testing opportunities for a point-of-service product offering such as the NC-stat System related to CTS. We further believe that this estimate is conservative, as there are many patients that visit physicians for hand and wrist pain, or medical conditions with a high association with CTS such as rheumatoid arthritis, diabetes and obesity. We also anticipate that the high costs of CTS-related workers' compensation claims could motivate employers to increasingly use a point-of-service product offering such as the NC-stat System to pre-screen and monitor employees for CTS.

Based on the data outlined above, we estimate that the potential market size for a point-of-service product offering such as the NC-stat System for nerve conduction studies in the diabetes, low back pain and CTS markets in the aggregate could be greater than 9.5 million annual patient tests in the United States. We estimate that the potential market for a point-of-service product offering such as the NC-stat System could be more than \$1.0 billion annually in the United States.

We estimate that the size of the market for a point-of-service product such as the DigiScope for the detection of diabetic retinopathy could be nearly \$700 million. There are estimated to be 21.0 million people in the United States with diabetes and it is estimated that 15.0 million have actually been diagnosed with diabetes. The American Diabetes Association recommends an annual eye

examination for all people with diabetes. Using an annual eye examination fee of \$45 per patient, this represents a potential market size of nearly \$700 million.

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 offerings such as the NC-stat System and the DigiScope 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 and for the DigiScope. The potential market opportunity is dependent on a number of factors including favorable reimbursement by third-party payers. There are no assurances that third-party payers will reimburse for an increasing level of nerve conduction studies at present levels or at all. Additionally, as there have been a number of adverse developments relating to the reimbursement for nerve conduction studies performed with the NC-stat System, our ability to access this market opportunity may be limited.

### **Clinical Studies and Clinical Validation**

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.

A study published in the December 2002 issue of *Spine* evaluated the ability of the NC-stat System to detect neurological impairment in 25 patients with sciatica, confirmed by MRI and clinical examination. The diagnostic accuracy of the NC-stat System was equivalent to traditional NCS/nEMG procedures as documented in several other published studies.

In a study published in the August 2005 *American Journal of Orthopedics*, the clinical utility of the NC-stat System was assessed in 72 patients with CTS. The NC-stat System was found to have a high correlation with traditional laboratory testing. The NC-stat System also measured statistically significant improvement in median nerve function six months following CTR surgery.

In a study published in the August 2006 *Diabetes Care*, the NC-stat System was shown to be comparable to conventional nerve conduction testing in a group of 72 patients with diabetes tested for DPN.

In a study published in the December 2006 *Diabetes Technology and Therapeutics*, the use of the NC-stat System in 1,400 patients with diabetes in 28 primary care/endocrinology clinics was assessed in a prospective open-label study. The NC-stat System identified nerve conduction abnormalities in 75% of patients, and over 50% had results suggestive of diabetic polyneuropathy. The NC-stat System identified meaningful levels of neuropathy in patients within ADA recommended blood glucose control and in those newly diagnosed with diabetes.

In a study published in the January 2007 *Physiological Measurements*, the validity of NC-stat System lower extremity nerve measurements was assessed in 60 patients referred to a Veterans Administration electrodiagnostic laboratory. The authors concluded "This study shows that the technology used by the NC-stat System for studying the peroneal and posterior tibial nerves compares favorably.... with that obtained with traditional EMG equipment used under neurologist supervision."

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

In the January-February 2007 *Journal of the American Board of Family Medicine*, a retrospective blinded study of NC-stat System utilization by 613 family medicine, primary care, and internal medicine physician practices was conducted. Over a two-week period 1,190 patients underwent NCS for evaluation of CTS. A total of 31% of tested limbs yielded normal results, 53% indicated CTS, and the remaining studies identified other neuropathies. The authors concluded "This study demonstrated that point-of-service NCS by physicians for CTS was applied to appropriate patient subpopulations, was performed in accordance with evidence-based testing parameters, and generated relevant diagnostic outcomes."

An article published in the Winter 2007 issue of *Perspectives on Biological Medicine*, contrasted our nerve conduction study technology with traditional NCS/nEMG procedures, examined the ways in which computer-based electrodiagnostic equipment serves as a disruptive innovation, addressed challenges that need to be overcome to support widespread adoption of the new technology, and discussed the opposition generated by its use among stakeholders in traditional NCS/nEMG.

A study published in the November/December 2007 issue of *Electromyography and Clinical Neurophysiology* examined 34 patients with clinical findings consistent with a lumbosacral radiculopathy, or LSR, who had both nerve conduction study with NCS/nEMG and a NC-stat System based multi-parameter electrodiagnostic study. The study concluded that "EDX [electrodiagnostic] information other than NCS/nEMG can be important in the evaluation of patients with possible LSR."

In a study published in the March 2008 issue of *Diabetes Care*, 72 consecutive patients with diabetes underwent a full neurological examination and a concurrent evaluation for nine standard electrophysiological parameters using conventional nerve conduction studies (the reference standard) and a point-of-care device (NC-stat System). Based on the study results, the authors concluded that "A novel point-of-care device [NC-stat System] has reasonable diagnostic accuracy and thus may represent a sufficiently accurate alternative for detecting the diffuse electrophysiological criteria necessary to make the diagnosis of diabetic sensorimotor polyneuropathy."

A study published in the March 2008 issue of *Journal of Diabetes Science and Technology* analyzed 63,779 nerve conduction studies performed by more than 3,400 physician practices using the NC-stat System. For over 70% of the patients, the specific diagnostic question of the presence of diabetic polyneuropathy was addressed by nerve conduction studies with evidence-based criteria. The rate of diabetic polyneuropathy was found to be comparable to levels seen by academic electromyography laboratories. This study demonstrated that nerve conduction studies using computer-based electrodiagnostic equipment was a suitable tool for the diagnosis of diabetic polyneuropathy in large populations.

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

The performance of the DigiScope has been validated in clinical studies, the results of which have been published in peer-reviewed medical journals as highlighted below.

In a study published in the May 2002 issue of *Investigational Ophthalmology and Visual Science*, the conclusions drawn were that "the DigiScope fulfills the instrumental requirements for a practical and cost-effective tool to acquire data needed to identify diabetic patients who must be referred to an eye care specialist." The study further concluded that the "DigiScope may help reduce the risk of vision loss in.....individuals who currently do not undergo an annual eye examination."

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

In a study of over 2,700 patients published in a 2006 issue of *Telemedicine and e-Health*, the conclusions were that the "DigiScope can be used in the primary care setting to identify patients with diabetes not currently under the care of an eye specialist who require referral to an ophthalmologist for evaluation and management of retinopathy."

### Customers

We market our products directly to primary care and specialist physicians and clinics. We plan to begin marketing the DigiScope to optometrists in 2008. The NC-stat System provides primary care physicians and other physicians including orthopedic surgeons, endocrinologists, rheumatologists, and pain medicine 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 product that can potentially improve the care of their patients and with a potential new source of revenues. As of December 31, 2007, we had over 5,500 active NC-stat customers. No single customer accounted for more than 10% of our revenues in 2007, 2006 or 2005.

Currently, there are approximately 190 customers using the DigiScope. We launched our sales and marketing efforts for this product in the first quarter of 2007.

### Strategic Alliance

In November 2007, we entered into a strategic alliance with Cyberkinetics, a medical device company focused on neurological conditions. We made an investment of \$2.5 million in shares of Cyberkinetics common stock and agreed to negotiate the terms of a joint venture with Cyberkinetics. In February 2008, we formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with initial ownership of 50% by NeuroMetrix and 50% by Cyberkinetics, and entered into a Collaboration Agreement and Operating Agreement with them. The focus of the joint venture is on the development and commercialization of a product for the treatment of peripheral nerve injury using the Andara OFS (Oscillating Frequency Stimulation) technology licensed by Cyberkinetics from Purdue University and using other technologies to be developed. The Andara OFS technology utilizes an oscillating electrical field to stimulate the regeneration of injured nerves and has been shown in initial human clinical studies to provide a statistically significant improvement in sensory and motor function of patients with acute spinal cord injuries.

Together with Cyberkinetics, we are in the preclinical stage of development of this product, which we expect will require the filing of a premarket approval application, or PMA, with the FDA. Under the terms of our joint venture agreement with Cyberkinetics, we have agreed to fund the first \$2.0 million of program costs under the joint venture and any required funding beyond the initial \$2.0 million will be shared equally by NeuroMetrix and Cyberkinetics. Cyberkinetics has agreed to contribute the Andara OFS technology and certain additional technology, know-how and intellectual property. Cyberkinetics will manufacture products commercialized under the agreement and we have received sales and marketing rights to all products commercialized under the joint venture. The two companies have agreed to charge the joint venture at actual cost for all expenses associated with the manufacturing of the products commercialized under the agreement and all expenses associated with the sales and marketing of the products commercialized.

There are estimated to be approximately 800,000 peripheral nerve injuries annually and it is believed that at least 100,000 of these injuries could benefit from electrical stimulation to provide neural repair and regeneration. It is believed that the market opportunity for a therapeutic for peripheral nerve injury is substantial.

As part of the strategic alliance, NeuroMetrix also received a right of first negotiation for the commercialization and distribution rights in North America to a product under development by Cyberkinetics for the treatment of acute spinal cord injury using the Andara OFS technology. This right

expires on December 31, 2008. Cyberkinetics has filed a Humanitarian Device Exemption, or HDE, with the FDA for this product, since there are fewer than 4,000 patients who could potentially benefit from the Andara OFS product. The product consists of a device which is implanted in close proximity to the spine and a series of electrodes which are attached to the spine above and below the site of the spinal cord injury. The implant remains in place for approximately 15 weeks and is then removed. The market opportunity for the Andara OFS device for acute spinal cord injury is believed to be as large as \$150 million annually. There are no assurances that Cyberkinetics will receive FDA approval of their HDE filing and there are no assurances that we will be able to successfully obtain the commercialization and distribution rights to the product.

We also obtained a first right of negotiation to acquire Cyberkinetics and this right expires on December 31, 2008.

### **Geographic Information**

Substantially all of our assets, revenues and expenses for the years ended December 31, 2007, 2006 and 2005 were located at or derived from operations in the United States. As a result of the launch of the NC-stat System in the United Kingdom, which has been on a limited basis to date, we had initial revenues from sales outside the United States beginning in the third quarter of 2007.

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

Currently, we employ 50 regional sales managers, 5 regional sales directors and a national sales director who sell directly to physician practices. During 2007, we terminated the relationships we had with independent sales agencies including national firms such as Physician Sales & Service and Henry Schein, Inc. Our products are primarily marketed and distributed within the United States, although we initiated sales efforts in the United Kingdom during the third quarter of 2007.

We launched our sales and marketing efforts for the DigiScope product for the detection of diabetic retinopathy in the first quarter of 2007. This product is being sold directly to primary diabetes care physicians through our sales force. The DigiScope is being marketed to our installed base of NC-stat System customers and to potentially new physician office customers. We obtained an exclusive sales and marketing license to the DigiScope from EyeTel in the fourth quarter of 2006 for the primary diabetes care market and acquired substantially all of the assets and assumed certain liabilities of EyeTel on December 26, 2007, expanding the market opportunity into the optometry clinic and vision center market. We recently launched our sales and marketing efforts for the DigiScope into the optometry market. EyeTel had conducted pilot studies in a number of vision centers at Wal-Mart stores, For Eyes clinics and CostCo clinics. Our sales force plans to market the DigiScope to these vision centers starting in 2008 once a comprehensive sales and marketing strategy has been developed.

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

We generally market our products directly to primary care and specialist physicians. The NC-stat System provides primary care and specialist 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 product that can potentially improve the care of their patients and with a potential new source of revenues. We believe that there are important marketing advantages of the NC-stat System. The NC-stat System can potentially help to accelerate the diagnosis



of neuropathies by allowing primary care and specialist physicians to perform a nerve conduction study at the point-of-service rather than having to make a referral to a neurologist. We also market our products at various industry conferences in order to accelerate the market awareness of our products, and market adoption for our products.

We are evaluating our options for sales and marketing of our products outside the United States. We will likely use distributors in these foreign markets given their direct understanding of each relevant market and the unique requirements of selling products in each market. Consistent with this strategy, we recently launched our sales efforts for the NC-stat System on a limited basis into the United Kingdom through a distributor of medical device products, representing our initial commercial sales in Europe. We expect to sell our products such as the NC-stat System in Europe through distributors who will stock inventory and ship product and bill directly to customers.

We generally invoice products purchased by our customers directly to physician offices and other customers. Our regional managers are compensated by a combination of base salary, commissions and goal-based bonus compensation.

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

Promotion and sales of medical devices are also highly regulated not only by the FDA, but also by the Federal Trade Commission, and, outside the United States, by other international bodies, and are subject to federal and state fraud and abuse enforcement activities.

We have products in development that, if successfully commercialized, may require us to develop a separate specialized sales force to call on anesthesiologists or other specialists.

## **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, the DigiScope 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 2007, although we did experience some delays in production with Parlex Corporation, or Parlex, the manufacturer of our biosensors. If our third-party manufacturers are unable to manufacture our products to keep up with demand, we would not meet expectations for our business.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Parlex has been manufacturing our NC-stat biosensors since early 1999. In August 2006, we entered into a mutually exclusive manufacturing and supply agreement with Parlex pursuant to which Parlex will manufacture and supply to us, and we will purchase from Parlex, at agreed upon prices per unit, all of our requirements of biosensors for resale in the United States. Under the agreement, Parlex has agreed not to manufacture biosensors to be used to measure nerve conduction for any other company during the term of the agreement and, in some cases, for a period of one year thereafter. Either party may terminate the agreement at any time upon not less than 18 months prior written notice, provided that neither party may terminate the agreement prior to August 2, 2008. Parlex manufactures our biosensors at a facility in Massachusetts and also has the ability to perform certain manufacturing steps for our biosensors at a second site located in the United Kingdom. We have been working closely with Parlex on certain production issues they have experienced which we believe relate primarily to the transition of manufacturing of our biosensors to a new facility operated by Parlex. We have experienced an increase in the number of biosensors that have not produced a usable result when used by our customers and have been working to resolve this issue with Parlex.

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

The DigiScope is manufactured by TopZone Electronics, Inc., or TopZone, a manufacturer located in China. We currently purchase DigiScopes from TopZone through purchase orders rather than a formal manufacturing agreement.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. The NC-stat System and the DigiScope are cleared for marketing within the United States and Canada, and the NC-stat System is also approved for marketing in the European Union, although to date our sales have been primarily in the United States. Our facility and the facilities of our manufacturers are subject to periodic inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. We were inspected by the FDA in May 2003. During its inspection, the FDA issued a Form 483, which is a notice of inspection observations. Two minor items were identified and the corrective actions for both were initiated prior to the completion of the audit. The responses provided to the FDA were deemed adequate and no further action has been requested. As a registered device manufacturer, we and our manufacturers will undergo regularly scheduled FDA quality system inspections. However, additional FDA inspections may occur if deemed necessary by the FDA.

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

Our research and development efforts are focused in the near term on further enhancing our existing products, which includes developing the ADVANCE System and new nerve conduction electrodes, as well as developing the NAVIGATOR platform, a system for the minimally invasive delivery of drugs and other therapeutic agents for regional anesthesia, pain control and local treatment of neuropathies by both specialist physicians and primary care physicians.

Our research and development staff consists of 33 people, including seven who hold Ph.D. or M.D. degrees. Our research and development group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors, optics 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 outcomes.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

In pursuit of our objective to develop medical devices that provide solutions for the diagnosis and treatment of patients with nervous system disorders, including neuropathies, and neurovascular diseases and that provide solutions for regional anesthesia and pain control, we are expanding our product base beyond the diagnostic arena and into the treatment arena. We believe that our core technology can be adapted and extended to provide minimally invasive approaches to nerve localization and specifically to provide regional anesthesia, pain control and treatments for neuropathies. We are developing the NAVIGATOR platform, a proprietary neuro-electrical guidance system, that is designed to help physician's position drug delivery devices such as hypodermic needles and catheters safely and quickly in very close proximity to specific nerves to optimize the therapeutic benefit.

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

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

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

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

We expect that our NAVIGATOR products will resemble our diagnostic products in that there will be three key components:

consumables that will include proprietary nerve localization and drug delivery needles;

electrodes and other disposables; and

an electronic instrument linked to our onCall Information System.

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

### *NCS/nEMG Systems*

We have an ongoing program of making enhancements and improvements to our nerve conduction products. We are developing new biosensors and associated software for the medically appropriate testing of additional nerves. We have also developed a more advanced diagnostic device, the ADVANCE System, for which we submitted a 510(k) filing to the FDA in 2007.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

The ADVANCE System has a number of important innovations and features:

Key technical and engineering specifications that we believe meet or exceed those of other electrodiagnostic devices on the market.

Advanced signal processing algorithms that provide physicians with high quality and detailed nerve conduction data to incorporate into their diagnostic assessment. We have filed two patents on these algorithms.

A user interface consisting of a high resolution color touch screen that allows physicians and their clinical staff to conduct accurate nerve conduction studies and other electrodiagnostic tests in a straightforward manner. This user interface provides for real-time data review including waveforms.

Compatibility with existing disposables and with new electrode sets that we develop in the future.

The capability to support the performance of nEMG studies.

### *Neural Repair and Regeneration*

In February 2008, we formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with Cyberkinetics. The focus of the joint venture is on the development and commercialization of a product for the treatment of peripheral nerve injury using the Andara OFS technology licensed by Cyberkinetics from Purdue University and using other technologies to be developed within the joint venture. The Andara OFS technology utilizes electrical stimulation for the regeneration of injured nerves. Together with Cyberkinetics, we are in the preclinical stage of development of this product, which we expect will require the filing of a PMA with the FDA.

There are estimated to be approximately 800,000 peripheral nerve injuries annually and it is believed that at least 100,000 of these injuries could benefit from electrical stimulation to provide neural repair and regeneration. It is believed that the market opportunity for a therapeutic for peripheral nerve injury could be substantial.

As part of the strategic alliance with Cyberkinetics, we also received a right of first negotiation for the commercialization and distribution rights in North America to a product under development by Cyberkinetics for the treatment of acute spinal cord injury using the Andara OFS technology. This right expires on December 31, 2008. Cyberkinetics has filed an HDE with the FDA for this product, since there are fewer than 4,000 patients who could potentially benefit from the Andara OFS product. The product consists of a device which is implanted in close proximity to the spine and a series of electrodes which are attached to the spine above and below the site of the spinal cord injury. The implant remains in place for approximately 15 weeks and is then removed. The market opportunity for the Andara OFS device for acute spinal cord injury is believed to be approximately \$150 million annually. There are no assurances that Cyberkinetics will receive FDA approval of their HDE filing and there are no assurances that we will be able to successfully obtain the sales and marketing rights to the product.

NEUROMetrix®, NC-stat®, ADVANCE , DigiScope® and onCall® are trademarks of ours. Andara and OFS are registered trademarks of Cyberkinetics.

During 2007, 2006 and 2005, we spent \$4.9 million, \$5.0 million and \$3.8 million, respectively, on research and development.

## Competition

We consider the primary competition for the NC-stat System 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 Cardinal Healthcare (acquired Viasys Healthcare Inc. in 2007), Cadwell Laboratories, Inc and Natus (acquired Xltec, Inc. in 2007). Cardinal Healthcare has substantially greater financial resources than we do, and they have established a reputation as an effective worldwide distribution channel for medical instruments to neurologists and other physicians. Xltec, Inc. launched a product for the point-of-service nerve conduction studies market in 2006 and subsequently announced that they were withdrawing this product from the market. We are aware of one additional company, Neumed Inc., that markets a nerve conduction study system to the point-of-service market.

We believe that among systems marketed for the performance of nerve conduction studies today, only the NC-stat System provides the level of diagnostic accuracy, the level of automation and the ease of use required for successful penetration of the point-of-service market. We also believe that the reporting and data repository functions provided by the onCall Information System, although entirely optional, provide our customers who use this service with added 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.

There are a number of companies that sell equipment for the detection of eye disorders such as diabetic retinopathy. These companies, such as Optos plc, sell primarily to the ophthalmologist market rather than to the primary care, endocrinology and optometry markets.

## 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. We also hold an exclusive license with Johns Hopkins University to manufacture, use and sell the DigiScope pursuant to a patent held by the university that will remain in-force until 2018. 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, 2007, we had 16 issued U.S. patents, 21 issued foreign patents and 38 pending patent applications, including 25 U.S. applications, 4 International PCT applications and 9 foreign national applications. We also hold an exclusive license from the Massachusetts Institute of Technology to two issued U.S. patents and two issued foreign patents. We hold an exclusive license to one U.S. patent and 5 foreign patents held by Johns Hopkins University to manufacture, use and sell

the DigiScope. The license also covers one additional pending foreign 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;

NC-stat System industrial design; and

Ophthalmic imaging service with certain capabilities.

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.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of these potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

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

A patent infringement suit brought against us may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third-party's intellectual property, unless that party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to the third-party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

#### *Trademarks*

We hold domestic registrations for the marks NEUROMETRIX, NC-STAT, onCall and DIGISCOPE. We also hold certain foreign trademark registrations for the marks NEUROMETRIX and NC-STAT. Andara OFS (Oscillating Field Stimulator) is a registered trademark of Cyberkinetics.

### Third-Party Reimbursement

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

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

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

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

The AMA formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies and nerve conduction equipment, including the NC-stat System. The findings of this committee were presented to the AMA CPT Editorial Panel at a meeting in February 2008. During the CPT Panel meeting, several proposals for new Category I CPT codes, which generally are included in the Medicare physician fee schedule and are assigned specified reimbursement values, were presented by the chairpersons of the work group and were supported by several physician societies. In spite of this, the only proposal voted on was for the creation of a new Category III CPT code, which generally would not be included on the Medicare physician fee schedule and would not generally have an assigned reimbursement value, for nerve conduction studies performed using equipment with certain automated features such as the NC-stat System. At this meeting, we believe that the CPT Panel approved a new Category III CPT Code for nerve conduction studies performed using equipment with certain automated features such as the NC-stat System. Unless we are able to successfully challenge this decision, a new Category III CPT Code would likely be published in July 2008 and become effective in January 2009. In the event that a Category III CPT code is published which describes nerve conduction studies performed with the NC-stat System, it would likely result in limited or no Medicare reimbursement for such studies as a result of the potential that no specified reimbursement values would be assigned to these codes. This is likely to adversely impact reimbursement by other third party payers and is likely to have an adverse and material impact on our revenues and results of operations.

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

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



## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

We believe that eye scans performed using the DigiScope are being reimbursed by the majority of third-party payers. Many commercial payers have policies in place providing for reimbursement for the use of the DigiScope and many of these payers have published favorable articles about the DigiScope in their newsletters. However, several Medicare carriers have issued draft LCDs and coding articles that require a diagnosis of pre-existing retinal disease and/or will only reimburse for fundus photography, a highly specialized form of medical imaging, when performed in conjunction with an eye examination performed by an eye specialist. There are no assurances that other Medicare carriers will not issue similar draft LCDs, final LCDs or coding articles restricting the reimbursement for the use of the DigiScope. We believe that eye examinations performed on patients covered by Medicare represented less than 25% of our DigiScope revenues in 2007. However, the restrictions on reimbursement by Medicare carriers could have an adverse impact on our ability to grow our DigiScope revenues in future periods.

In the optometry clinic market, we may not be as dependent on reimbursement by third parties since many of the screenings performed in these clinics using the DigiScope are paid for by patients out of pocket. The more comprehensive tests performed in the optometry clinics using the DigiScope are submitted for reimbursement and our ability to penetrate this market and grow our revenues will be dependent on favorable reimbursement from third-party payers.

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

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. We cannot assure you that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payer coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition. In addition, we believe that pressure is being applied on payer organizations by specialists, such as neurologists, who perform traditional nerve conduction studies and view the NC-stat System as competitive with their business.

### **FDA and Other Governmental Regulation**

#### *FDA Regulation*

Our products are medical devices subject to extensive regulation by the FDA under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, and the regulations promulgated thereto, as well as other regulatory bodies in the U.S. and abroad. The FDA classifies medical devices into one of three classes on the basis of the controls deemed necessary to reasonably ensure their safety and effectiveness:

Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; and

Class III, requiring general controls and PMA, which may include post-approval conditions and post-market surveillance.

Before being introduced into the market, our products must obtain market clearance or approval through the 510(k) pre-market notification process, the *de novo* review process or the PMA process.

### *510(k) Pre-Market Notification Process*

To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use, safety and effectiveness to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not yet required the submission of a PMA application. In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. If clinical trials are required, we must submit an application for an investigational device exemption, or IDE, which must be cleared by the FDA prior to the start of a clinical investigation, unless the device and clinical investigation are considered non-significant risk by the FDA or are exempt from the IDE requirements. It generally takes three months from the date of the pre-market notification submission to obtain 510(k) clearance, but it can be significantly longer.

After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require *de novo* classification or PMA. The FDA allows each company to make this determination, but the FDA can review the decision. If the FDA disagrees with a company's decision not to seek FDA authorization, the FDA may require the company to seek 510(k) clearance or PMA. The FDA also can require the company to cease marketing and/or recall the medical device in question until 510(k) clearance, *de novo* classification or PMA is obtained or take other action.

### *De Novo Review Process*

If a previously unclassified medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for *de novo* classification through what is called the *de novo* review process. In order to use the *de novo* review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not yet required the submission of a PMA application, it has been placed into Class III. After receiving this letter, the company, within 30 days, must submit to the FDA a request for *de novo* classification into Class I or II. The FDA then has 60 days in which to classify the device. If the FDA grants *de novo* classification, the device will be placed into either Class I or Class II, and allowed to be marketed. If a product is classified into Class I or II through the *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

### *PMA Process*

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for clearance through the *de novo* review process, a company must file a PMA application. The PMA process generally requires more extensive pre-filing testing than is required in the 510(k) pre-market notification process and is more costly, lengthy and uncertain. The PMA process can take one to three years or longer, from the time the PMA application is filed with the FDA. The PMA process requires the company to prove that there is a reasonable assurance of the safety and

effectiveness of the device to the FDA's satisfaction through extensive submissions, including pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before granting PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA's quality system regulations.

If FDA grants PMA, the approved indications may be more limited than those originally sought. In addition, FDA's approval order may include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and post-market study requirements. Failure to comply with the post-approval conditions can result in adverse enforcement or administrative actions, including the withdrawal of the approval. After any PMA, a new PMA 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 that affect safety and effectiveness.

*Post-Approval Obligations*

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

the FDA's Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits;

medical device reporting, or MDR, regulations, which require that manufacturers report to FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and device recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health;

post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility;

regular and for cause inspections by FDA to review a manufacturer's facilities and their compliance with applicable FDA requirements; and

the FDA's recall authority, whereby it can ask, or order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

### *NC-stat System*

The NC-stat System has received six 510(k) clearances as a Class II medical device, the first of which was received in 1998, and the most recent (K060584) in July 2006. The NC-stat System has the following intended use, as stated in the most recent 510(k) clearance:

*"The NeuroMetrix NC-stat is intended to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies."*

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

As noted above, during the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) filing relating to portions of the onCall Information System that are currently in use. We are currently in the process of responding to the second additional information request that we have received from the FDA relating to this filing. During the first quarter of 2007, we also submitted a 510(k) for the ADVANCE System, which is also pending review by the FDA.

### *DigiScope*

The DigiScope received a 510(k) clearance (K990205) as a Class II medical device in March 1999 and the indications for use statement is as follows:

*"The DigiScope is indicated for use as an ophthalmic camera for individuals where examination of the fundus for pathologies is requested."*

### *Manufacturing Facilities*

The facilities utilized by Parlex and Sunburst, two of our contract manufacturers, to supply our products have each been inspected by FDA in the past, and observations were noted. There were no findings that involved a significant violation of regulatory requirements. The responses to these observations have been accepted by FDA, and we believe that we are in substantial compliance with the QSR. Like all manufacturers, we expect our contract manufacturers to be inspected by FDA again in the future. If FDA finds significant violations, we could be subject to fines, recalls, requirements to halt manufacturing or other administrative or judicial sanctions. TopZone, our contract manufacturer for the DigiScope in China, has not been inspected by the FDA.

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

In the United States, there are federal and state anti-kickback laws that prohibit the offer, payment, solicitation or receipt of kickbacks, bribes or other remuneration, whether direct or indirect, overt or covert, in cash or in kind, intended, among other things, to induce the purchase or recommendation of healthcare products and services. While the federal law applies only to products and services for which payment may be made by a federal healthcare program, the state laws may apply regardless of whether any public healthcare funds are involved. Violations of these laws can lead to severe civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of medical devices, such as us, and to hospitals, physicians and other potential purchasers of medical devices. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. Under the federal civil False Claims Act, in addition to actions initiated by federal law enforcement authorities, the statute authorizes "qui tam" actions to be brought on behalf of the federal government by a private party in certain circumstances and, if successful, that private party can share in any monetary recovery. Any challenge by federal or state enforcement officials or others under these laws, including the current investigation by the Office of Inspector

General, or OIG, within the Department of Health and Human Services and by the United States Department of Justice, or DOJ, could have a material adverse effect on our business, financial condition and results of operations. As described in more detail in the section titled "Legal Proceedings," we are currently subject to investigations by the OIG and the DOJ of various aspects of our practices related to the NC-stat System.

### **Employees**

As of December 31, 2007, we had a total of 143 employees. Of the total employees, 33 were in research and development, 75 in sales and marketing and 35 in general and administrative services. One employee holds both M.D. and Ph.D. degrees, six additional employees hold Ph.D. degrees and one additional employee holds an M.D. degree.

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

### **Available Information**

We were organized as a corporation in the state of Delaware in 1996. Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed with or furnished to the Securities and Exchange Commission, or SEC, may be obtained through the Investor Relations section of our website at [www.neurometrix.com/investor](http://www.neurometrix.com/investor) as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information on our Investor Relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval system at [www.sec.gov](http://www.sec.gov). All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

**ITEM 1A. Risk Factors**

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

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

The extent of our future operating income or losses is highly uncertain, and we may not be able to reach and sustain profitability. We have incurred significant cumulative net losses since our inception, including net losses of approximately \$3.9 million in 2003 and \$4.7 million in 2004. In 2005 and 2006, we recorded net income of approximately \$249,000 and \$4.3 million, respectively. However, we incurred a net loss of approximately \$8.4 million in 2007 as a result of a decline in revenues and increases in operating expenses. At December 31, 2007, we had an accumulated deficit of approximately \$62.1 million. We cannot assure you that we will be able to reach profitability again and sustain profitability.

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

Widespread adoption of our products by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing procedures using our products. If physicians are unable to obtain adequate reimbursement for procedures performed using our products, we may be unable to sell our products and our business would suffer significantly. Additionally, even if these procedures are reimbursed by third-party payers, adverse changes in payers' policies toward reimbursement for the procedures would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs, private health insurers and other organizations. These organizations may deny coverage if they determine that a procedure was not reasonable or necessary, for example, if its use was not considered medically appropriate, or was experimental, or was performed for an unapproved indication. In addition, some health care systems are moving towards managed care arrangements in which they contract to provide comprehensive healthcare for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control healthcare costs, are increasingly challenging the prices charged for medical products and services and, in some instances, have pressured medical suppliers to lower their prices. If we are pressured to lower our prices, our revenues may decline and our profitability could be harmed. CMS guidelines set the reimbursement rates for procedures covered by Medicare. Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using our products in an adequate amount, if at all. Additionally, some private payers do not follow the CMS and Medicaid guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers.

During the second half of 2006 and in 2007, several local Medicare carriers issued draft LCDs, final LCDs or coding articles particularly addressing coverage and reimbursement policies under

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

The AMA formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies and nerve conduction equipment, including the NC-stat System. The findings of this committee were presented to the AMA CPT Editorial Panel at a meeting in February 2008. During the CPT Panel meeting, several proposals for new Category I CPT codes, which generally are included in the Medicare physician fee schedule and are assigned specified reimbursement values, were presented by the chairpersons of the work group and were supported by several physician societies. In spite of this, the only proposal voted on was for the creation of a new Category III CPT code, which generally would not be included on the Medicare physician fee schedule and would not generally have an assigned reimbursement value. At this meeting, we believe that the CPT Panel approved a new Category III CPT Code for nerve conduction studies performed using equipment with certain automated features such as the NC-stat System. Unless we are able to successfully challenge this decision, a new Category III CPT Code would likely be published in July 2008 and become effective in January 2009. In the event that a Category III CPT code is published which describes nerve conduction studies performed with the NC-stat System, it would likely result in limited or no Medicare reimbursement for such studies as a result of the potential that no specified reimbursement values would be assigned to these codes. This could also adversely impact reimbursement by other third party payers and could have an adverse and material impact on our revenues and results of operations.

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

Additionally, a significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, have adopted policies indicating that they will not provide reimbursement for the use of the NC-stat System. These commercial payers have cited

various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. We are in the process of communicating with these payers, directly, through our customers or through our network of reimbursement consultants, to attempt to address their concerns. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues.

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

If physicians do not receive access to and adequate reimbursement under the miscellaneous CPT code from those local carriers that currently, or in the future, require procedures performed using the NC-stat System to be submitted using that code, or if the AMA publishes a Category III CPT code for nerve conduction studies performed using equipment such as the NC-stat System, our existing customers may limit or curtail their use of the NC-stat System, we may be unable to obtain new customers and we may face increasing pricing pressure, all of which could materially adversely impact our business and our revenues and profitability, in particular. If the LCDs recently adopted or reimbursement determinations adopted in the future relating to the reimbursement of nerve conduction studies place additional restrictions or qualifications on the performance of these procedures generally or using the NC-stat System, our business, revenues and profitability could be materially adversely affected. Additionally, in the short-term, the uncertainty caused by these recent changes, or other future changes, in third-party payers' reimbursement policies regarding nerve conduction studies may cause existing customers to reduce their use of the NC-stat System and potential new customers to defer a decision or decline to purchase the NC-stat System, which could materially adversely affect our business. We are expending and anticipate continuing to expend substantial resources to address potential reimbursement issues with third-party payers. Widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not receive satisfactory reimbursement from third-party payers for procedures performed with the NC-stat System.

Many Medicare regions, including those accounting for 30 of the 50 states, allow examinations using the DigiScope to be reimbursed on the basis of a general diabetes diagnosis. All or part of six states require a diagnosis of pre-existing retinal disease before reimbursement for an examination using the DigiScope and another six states will only reimburse for fundus photography when performed in conjunction with an eye exam performed by an ophthalmologist or optometrist. Of the latter, a Medicare carrier for four of the six states issued informal directives curtailing reimbursement in the second quarter of 2007. Also during this period, regional Medicare carriers covering all or parts of nine other states issued proposed LCDs indicating that they would only reimburse for retinal photography, including "telescreening," when performed concurrently with a personal examination by an ophthalmologist or optometrist and that digital imaging systems used for the detection of diabetic retinopathy, which acquire images and transmit them to a remote area for interpretation, are considered screening and do not meet Medicare's reasonable and necessary criteria for reimbursement. Although this decision does not have a material impact on our current business, we can offer no assurance that other Medicare carriers will not propose and adopt similar no coverage decisions.

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

We believe that the drawbacks of traditional nerve conduction studies, including those related to the referral process, and the limited treatment options for DPN, have limited the number of nerve conduction studies that are performed. For our future growth, we are relying, in part, on increased use



of nerve conduction studies. A number of factors could limit the increased use of nerve conduction studies and the NC-stat System, including:

third-party payers challenging, or the threat of third-party payers challenging, the necessity of increased levels of nerve conduction studies;

third-party payers reducing or eliminating reimbursement for procedures performed by physicians using the NC-stat System;

unfavorable experiences by physicians using the NC-stat System;

physicians' reluctance to alter their existing practices; and

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

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

**Under-utilization of the DigiScope by customers may negatively affect our cash flow and potential profitability.**

We lease our DigiScopes to our customers and retain title to the device. We generate revenues through an initial installation fee, ongoing rental fees and per patient examination fees. As such, we are responsible for all the costs of DigiScopes placed with our customers and a significant portion of our recovery of these costs takes place over time as we collect rental and per patient fees. If our customers fail to utilize or under-utilize the DigiScopes, we may not be able to recover all of our production costs and our cash flow and potential profitability will be negatively affected.

**We may not be able to accurately predict the size of the market for our products.**

We may not be able to accurately predict the size of the market for our products. Neuropathies traditionally have been diagnosed by an NCS/nEMG procedure, performed by a neurologist or physician in a related specialty. We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures performed each year in the United States. However, we anticipate that the advantages and increased availability of point-of-service nerve conduction product offerings could significantly increase the number of nerve conduction studies performed if satisfactory third-party reimbursement is available. Based on our analysis of current data, we estimate that the potential market size for point-of-service nerve conduction product offerings such as the NC-stat System in the diabetes, low back pain and CTS markets in the aggregate could be greater than 9.5 million annual patient tests. This represents a significant increase in the size of the market for nerve conduction studies and is based upon a number of assumptions and estimates, which themselves may not be accurate. For example, we have assumed that all initial office visits for low back pain may represent an opportunity for use of the NC-stat System, and we have estimated that an annual testing rate of 50% for all individuals diagnosed with diabetes represents the potential addressable market in diabetes. We estimate that the size of the market for a point-of-service product for the detection of diabetic retinopathy could be nearly \$700 million. There are estimated to be 21 million people in the United States with diabetes and it is estimated that 15 million have actually been diagnosed with diabetes. Using an eye examination fee of \$45 per patient, this represents a potential market size of nearly \$700 million. Market size is difficult to predict, and we cannot assure you that our assumptions or estimates will prove to be correct. The industry and market data in this Annual Report on Form 10-K, on which we have based our assumptions and estimates of future market size, may be inaccurate or incomplete, and we have not independently verified those data. If our estimates of the sizes of the markets for our products is incorrect, our potential revenue growth may be limited.

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

We are focusing our sales and marketing efforts for the NC-stat System on primary care and specialist physicians and the DigiScope on primary care physicians, endocrinologists and optometrists. As these physicians and other healthcare providers traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies or eye scans, we may face difficulties in selling our products to them. Particularly, we may be unable to convince these physicians that our products provide effective alternatives or useful supplements to existing testing methods. In addition, these physicians may be reluctant to make the capital investment required to purchase the NC-stat System or use the DigiScope and alter their existing practices. If we are unable to successfully sell our products to primary care and specialist physicians, our ability to increase our revenues will be severely limited.

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

We rely on two third-party manufacturers to manufacture all of the components of the NC-stat System and one third-party manufacturer to produce all of the components of the DigiScope. In the event that our manufacturers cease to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products, particularly our NC-stat biosensors, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have entered into an exclusive manufacturing and supply agreements with Parlex for the manufacture of the NC-stat biosensors, and Sunburst for the manufacture of our NC-stat monitors and docking stations. TopZone manufactures DigiScopes on a purchase order basis, rather than pursuant to a long-term contract. TopZone contracts with Xintian Fine Optical Instrument Corporation, or Xintian, in Guiyang, China for the optical head of the DigiScope, which is the most complex and important sub-component of the DigiScope. If Xintian were to fail to provide optical heads for the DigiScope production, we would be required to find alternative suppliers of optical heads. Since most of the components are standard off the shelf optical materials, we believe we could find alternative suppliers, but we could experience a temporary reduction in supply and an increase in cost for the DigiScope. In addition, we rely on TopZone to provide certain hardware and software development services. The loss of these services would likely delay and increase the cost of our research and development efforts.

In addition, because TopZone is organized and operates in China, we will be subject to business risks associated with foreign operations, including:

failure to fulfill Chinese regulatory requirements to manufacture DigiScopes or other future products;

adapting to the differing business practices and laws in China;

limited protection for intellectual property rights in China;

costs of enforcing contractual obligations in China;

political instability and unexpected changes in diplomatic and trade relationships;

currency exchange rate fluctuations; and

potentially adverse tax consequences.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

We do occasionally experience transient inventory shortages on new products during the initial production ramp-up phase. If any of the changes in our relationships with these manufacturers as described above occurs, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers.

**If our manufacturers are unable to supply us with an adequate supply of products as we expand our markets, we could lose customers, our potential future growth could be limited and our business could be harmed.**

In order for us to successfully expand our business within the United States and internationally, our contract manufacturers must be able to provide us with our products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our potential future growth could strain the ability of our manufacturers to deliver products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed.

**We currently rely entirely on sales of the products that comprise the NC-stat System to generate a substantial portion of our revenues, and any factors that negatively impact our sales of these products could significantly reduce our ability to generate revenues.**

We introduced the NC-stat System to the market in May 1999. We derive substantially 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 majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is reliant on our ability to market and sell the products that comprise the NC-stat System, particularly the disposable biosensors, sales of which accounted for approximately 86-88% of our total revenues in each of the past three years. Our sales of these products may be negatively impacted by many factors, including:

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

decisions made by the AMA CPT Editorial Panel relating to the reimbursement of nerve conduction studies performed using the NC-stat System;

the failure of the market to accept our products;

manufacturing problems;

claims that our products infringe on patent rights or other intellectual property rights owned by other parties;

adverse regulatory or legal actions relating to our products;

competitive pricing and related factors; and

results of clinical studies relating to our products or our competitors' products.

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

**The patent rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would harm our ability to compete in the market.**

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. Our patent position is generally uncertain and involves

complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

other parties may challenge patents, patent claims or patent applications licensed or issued to us; and

other companies may design around technologies we have patented, licensed or developed.

We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

**We depend on a patent licensed to us by Johns Hopkins University as well as other contractual relationships with the Wilmer Eye Institute.**

We possess our rights with respect to the patent underlying the DigiScope through a patent licensing agreement with Johns Hopkins University. The license agreement generally grants us exclusive rights with respect to the patent, subject to certain rights retained by Johns Hopkins University for non-profit research purposes. However, if we determine not to seek patent protection in any given country, Johns Hopkins University may seek patent protection and license any resulting patents to third parties or otherwise exploit such patents for its own exclusive benefit. Currently, we are the exclusive licensee with respect to patents issued in the United States, China, Indonesia, Australia, Israel, Hong Kong and Mexico. We have determined not to seek patent protection in Canada or the European Union, although Johns Hopkins University has agreed that nonetheless we may retain exclusive rights in those jurisdictions. Our decision not to seek patent protection in Canada and the European Union could negatively impact our ability to compete in those jurisdictions.

Under the license agreement, we are required to pay Johns Hopkins University royalties ranging from three to three and one-half percent of our net collected revenues, exclusive of installation fees, on a quarterly basis. In the event that we breach the licensing agreement, including as a result of the failure to make required royalty payments to Johns Hopkins University, or the failure to exercise commercially reasonable efforts to commercialize the technology, we could lose the licensing rights to the DigiScope technology.

Also, since Johns Hopkins University is an academic institution, our license agreement with it is subject to the federal Bayh-Dole Act, pursuant to which the federal government has certain limited rights to use the technology and even to require us to grant a license to one or more third parties if we are not fully developing the technology.

In addition to the licensing agreement, we have also entered into an agreement with the Wilmer Eye Institute at Johns Hopkins University pursuant to which the Wilmer Eye Institute receives digital scans from physicians using the DigiScope and eye specialists employed by the Wilmer Eye Institute analyze the images. Within 24-48 hours after receipt of the images, the eye specialists provide a report to the physician who performed the eye scan indicating the results of the scan. If the Wilmer Eye Institute could not continue to perform this service to our customers in a timely manner, our ability to generate revenues from the DigiScope could be adversely impacted.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

We also may benefit from contractual relationships with Johns Hopkins University in the area of research and development. Johns Hopkins University conducts certain research projects, funded by outside sources, involving the DigiScope. We have contractual commitments to support these research projects and if results are positive, we may benefit indirectly from the studies and the publication of the results. However, it may be necessary in the future for us to increase our research and development budget to conduct ongoing or additional research.

### **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 the technology and algorithms we use in connection with the DigiScope. We rely on trade secrets to protect this information. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur:

the agreements may be breached;

we may have inadequate remedies for any breach;

trade secrets and other proprietary information could be disclosed to our competitors; or

others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position.

### **We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.**

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events could harm our business, our ability to compete in the market or our reputation.

**Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our products and increase our costs.**

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that our products could be increasingly subject to third-party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlap. Third parties may currently have, or may eventually be issued, patents on which our products or technologies may infringe. Any of these third parties might make a claim of infringement against us. Any litigation regardless of its impact would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability.

**We are subject to extensive regulation by the FDA, which could restrict the sales and marketing of the NC-stat System and could cause us to incur significant costs.**

We sell medical devices that are subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive 510(k) clearance, grant of a *de novo* classification or pre-marketing approval from the FDA, unless an exemption applies. Medical devices may be marketed only for the indications for which they are approved or cleared. We may also be required to obtain a new 510(k) clearance or *de novo* classification or PMA for significant post-market modifications to our products including changes to the intended use. Each of these processes can be expensive and lengthy. The FDA's process for granting 510(k) clearance usually takes approximately three months, but it can be significantly longer. The process for obtaining *de novo* classification involves a level of scrutiny similar to the 510(k) clearance process, but may require more data. The process for obtaining PMA is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Our clearances can be rescinded if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or 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 or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occur or if the FDA takes other administrative or judicial actions, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs. In particular, our business could be adversely impacted in the event that we do not obtain 510(k) clearance for the ADVANCE System or the portions of the onCall Information System that are the subject of our 510(k) filing in the fourth quarter of 2006. Because the portions of the onCall Information System under review are currently in use, if the FDA does not clear them, we may be required to modify or remove the portions of the onCall Information System that are under review. Any such modifications could make the NC-stat System more difficult to use by physicians, which could adversely impact our ability to generate revenues from

the NC-stat System, or more expensive for us to operate. Either of these could have a material adverse impact on our business.

We also are subject to numerous post-marketing regulatory requirements, including quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and servicing of our products, labeling regulations, medical device reporting regulations and correction and removal reporting regulations. Our failure or the failure by any manufacturer of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following sanctions:

warning letters, fines, injunctions, product seizures, consent decrees and civil penalties;

requiring repair, replacement, refunds, notifications or recall of our products;

imposing operating restrictions, suspension or shutdown of production;

refusing our requests for 510(k) clearance or PMA of new products, new intended uses, or modifications to existing products;

rescinding 510(k) clearances or withdrawing PMAs that have already been granted; and

criminal prosecution.

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

Also, from time to time, legislation is introduced into Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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

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

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

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

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

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain a medical device company's sales, marketing and other promotional activities by limiting the kinds of business relationships and financial arrangements, including sales programs we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. From time to time, we may provide coding and billing information as product support to purchasers of our products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be quite substantial including exclusion from participation in federal healthcare programs. In the event that we are found to have violated these laws or determine to settle a claim that we have done so, our business may be materially adversely affected as a result of any payments required to be made, restrictions on our future operations or actions required to be taken, damage to our business reputation or adverse publicity in connection with such a finding or settlement or other adverse effects relating thereto. Additionally, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

In the second quarter of 2006, we received a subpoena from the Office of Inspector General, or OIG, of the Department of Health and Human Services requesting documents from us in connection with an investigation of potential violations of the federal anti-kickback statute and False Claims Act. In addition, on June 21, 2007, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents from us in connection with an investigation by the U.S. Department of Justice, or DOJ. We understand that the DOJ is investigating various aspects of our practices relating to the NC-stat System, including sales and marketing practices. We are cooperating with both investigations. During 2007, we formed a Special Committee of our Board of Directors to provide oversight of an ongoing independent review of our sales and marketing practices and of our continuing cooperation with the DOJ and OIG investigations. We cannot predict the ultimate outcome



of these investigations. We are unable to determine when these matters will be resolved, whether any additional areas of inquiry will be opened, or any outcome of this matter. Any negative findings in this matter could result in fines, penalties, or program exclusions, which could have a material adverse effect on our financial condition, results of operations and cash flows. We may also incur significant costs in responding to, and defending our company in these investigations, which could also have a material adverse effect on our financial condition, results of operations and cash flows.

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

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

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

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of medical devices. The medical device industry historically has been litigious, and we face financial exposure to product liability claims if the use of our products were to cause or contribute to injury or death. In particular, the NC-stat System may be susceptible to claims of injury because it involves the electric stimulation of a patient's nerves. Additionally, because the DigiScope tests for diabetic retinopathy, which is a condition that can lead to loss of vision or blindness if untreated, we could be subject to claims of injury relating to any actual or claimed inadequacy, error or malfunction of the DigiScope in testing for this condition or the Wilmer-EyeTel Reading Center in reading the results of the test performed by the DigiScope and communicating them to the physician. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. As sales and use of our products increase, we may be unable to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses.

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

We depend upon third parties for the manufacture of our products. Our products, particularly our NC-stat biosensors, require a significant degree of technical expertise to produce. If these

manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

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

loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

increased cost of our warranty program due to product repair or replacement;

inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal action.

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

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

Our success largely depends on the skills, experience and efforts of our officers, including Shai N. Gozani, M.D., Ph.D., our founder 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, our Chief Financial Officer; and our other key employees. We maintain a \$5.0 million key person life insurance policy on Dr. Gozani, for which the Company is the beneficiary, but do not maintain key person life insurance policies covering any of our other employees. The loss of any of our officers or key employees could weaken our management and technical expertise significantly and harm our business.

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

We are a small company with only 143 employees as of December 31, 2007, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel, particularly given the challenges our business has recently faced. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, 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 future potential growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.**

Future potential growth of our business may provide challenges to our organization and may strain our management and operations. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.

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

As of December 31, 2007, we employed approximately 50 regional sales managers, five regional sales directors and a national sales director. We are highly dependent on our regional sales managers to generate our revenues. Our ability to build and develop a strong sales force will be affected by a number of factors, including:

our ability to attract, integrate and motivate sales personnel;

our ability to effectively train our sales force;

the ability of our sales force to sell an increased number of products;

the length of time it takes new sales personnel to become productive;

the competition we face from other companies in hiring and retaining sales personnel;

our ability to effectively manage a multi-location sales organization;

our ability to enter into agreements with prospective members of our sales force on commercially reasonable terms; and

our ability to get our independent 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 or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects.**

For the year ended December 31, 2007, the majority of our revenues were derived from selling the NC-stat System. Our future business and financial success will depend, in part, on our ability to continue to introduce or sell new products 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 of our other current or future products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do, which could make our competitors' products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

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

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that 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 and specialist physicians to perform the same types of tests that may be performed by primary care and specialist 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 Cardinal Healthcare, having acquired Viasys Healthcare Inc. in 2007, Cadwell Laboratories, Inc. and Natus, having acquired Xltex, Inc. in 2007. Additionally, we are aware of one company, Neumed, Inc., that markets a nerve conduction study system to the point-of-service market. Of these companies, Cardinal Healthcare, in particular, enjoys significant competitive advantages, including:

greater resources for product development, sales and marketing;

more established distribution networks;

greater name recognition;

more established relationships with health care professionals, customers and third-party payers; and

additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

As we develop the market for point-of-service nerve conduction studies, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the point-of-service market may enjoy competitive advantages such as those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

With respect to the DigiScope, our principal competitor in the primary diabetes care market is Veraxa Health, Inc., an affiliate of the Joslin Diabetes Center, and our principal competitors in the optometry market are Carl Zeiss, Inc., Topcon America Corporation, Kowa. Some or all of these existing competitors, as well as, future competitors may enjoy advantages, such as those described above relating to the nerve conduction market. If we are unable to compete effectively against existing and future competitors, our ability to grow our DigiScope revenues could be adversely impacted and our business could be harmed.

**We are dependent upon the computer and communications infrastructure employed and utilized by our onCall Information System and the Wilmer EyeTel Reading Center, 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 and our DigiScopes. 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 and the DigiScopes 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 or the Wilmer EyeTel Reading Center, which could result in increased costs to eliminate these problems and address related security concerns and harm our reputation with our customers. In addition, if our infrastructure fails to accommodate growth in customer transactions, customer satisfaction could be impaired, we could lose customers, our ability to add customers could be impaired or our costs could be increased, any of which would harm our business.

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

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

**Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.**

We believe that our current cash and cash equivalents together with our short-term investments and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. Our capital requirements will depend on many factors, including:

the revenues generated by sales of our products;

the costs associated with our sales and marketing efforts;

the expenses we incur in manufacturing and selling our products;

the costs of developing new products or technologies and enhancements to existing products;

the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;

the costs associated with any expansion;

the costs of professional services associated with the government investigations to which we are subject;

the costs associated with capital expenditures, including the purchase of DigiScopes; 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.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

From time to time we may seek to acquire or invest in businesses, products or technologies, instead of developing them ourselves. On December 26, 2007, for example, we acquired substantially all of the assets and assumed certain liabilities of EyeTel and in November 2007 we made an investment in Cyberkinetics and in 2008 entered into a joint venture with them.

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

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

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

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

We had our initial revenues in the United Kingdom in the third quarter of 2007, representing our initial launch in Europe. If we continue to expand, or attempt to expand, into foreign markets, we will be subject to new business risks, including:

failure to fulfill foreign regulatory requirements to market our products;

availability of, and changes in, reimbursement within prevailing foreign health care payment systems;

adapting to the differing business practices and laws in foreign countries;



## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents;

limited protection for intellectual property rights in some countries;

difficulty in collecting accounts receivable and longer collection periods;

costs of enforcing contractual obligations in foreign jurisdictions;

recessions in economies outside of the United States;

political instability and unexpected changes in diplomatic and trade relationships;

currency exchange rate fluctuations; and

potentially adverse tax consequences.

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

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

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

changes in the availability of third-party reimbursement in the United States or other countries;

the timing of new product announcements and introductions by us or our competitors;

market acceptance of new or enhanced versions of our products;

changes in manufacturing costs or other expenses;

competitive pricing pressures;

the gain or loss of significant distribution outlets or customers;

increased research and development expenses;

the timing of any future acquisitions; or

general economic conditions.

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

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

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

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;

provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

require advance written notice of stockholder proposals and director nominations.

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

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

### **We do not intend to pay cash dividends.**

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

We have not received written comments from the Securities and Exchange Commission regarding our periodic or current reports under the Securities and Exchange Act of 1934, as amended, 180 days or more before December 31, 2007 that remain unresolved.

**ITEM 2. PROPERTIES**

Our headquarters is located in a 30,000 square foot facility in Waltham, Massachusetts, which we occupy under an office lease expiring in March 2013. We also operate in a 13,700 square foot facility in Columbia, Maryland, leased to us until October 31, 2009. We believe that our existing facilities are adequate for our current needs.

**ITEM 3. LEGAL PROCEEDINGS**

In the second quarter of 2006, we received a subpoena from the Office of Inspector General, or OIG, of the Department of Health and Human Services requesting documents from us in connection with an investigation of potential violations of the federal anti-kickback statute and False Claims Act. In addition, on June 21, 2007, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents from us in connection with an investigation by the DOJ. We understand that the DOJ is investigating various aspects of our practices relating to the NC-stat System, including sales and marketing practices. We are cooperating with both investigations. During 2007, we formed a Special Committee of our Board of Directors to provide oversight of an ongoing independent review of our sales and marketing practices and of our continuing cooperation with the DOJ and OIG investigations. We cannot predict the ultimate outcome of these investigations. We are unable to determine when these matters will be resolved, whether any additional areas of inquiry will be opened, or any outcome of this matter. Any negative findings in this matter could result in fines, penalties, or program exclusions, which could have a material adverse effect on our financial condition, results of operations, and cash flows.

**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, 2007, through the solicitation of proxies or otherwise.

## PART II

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

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

	Years ended December 31,			
	2007		2006	
	High	Low	High	Low
First quarter	\$ 14.50	\$ 9.25	\$ 39.19	\$ 28.00
Second quarter	\$ 10.76	\$ 8.62	\$ 40.39	\$ 25.73
Third quarter	\$ 9.12	\$ 7.25	\$ 33.18	\$ 18.74
Fourth quarter	\$ 10.25	\$ 7.79	\$ 19.85	\$ 13.52

On March 7, 2008, there were approximately 136 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 7, 2008, the last reported sale price per share of our common stock on the NASDAQ Global Market was \$2.03.

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.

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

**COMPARATIVE STOCK PERFORMANCE GRAPH**

The following graph shows the cumulative stockholder return of our common stock from July 22, 2004 (the first trading day for our common stock) through December 31, 2007 as compared with that of the Nasdaq (U.S. Companies) Index and the Nasdaq Medical Device Manufacturers Index. The total stockholder return is measured by dividing the per share price change of the respective securities, plus dividends, if any, for each period shown by the share price at the end of the particular period. The graph assumes the investment of \$100 in our common stock and each of the comparison groups on July 22, 2004 and assumes the reinvestment of dividends. We have never declared a dividend on our common stock. The stock price performance depicted in the graph below is not necessarily indicative of future price performance.

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

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

**ITEM 6: SELECTED FINANCIAL DATA**

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

Years Ended December 31,

	2007	2006	2005	2004	2003
(In thousands, except share and per share data)					
<b>Statement of Operations Data:</b>					
Revenues	\$ 44,622	\$ 55,250	\$ 34,298	\$ 17,920	\$ 9,168
Cost of revenues	12,062	13,558	8,858	4,853	2,707
Gross margin	32,560	41,692	25,440	13,067	6,461
Operating expenses:					
Research and development	4,892	5,011	3,821	3,268	2,397
Sales and marketing	22,964	22,014	14,150	8,488	4,768
General and administrative	14,834	11,805	8,022	5,267	3,052
Total operating expenses	42,690	38,829	25,993	17,024	10,217
Income (loss) from operations	(10,129)	2,862	(553)	(3,957)	(3,756)
Interest income (expense), net	1,751	1,598	837	(750)	(113)
Income (loss) before provision for income taxes	(8,378)	4,461	284	(4,707)	(3,869)
Provision for income taxes		193	35		
Net income (loss)	(8,378)	4,268	249	(4,707)	(3,869)
Accretion of dividend on redeemable convertible preferred stock				(1,386)	(2,009)
Deemed dividend on redeemable convertible preferred stock				(788)	
Beneficial conversion feature associated with redeemable convertible preferred stock				(7,051)	
Net income (loss) attributable to common stockholders	\$ (8,378)	\$ 4,268	\$ 249	\$ (13,932)	\$ (5,878)
Net income (loss) per common share:					
Basic	\$ (0.66)	\$ 0.34	\$ 0.02	\$ (2.42)	\$ (5.66)
Diluted	\$ (0.66)	\$ 0.33	\$ 0.02	\$ (2.42)	\$ (5.66)
Weighted average common shares outstanding:					
Basic	12,628,310	12,501,742	12,152,139	5,747,579	1,038,817
Diluted	12,628,310	13,097,891	12,986,365	5,747,579	1,038,817

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

As of December 31,

	2007	2006	2005	2004	2003
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 7,097	\$ 7,910	\$ 8,170	\$ 1,936	\$ 1,623
Short-term investments	22,622	32,411	24,082	18,575	
Working capital	33,304	41,894	33,268	21,774	2,451
Long-term investments	1,058			9,497	
Total assets	56,375	55,706	42,897	37,953	7,218
Long-term debt and other long-term liabilities	33	73	131	189	2,232
Warrants for redeemable convertible preferred stock					450
Redeemable convertible preferred stock					47,694
Accumulated deficit	(62,066)	(53,687)	(57,955)	(58,204)	(45,204)
Total stockholders' equity(deficit)	46,730	43,409	34,833	33,330	(45,805)

51



**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 condensed financial statements and the accompanying notes to those financial statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.*

**Overview**

NeuroMetrix was founded in June 1996. We design, develop and market proprietary medical devices used to help physicians diagnose and treat diseases of the nervous system such as neuropathies, which are disorders of the peripheral nerves and parts of the spine, and neurovascular disorders such as diabetic retinopathy. We are also developing medical devices designed to be used to provide regional anesthesia and pain control. To date, our focus has been on products that help physicians with the diagnosis of neuropathies and neurovascular disorders. We have two products lines cleared by the United States Food and Drug Administration, or FDA, that are currently being marketed to physicians and clinics, including the NC-stat System for the assessment of neuropathies and the DigiScope for the detection of eye disorders such as diabetic retinopathy.

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. The NC-stat System is comprised of: (1) disposable single use NC-stat biosensors that are placed on the patient's body, (2) the NC-stat monitor and related components and (3) the NC-stat docking station, an optional device that enables the physician's office to transmit data to our onCall Information System. The NC-stat System has been on the market since May 1999 and is used in over 5,500 physician's offices and clinics in the United States. Over 1.0 million patients have had nerve conduction tests performed using the NC-stat System. Substantially all of our revenues to date have been derived from sales of the NC-stat System. We are currently developing a traditional nerve conduction system, the ADVANCE System, for the diagnosis of neuropathies and have filed a 510(k) application with the FDA. Presuming it is successfully commercialized, the ADVANCE System is expected to provide physicians with even greater clinical functionality and is expected to be marketed to specialists such as neurologists as well as primary care physicians.

*Acquisition*

On December 26, 2007, we acquired substantially all of the assets and assumed certain liabilities of EyeTel Imaging, Inc., or EyeTel, and their product, the DigiScope, a product used for the detection of eye disorders such as diabetic retinopathy, for 1,050,297 shares of common stock, \$175,000 in cash and the assumption of certain liabilities.

Neurovascular disease includes conditions such as retinopathy, an eye disease prevalent in patients with diabetes. The DigiScope is marketed to the primary diabetes care physician office market and the optometry market. Prior to the acquisition of substantially all of the assets and the assumption of certain liabilities of EyeTel, we had been marketing the DigiScope to the primary diabetes care physician office market through an exclusive sales and marketing license with EyeTel. The DigiScope allows physicians to diagnose diabetic retinopathy and refer patients to an eye specialist for treatment if deemed necessary based on the results. It is recommended by the American Diabetes Association, or

ADA, that all patients with diabetes receive an annual dilated eye examination to monitor vision. According to the ADA, there are approximately 21.0 million people in the United States with diabetes and only approximately 50% comply with the recommendation to have an annual eye examination. We believe that a product such as the DigiScope in primary diabetes care physician offices and optometry clinics could potentially lead to an increase in the level of testing and result in the earlier detection of eye diseases in patients with diabetes and improved clinical outcomes.

#### *Corporate Collaborations*

In November 2007, we made an investment of \$2.5 million for the purchase of approximately 5.4 million shares of common stock of Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics, representing approximately 13% of the Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share. We also received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant, exercisable at \$0.46 per share, has a term of five years, and is required to be exercised if Cyberkinetics receives FDA approval of a Humanitarian Device Exemption, or HDE, filing for the Andara Oscillating Field Stimulator, or Andara OFS, device for acute spinal cord injuries. In addition, we received a seat on the Cyberkinetics Board of Directors. Dr. Shai Gozani M.D. Ph.D., our Chief Executive Officer and President, has been named as our initial designee.

In connection with the investment in Cyberkinetics, we also received certain rights, including a right of first negotiation for the acquisition of Cyberkinetics and a right of first negotiation for the commercialization of the Andara OFS device for the treatment of acute spinal cord injuries.

In February 2008, we entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics to develop and commercialize products for the treatment of peripheral nerve injury and formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with 50% ownership held by us and 50% ownership held by Cyberkinetics.

We derive the majority of our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physician practice groups. Our NC-stat biosensors are disposable products that are used once and inactivated after use. The NC-stat monitor is an electronic instrument that is used with the NC-stat biosensors to perform nerve conduction studies for the purpose of diagnosing neuropathies. The NC-stat monitor displays the results of nerve conduction studies on a 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 automatically formulates the data it receives for each test into a detailed report that is provided to the customer through facsimile or e-mail.

We also derive revenues from sales of the DigiScope to physicians through (1) eye scan fees, (2) monthly rental fees and (3) installation and training fees. During 2007, we were required to remit a percentage of the revenues related to the DigiScope to EyeTel under our sales and marketing license with EyeTel. As a result of our acquisition of substantially all of the assets of EyeTel on December 26, 2007, we are no longer required to remit any revenues to EyeTel. In addition, we expanded the market opportunity for the DigiScope into the optometry market in addition to the primary diabetes care physician office market.

Our revenues declined to \$44.6 million for the twelve months ended December 31, 2007, compared to \$55.2 million for the same period in 2006. Additionally, we incurred a net loss of \$8.4 million for the twelve months ended December 31, 2007, compared to net income of \$4.3 million for the same period in 2006. We believe that the decline in our revenues has been caused primarily by adverse developments over the past year relating to the reimbursement by third-party payers of nerve conduction studies performed using the NC-stat System, and we expect that our revenues will continue

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

to be adversely affected by the uncertainty regarding reimbursement and by the outcome of the February 2008 AMA CPT Editorial Panel meeting to review the reimbursement coding for nerve conduction studies.

Significant developments impacting and relating to our financial condition and results of operations as of and for the year ended December 31, 2007 and expected to impact future periods include:

the impact of reimbursement developments relating to nerve conduction studies on our revenues as described above, including the outcome of the AMA CPT Editorial Panel meeting and the material and adverse impact the potential issuance of a Category III CPT code by the AMA is likely to have on our revenues and operating results;

expanded sales and marketing efforts for the DigiScope as a result of the acquisition of substantially all of the assets and the assumption of certain liabilities of EyeTel and the broader market opportunity we can now address including the optometry market. We expect to continue to increase revenues from the DigiScope and we expect that the gross margin on DigiScope revenues will improve due to our acquisition and the elimination of the amounts we were previously remitting to EyeTel;

increased capital expenditures relating to purchases of DigiScope units, resulting from the acquisition of substantially all of the assets and the assumption of certain liabilities of EyeTel and our responsibility for all units produced by our third party manufacturer;

our decision to terminate the relationships with our independent sales agencies in the second half of 2007, which we believe has adversely impacted our revenues, but is expected to reduce sales and marketing expenses in 2008 as a result of the elimination of commissions on recurring revenues from accounts originally sourced through our independent sales agencies. In 2007, total commissions relating to independent sales agencies were \$3.0 million;

the delay of the expected launch of the ADVANCE System, our traditional neurodiagnostic system, for which we have invested approximately \$3.0 million in inventories as of December 31, 2007, and for which we continue to seek 510(k) regulatory approval from the FDA;

the government investigations by the Office of Inspector General, or OIG, of the Department of Health and Human Services and the U.S. Department of Justice, or DOJ, that we are subject to, which resulted in significantly increased legal expenses in 2007. We cannot predict the potential impact of these investigations on our financial condition or financial results in 2008;

continued progress with our product in development, referred to as NAVIGATOR, a minimally invasive nerve localization system for regional anesthesia, pain control and the treatment of neuropathies such as carpal tunnel syndrome, or CTS, for which we expect to file a 510(k) application with the FDA in 2008. We continue to invest resources on the development of this product; and

the investment we made in Cyberkinetics in the fourth quarter of 2007, which included the purchase of \$2.5 million of Cyberkinetics common stock and the receipt of a warrant to purchase an additional \$1.25 million of Cyberkinetics common stock that we must exercise in certain circumstances, as well as the joint venture we have entered into with Cyberkinetics for the development of a treatment for peripheral nerve injury, for which we have committed to fund the first \$2.0 million in development expenses and 50% of any development costs exceeding the initial \$2.0 million.

Reimbursement from third-party payers is an important element of success for medical products companies. As our presence in the market expands and the use of the NC-stat System increases, we have experienced and are likely to continue to experience an increased focus from third-party payers and governmental agencies regarding the reimbursement of nerve conduction studies performed using

the NC-stat System and an increased focus from these organizations regarding the professional requirements for performing nerve conduction studies in general. A number of third-party payers, including commercial payers, have taken and may continue to take the position of not reimbursing our customers for their use of the NC-stat System.

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

The AMA formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies and nerve conduction equipment, including the NC-stat System. The findings of this committee were presented to the AMA CPT Editorial Panel at a meeting in February 2008. During the CPT Panel meeting, several proposals for new Category I CPT codes, which generally are included in the Medicare physician fee schedule and are assigned specified reimbursement values, were presented by the chairpersons of the work group and were supported by several physician societies. In spite of this, the only proposal voted on was for the creation of a new Category III CPT code, which generally would not be included on the Medicare physician fee schedule and would not generally have an assigned reimbursement value. At this meeting, we believe that the CPT Panel approved a new Category III CPT Code for nerve conduction studies performed using equipment with certain automated features such as the NC-stat System. Unless we are able to successfully challenge this decision, a new Category III CPT Code would likely be published in July 2008 and become effective in January 2009. In the event that a Category III CPT code is published which describes nerve conduction studies performed with the NC-stat System, it would likely result in limited or no Medicare reimbursement for such studies as a result of the potential that no specified reimbursement values would be assigned to these codes. This could also adversely impact reimbursement by other third party payers and could have an adverse and material impact on our revenues and results of operations.

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

or implemented in a manner that impacts the ability of physicians to receive reimbursement under Medicare, including lower levels of reimbursement and an increase in the number of claims being denied, for nerve conduction studies performed using the NC-stat System, which are having an adverse impact on our revenues.

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

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

We believe that eye scans performed using the DigiScope are being reimbursed by the majority of third-party payers. Many commercial payers have policies in place providing for reimbursement for the use of the DigiScope and many of these payers have published favorable articles about the DigiScope in their newsletters. However, several Medicare carriers have issued draft LCDs and coding articles that require a diagnosis of pre-existing retinal disease and/or will only reimburse for fundus photography, a highly specialized form of medical imaging, when performed in conjunction with an eye examination performed by an eye specialist. There are no assurances that other Medicare carriers will not issue similar draft LCDs, final LCDs or coding articles restricting the reimbursement for the use of the DigiScope. We believe that eye examinations performed on patients covered by Medicare represented less than 25% of our DigiScope revenues in 2007. However, the restrictions on reimbursement by Medicare carriers could have an adverse impact on our ability to grow our DigiScope revenues in future periods.

One of the primary challenges we face in our business is successfully expanding the market for nerve conduction studies. A successful market expansion will depend upon, in part, our targeting of primary care and specialist 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. Our strategy had been to sell the NC-stat System through a combination of independent sales agencies and a direct sales force of experienced sales representatives. The independent sales agencies, including small to medium sized regional firms and larger national firms, had primarily been responsible for generating sales leads and our direct sales force had been responsible for bringing these sales leads to closure. These independent sales agencies typically had not served in a traditional distribution role and therefore had not been responsible for maintaining inventories, for making shipments to customers or for billing and collection functions.

Our strategy of utilizing independent sales agencies had been effective historically, but we experienced a significant decline in the percentage of new customers being sourced through our independent sales agency network in the first half of 2007. As a result, consistent with our long term business objectives, in the second half of 2007, we made a decision to terminate our relationships with all independent sales agencies and focus our selling efforts exclusively through our direct sales force,

which, as of December 31, 2007, was comprised of approximately 50 regional sales managers, five regional sales directors and one national sales director.

We expect that our direct sales force will expand their role in generating new customer sales leads, and we plan to increase efforts to generate sales leads through various marketing activities including mailings and tradeshows. However, we experienced a decline in the number of new customers added in the last several quarters along with a decline in sales to our existing customers. We believe the decision to terminate the independent sales agency relationships may have contributed to these declines and could potentially have an adverse impact on our revenues and our ability to secure new customers in future periods as well.

*Business Focus*

Our long-term financial objectives are to grow our business through the sale of proprietary medical devices and to achieve and sustain profitability. We expect to achieve these objectives through sales of the NC-stat System and the DigiScope and additional products that may be commercialized to help physicians in the diagnosis and treatment of nervous system disorders, including neuropathies, and neurovascular disorders and products designed to provide regional anesthesia and pain control. However, during 2008 our revenues are likely to continue to decline and we are likely to continue to incur losses as a result of the reimbursement and other issues we are currently facing. Our efforts in 2008 will focus on (1) efforts to manage the reimbursement challenges posed by third-party payers for the NC-stat System after the AMA CPT Editorial Panel issues their final determination on the reimbursement coding for nerve conduction studies performed using automated equipment such as the NC-stat System, (2) sales of the NC-stat System, (3) sales and marketing of the DigiScope for the detection of diabetic retinopathy, including a market expansion into optometry clinics, (4) seeking regulatory clearance from the FDA for our traditional neurodiagnostic system, the ADVANCE System, in order to launch this product into the specialist physician and primary care physician markets and for portions of the onCall Information System, (5) cooperating with, and working to resolve, the government investigations of which we are subject and (6) our ongoing research and development programs, including NAVIGATOR, and a peripheral nerve injury product being jointly developed with Cyberkinetics.

Our launch of the ADVANCE System will depend upon our receipt of regulatory clearance from the FDA. We submitted our initial 510(k) filing for the ADVANCE System in the first quarter of 2007 and FDA clearance is still pending. During the fourth quarter of 2006, at the request of the FDA, we submitted a 510(k) filing relating to portions of the onCall Information System that are currently in use and the 510(k) clearance is still pending. If 510(k) clearance for the portions of the onCall Information System that are under review is not obtained, it may require additional product development and potential changes in the configuration of our products.

With respect to our research and development programs, during 2008, we expect to continue efforts to develop new biosensors, on the development of the ADVANCE System and its accessories, on the development of NAVIGATOR, for which we anticipate filing a 510(k) application with the FDA in 2008, and on a product for the treatment of peripheral nerve injury in collaboration with our joint venture partner, Cyberkinetics.

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

**Results of Operations**

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

	Years Ended December 31,		
	2007	2006	2005
<b>Revenues:</b>			
Diagnostic device	9.5%	13.6%	12.3%
Biosensor	88.3	86.4	87.7
Other	2.1		
<b>Total revenues</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>
Cost of revenues	27.0	24.5	25.8
Gross margin	73.0	75.5	74.2
<b>Operating expenses:</b>			
Research and development	11.0	9.1	11.1
Sales and marketing	51.5	39.8	41.3
General and administrative	33.2	21.4	23.4
<b>Total operating expenses</b>	<b>95.7</b>	<b>70.3</b>	<b>75.8</b>
Income (loss) from operations	(22.7)	5.2	(1.6)
Interest income, net	3.9	2.9	2.4
<b>Income (loss) before provision for income taxes</b>	<b>(18.8)</b>	<b>8.1</b>	<b>0.8</b>
Provision for income taxes		0.3	0.1
<b>Net income (loss)</b>	<b>(18.8)%</b>	<b>7.7%</b>	<b>0.7%</b>

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

*Revenues*

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

	Years Ended December 31,			
	2007	2006	Change	% Change
Customers	5,555	4,929	626	12.7%
Biosensor units used	1,055,500	1,155,300	(99,800)	(8.6)

	Years Ended December 31,			
	2007	2006	Change	% Change
(in thousands, except percentage data)				
<b>Revenues:</b>				
Diagnostic device	\$ 4,254.0	\$ 7,538.3	\$ (3,284.3)	(43.6)
Biosensor	39,413.3	47,711.4	(8,298.1)	(17.4)
Other	954.9		954.9	N/A
<b>Total revenues</b>	<b>\$ 44,622.2</b>	<b>\$ 55,249.7</b>	<b>\$ (10,627.5)</b>	<b>(19.2)</b>

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Diagnostic device revenues were \$4.3 million and \$7.5 million for the years ended December 31, 2007 and 2006, respectively, a decrease of \$3.3 million, or 43.6%. This decrease is primarily attributable to a lower number of units sold, which we believe resulted primarily from uncertainty and adverse



developments relating to the reimbursement for procedures performed with the NC-stat System. Diagnostic device revenues accounted for 9.5% and 13.6% of our total revenues for the years ended December 31, 2007 and 2006, respectively.

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

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

Other revenues are attributable to the DigiScope, which we had been selling under an exclusive sales and marketing license agreement entered into with EyeTel in October 2006 and we launched our sales and marketing efforts during the first quarter of 2007. Revenues related to the DigiScope were derived from a mix of new customers and customer accounts that existed at the time of our signing of the license agreement with EyeTel and were transferred to us. On December 26, 2007, we acquired substantially all of the assets and assumed certain liabilities of EyeTel, including all the rights to the DigiScope.

Our total revenues were \$44.6 million and \$55.2 million for the years ended December 31, 2007 and 2006, respectively, a decrease of \$10.6 million, or 19.2%. The decline in our total revenues is attributable to the previously mentioned lower number of NC-stat Systems and biosensors sold, which we believe resulted primarily from uncertainty and adverse developments relating to the reimbursement for nerve conduction studies performed with the NC-stat System.

We anticipate that revenues in 2008 will continue to decline. In the fourth quarter of 2007, we experienced a decline in revenues of 10.5% from the third quarter of 2007, which we believe primarily resulted from the uncertainty created by the issuance of draft LCDs, final LCDs and coding articles addressing reimbursement for nerve conduction studies and policies issued by commercial payers intended to deter usage or limit the reimbursement for the NC-stat System. These developments and other future reimbursement decisions, including the potential issuance of a Category III CPT code by the AMA CPT Editorial Panel, could continue to adversely impact reimbursement for procedures performed using the NC-stat System. Our revenues in 2008 are likely to be impacted by (a) the potential issuance of a Category III CPT code by the AMA CPT Editorial Panel; (b) the level of reimbursement, if any, established for procedures performed using the NC-stat System by insurance carriers and other third-party payers; (c) whether final LCDs are applied in a manner that places additional restrictions or qualifications on the performance of these procedures; (d) any other reimbursement determinations relating to nerve conduction studies that may be issued by third-party payers; or (e) any other events causing uncertainty as to the existence or amount of reimbursement physicians are likely to receive for performing procedures using the NC-stat System. Separately, we expect revenues to continue to be positively impacted by expanded sales and marketing efforts in the optometry market for the DigiScope. Overall, revenues could be impacted by a variety of factors, including the level of demand for our products, potential for changes in third-party reimbursement for nerve conduction studies, the decision to terminate our relationships with independent sales agencies,

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

the overall economy, competitive factors and the factors described in the section of this Annual Report on Form 10-K titled "Cautionary Note Regarding Forward-Looking Statements."

### *Costs and expenses*

The following table presents our costs and expenses and net income (loss):

	Years Ended December 31,		Change	% Change
	2007	2006		
(in thousands)				
<b>Cost of revenues:</b>				
Diagnostic device	\$ 915.8	\$ 1,320.5	\$ (404.7)	(30.7)%
Biosensor	10,422.1	12,237.6	(1,815.5)	(14.8)
Other	724.0		724.0	N/A
<b>Total cost of revenues</b>	<b>12,061.8</b>	<b>13,558.1</b>	<b>(1,496.3)</b>	<b>(11.0)</b>
<b>Gross margin:</b>				
Diagnostic device	3,338.2	6,217.8	(2,879.6)	(46.3)
Biosensor	28,991.2	35,473.9	(6,482.6)	(18.3)
Other	231.0		231.0	N/A
<b>Total gross margin</b>	<b>32,560.4</b>	<b>41,691.7</b>	<b>(9,131.2)</b>	<b>(21.9)</b>
<b>Gross Margin %:</b>				
Diagnostic device	78.5%	82.5%		
Biosensor	73.6	74.4		
Other	24.2			
<b>Total gross margin</b>	<b>73.0</b>	<b>75.5</b>		
<b>Operating expenses:</b>				
Research and development	\$ 4,891.9	\$ 5,010.5	\$ (118.6)	(2.4)
Sales and marketing	22,963.8	22,013.7	950.2	4.3
General and administrative	14,834.1	11,805.1	3,029.0	25.7
<b>Total operating expenses</b>	<b>42,689.9</b>	<b>38,829.3</b>	<b>3,860.6</b>	<b>9.9</b>
<b>Income (loss) from operations</b>	<b>(10,129.4)</b>	<b>2,862.4</b>	<b>(12,991.8)</b>	<b>(453.9)</b>
Interest income	1,751.0	1,598.4	152.6	9.5
<b>Income (loss) before provision for income taxes</b>	<b>(8,378.5)</b>	<b>4,460.8</b>	<b>(12,839.3)</b>	<b>(287.8)</b>
Provision for income taxes		193.0	(193.0)	(100.0)
<b>Net income (loss) available to common stockholders</b>	<b>\$ (8,378.5)</b>	<b>\$ 4,267.8</b>	<b>\$ (12,646.3)</b>	<b>(296.3)</b>

### *Gross Margin*

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

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

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Other gross margin percentage, which related entirely to the DigiScope, was 24.2% for the year ended December 31, 2007. DigiScope revenues in 2007 represent monthly rental fees and eye scan fees as well as the amortization of deferred revenues relating to installation and training fees. Under the

terms of agreement, we were required to remit a percentage of the revenues related to the DigiScope to EyeTel. The agreement included a provision for a higher percentage of the scan fees to be remitted to EyeTel for these existing customers for the first nine months of 2007. Effective October 1, 2007, consistent with the terms of our original agreement with EyeTel, the percentage of revenues we retained from these existing customers increased from 25% to 50%, which resulted in an increase in gross margins on DigiScope revenues in the fourth quarter of 2007 to 30.7% from 25.0% in the third quarter of 2007. As a result of our December 26, 2007 acquisition of substantially all of the assets of EyeTel, we expect gross margin on DigiScope revenues will increase in 2008.

Our overall gross margin decreased to \$32.6 million, or 73.0% of revenues, for the year ended December 31, 2007, as compared to \$41.7 million, or 75.5% of revenues, for same period in 2006.

Our gross margins may continue to decline during 2008 due to the expected decline in revenues derived from the NC-stat System and due to an expected increase in the percentage of total revenues derived from the DigiScope, which has lower gross margins as compared with our other products.

#### *Research and Development*

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

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

We expect our spending on R&D will be relatively unchanged during 2008. We anticipate that resources devoted to the development of the ADVANCE System may be reallocated to other research and development efforts. This amount may vary, however, depending on the opportunities and challenges that arise during the year and depending on the outcome of the FDA review of our 510(k) submission for the ADVANCE System, the FDA review of our 510(K) submission for portions of the onCall Information System and our revenues during 2008.

#### *Sales and Marketing*

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

Sales and marketing expenses increased \$950,200, or 4.3%, to \$23.0 million for year ended December 31, 2007 from \$22.0 million for the year ended December 31, 2006. As a percentage of revenues, sales and marketing expenses were 51.5% and 39.8% for the years ended December 31, 2007 and 2006, respectively. The increase in expenses was primarily due to (a) an increase of \$1.4 million in employee compensation and benefit costs attributable to the expansion of our sales force; (b) an increase of \$511,100 in consulting services, primarily to assist us with the reimbursement challenges we are facing; (c) an increase of \$245,400 in stock-based compensation expense; and (d) an increase of \$335,400 in advertising and promotional expenses. These amounts were partially offset by a decrease in third-party sales commissions of \$2.0 million, primarily due to our decision to terminate our relationships with all independent sales agencies and focus our selling efforts exclusively through our direct sales force and also due to decreased revenues.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

We anticipate that our sales and marketing expenses may decline in 2008 as a result of reduced payments to independent sales agencies and reduced commissions to our direct sales force attributable to potentially lower revenues, however, this may vary, depending primarily upon our revenues for 2008.

Our sales force is comprised of 56 employees, including 50 regional sales managers, as of December 31, 2007 compared to 53 employees, including 50 regional sales managers as of December 31, 2006. We plan to continue selling the DigiScope through the same sales force used to sell the NC-stat System and as a result we do not anticipate the need to expand the sales force to support the sales and marketing efforts for the DigiScope.

### *General and Administrative*

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

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

We believe our general and administrative expenses will increase in 2008 as a result of our acquisition of substantially all of the assets of EyeTel and may increase or decrease depending upon the amount incurred for professional fees and consulting services relating to the government investigations and reimbursement matters previously disclosed by us.

### *Interest Income*

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

### *Provision for Income Taxes*

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

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Comparison of Years Ended December 31, 2006 and December 31, 2005

Revenues

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

	Years Ended December 31,			
	2006	2005	Change	% Change
Customers	4,929	3,282	1,647	50.2%
Biosensor units used	1,155,300	704,800	450,500	63.9

  

	Years Ended December 31,			
	2006	2005	Change	% Change
(in thousands, except percentage data)				
Revenues:				
Diagnostic device	\$ 7,538.3	\$ 4,221.3	\$ 3,317.0	78.6
Biosensor	47,711.4	30,076.8	17,634.6	58.6
Total revenues	\$ 55,249.7	\$ 34,298.1	\$ 20,951.6	61.1

Diagnostic device revenues were \$7.5 million and \$4.2 million for the years ended December 31, 2006 and 2005, respectively, an increase of \$3.3 million, or 78.6%. Of this increase, approximately \$2.6 million is attributable to a greater number of units sold, primarily as a result of increased demand for the NC-stat System and an increase in the number of regional sales managers. In addition, \$0.7 million of this increase is attributable to an increase in the list price of our NC-stat monitors and docking stations from \$4,000 to \$5,000 effective January 1, 2006, which resulted in a higher average selling price during 2006 as compared to 2005. Diagnostic device revenues accounted for 13.6% and 12.3% of our total revenues for the years ended December 31, 2006 and 2005, respectively.

Biosensor revenues were \$47.7 million and \$30.1 million for the years ended December 31, 2006 and 2005, respectively, an increase of \$17.6 million, or 58.6%. The increase is primarily due to an increased customer base for our biosensors and an increased frequency of testing by our customers. Biosensor revenues accounted for 86.4% and 87.7% of our total revenues for the years ended December 31, 2006 and 2005, respectively.

Our customers used 1,155,300 biosensor units in the year ended December 31, 2006, compared to 704,800 units in the year ended December 31, 2005, an increase of 450,500 units, or 63.9%. The increase in biosensor usage is primarily attributable to the increase in our customer base and to an increase in usage per customer. During the 12-month period ending December 31, 2006, a total of 4,929 customers used our NC-stat System compared to 3,282 customers for the same period ending December 31, 2005. This represents a 50.2% year-over-year increase in the number of customers that used our NC-stat System. The average usage per account increased to 234 biosensors for the year ended December 31, 2006 from 215 biosensors for the same period in 2005.

Our total revenues were \$55.2 million and \$34.3 million for the years ended December 31, 2006 and 2005, respectively, an increase of \$21.0 million, or 61.1%.

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Costs and expenses

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

	Years Ended December 31,		Change	% Change
	2006	2005		
	(in thousands)			
<b>Cost of revenues:</b>				
Diagnostic device	\$ 1,320.5	\$ 1,059.7	\$ 260.8	24.6%
Biosensor	12,237.6	7,798.4	4,439.2	56.9
Total cost of revenues	13,558.1	8,858.1	4,700.0	53.1
<b>Gross margin:</b>				
Diagnostic device	6,217.8	3,161.6	3,056.2	96.7
Biosensor	35,473.9	22,278.5	13,195.4	59.2
Total gross margin	41,691.7	25,440.0	16,251.6	63.9
<b>Gross Margin %:</b>				
Diagnostic device	82.5%	74.9%		
Biosensor	74.4	74.1		
Total gross margin	75.5	74.2		
<b>Operating expenses:</b>				
Research and development	\$ 5,010.5	\$ 3,820.6	\$ 1,189.9	31.1
Sales and marketing	22,013.7	14,150.2	7,863.5	55.6
General and administrative	11,805.1	8,021.8	3,783.3	47.2
Total operating expenses	38,829.3	25,992.6	12,836.7	49.4
Income from operations	2,862.4	(552.5)	3,414.9	(618.1)
Interest income	1,598.4	838.8	759.6	90.6
Interest expense		(2.0)	2.0	(100.0)
Income before provision for income taxes	4,460.8	284.3	4,176.5	1,469.3
Provision for income taxes	193.0	35.0	158.0	451.4
Net income available to common stockholders	\$ 4,267.8	\$ 249.3	\$ 4,018.5	1,612.2

Gross Margin

Diagnostic device gross margin increased to \$6.2 million, or 82.5% of diagnostic device revenue, for the year ended December 31, 2006, as compared to \$3.2 million, or 74.9% of diagnostic device revenue, for same period in 2005. The increase in the gross margin percentage in 2006 compared to 2005 is primarily attributable to an increase in the list price of our NC-stat System from \$4,000 to \$5,000 effective January 1, 2006 and manufacturing price reductions realized for our device beginning in the second quarter of 2006.

Biosensor gross margin increased to \$35.5 million, or 74.4% of biosensor revenue for the year ended December 31, 2006, as compared to \$22.3 million, or 74.1% of biosensor revenue, for the same period in 2005. The increase in biosensor gross margin percentage is primarily due to manufacturing price reductions realized for several of our biosensors during the second half of 2005 and the first quarter of 2006 partially offset by a change in the mix of biosensors sold.

Our overall gross margin increased to \$41.7 million, or 75.5% of revenues, for the year ended December 31, 2006, as compared to \$25.4 million, or 74.2% of revenues, for same period in 2005.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

### *Research and Development*

R&D expenses increased \$1.2 million, or 31.1%, to \$5.0 million for the year ended December 31, 2006 from \$3.8 million for the year ended December 31, 2005. As a percentage of revenues, R&D expenses were 9.1% and 11.1% for the years ended December 31, 2006 and 2005, respectively. The increase in expenses is primarily due to an increase of \$614,000 in personnel costs resulting from the hiring of additional employees in our R&D department and increases in employee compensation. In addition, product development and temporary labor costs increased \$77,700 and \$51,700, respectively. These increases are primarily related to the development of the ADVANCE System and new biosensors. Also contributing to the increase was an increase of \$393,200 in stock-based compensation expense due to the adoption of the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share Based Payment," or SFAS No. 123(R).

### *Sales and Marketing*

Sales and marketing expenses increased \$7.9 million, or 55.6%, to \$22.0 million for year ended December 31, 2006 from \$14.2 million for the year ended December 31, 2005. As a percentage of revenues, sales and marketing expenses were 39.8% and 41.3% for the years ended December 31, 2006 and 2005, respectively. The change in expenses is primarily due to an increase of \$4.1 million in employee compensation and benefit costs, including sales commissions paid to our regional sales managers. This increase is attributable to the expansion of the sales force and higher revenues in 2006 as compared to 2005. Also contributing to the change in expenses are (a) an increase of \$1.6 million in sales commissions paid to our independent regional sales agencies, which is related to our higher revenues in 2006 as well as the addition of a distributor in May 2006; (b) an increase in stock-based compensation expense of \$653,300 due to the adoption of the provisions of SFAS No. 123(R); (c) an increase of \$400,700 in travel expenses due to the expansion of the sales force; (d) an increase in consulting services of \$299,300, primarily to assist us with reimbursement matters; and (e) an increase of \$267,500 in costs for new promotional materials.

### *General and Administrative*

General and administrative expenses increased \$3.8 million, or 47.2%, to \$11.8 million for year ended December 31, 2006 from \$8.0 million for the year ended December 31, 2005. As a percentage of revenues, general and administrative expenses were 21.4% and 23.4% for the years ended December 31, 2006 and 2005, respectively. The increase in expenses is primarily due to (a) an increase in stock-based compensation expense of \$1.2 million from the adoption of the provisions of SFAS No. 123(R); (b) an increase of \$661,300 in bad debt expense resulting from an increase in past due accounts; (c) an increase of \$538,400 in professional fees for legal services; (d) an increase of \$456,000 in our accrual for sales taxes; (e) an increase of \$268,800 in our insurance costs; (f) an increase in credit card and bank fees of \$238,800 related to increased customer transactions; and (g) an increase in personnel costs of \$120,700 from the expansion of staff and increases in employee compensation.

### *Interest Income*

Interest income was \$1,598,400 and \$838,800 during the years ended December 31, 2006 and 2005, respectively, representing an increase of \$759,600. Interest income was earned from cash equivalents, short-term investments and long-term investments. The increase in interest income for the year ended December 31, 2006, as compared to the year ended December 31, 2005 is primarily due to higher average cash balances and an increase in the average portfolio yield attributable to the impact of higher market interest rates in 2006. Interest expense was not material for the years ended December 31, 2006 and 2005.



## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

### Provision for Income Taxes

We recorded a tax provision related to alternative minimum tax of \$193,000 and \$35,000 for the years ended December 31, 2006 and 2005, respectively.

### Liquidity and Capital Resources

Our principal source of liquidity is our current cash and cash equivalents and short-term held-to-maturity investments. As of December 31, 2007, the weighted average maturity of our short-term held-to-maturity investments was 136 days. Our ability to generate cash from operations is dependent upon our ability to generate revenue from sales of our products, as well as our ability to manage our operating costs and net assets. A decrease in demand for our products or unanticipated increases in our operating costs would likely have an adverse effect on our liquidity and cash generated from operations. The following sets forth information relating to our liquidity:

	December 31,			
	2007	2006	Change	% Change
(in thousands)				
Cash and cash equivalents	\$ 7,097.2	\$ 7,909.8	\$ (812.6)	(10.3)%
Short-term held-to-maturity investments	22,621.7	32,410.7	(9,788.9)	(30.2)
Total cash, cash equivalents and short-term held-to-maturity investments	\$ 29,718.9	\$ 40,320.5	\$ (10,601.5)	(26.3)%

During 2007, our cash and cash equivalents and short-term held-to-maturity investments decreased by \$10.6 million, primarily due to \$8.0 million of cash used in operations, \$2.5 million of cash used for our investment in Cyberkinetics common stock, \$257,500 of cash used for capital expenditures and \$175,000 of cash used to fund our acquisition of substantially all of the assets of EyeTel, offset partially by \$285,900 of proceeds received from the issuance of common stock under our employee stock purchase plan and the exercise of stock options. The current estimated market value of the \$2.5 million investment made in Cyberkinetics common stock is approximately \$1.4 million and we are restricted from selling this investment until November 2008.

In managing our working capital, two of the financial measurements 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, 2007 and 2006:

	Years Ended December 31,	
	2007	2006
Days' sales outstanding (days)	54	40
Inventory turnover rate (times per year)	2.7	4.3

Our payment terms extended to our customers generally require payment within 30 days from invoice date. At December 31, 2007, we experienced an increase in DSO to 54 days from 40 days at December 31, 2006 attributable to a significant increase in the percentage of accounts receivable past due 60 days that began during the fourth quarter of 2006. We believe that these increases were primarily the result of challenges surrounding the reimbursement by Medicare and commercial payers in certain regions of the United States for nerve conduction studies performed using the NC-stat System. As long as we continue to face these reimbursement challenges our DSO and our working capital may continue to be adversely impacted. Accounts payable are normally paid within 30 to 40 days from receipt of a vendor's invoice.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

Our inventory turnover for the year ended December 31, 2007 was 2.7 times, compared with 4.3 times for the year ended December 31, 2006. The decrease in the inventory turnover rate for the year ended December 31, 2007, as compared to the year ended December 31, 2006, was primarily due to the initial production of the ADVANCE System and decreased demand for the NC-stat System, offset in part by a decline in inventories of biosensors due to production challenges being experienced by our third-party manufacturer resulting from their transition to a new manufacturing facility.

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

	Years Ended December 31,		
	2007	2006	2005
	(in thousands)		
Net cash provided by (used in) operating activities	\$ (7,989.1)	\$ 7,297.9	\$ 1,908.1
Net cash provided by (used in) investing activities	\$ 6,898.2	\$ (9,133.4)	\$ 3,514.5
Net cash provided by financing activities	\$ 278.3	\$ 1,575.3	\$ 812.2

Our operating activities used \$8.0 million of cash in 2007 while providing cash of \$7.3 million and \$1.9 million in 2006 and 2005, respectively. In 2007, a net loss of \$8.4 million and a net use of cash of \$3.4 million for our investment in working capital were offset by \$3.8 million in non-cash items, mainly compensation expense associated with stock options. The primary driver for the use of cash in our investment in working capital was a decrease in accrued expenses of \$3.4 million. This decrease was primarily due to the reversal of \$1.7 million of sales tax liability as a result of receiving amnesty from a number of states and receiving relief from other states in the form of a limited look back period and waiver of penalties. Also impacting working capital was an increase in our inventories of \$1.7 million primarily for the production of the ADVANCE System. These items were offset by a \$1.6 million decrease in accounts receivable, excluding the provision for doubtful accounts, due to a decline in revenues. In 2006, a net use of cash of approximately \$1.2 million for our investment in working capital was offset by \$4.3 million in net income and \$4.2 million in non-cash items, mainly compensation expense associated with stock options. The primary drivers of our investment in working capital were as follows: our accounts receivable increased \$4.1 million, excluding the change in the allowance for doubtful accounts, primarily due to growth in revenues and our inventories increased \$950,000 primarily due to the growth in our business and our preparation for the release of the ADVANCE System. These items were partially offset by a \$2.1 million increase in accrued expenses. In 2005, increases in accrued expenses, deferred revenue (net of deferred costs) and accounts payable of \$1.9 million, \$588,900 and \$799,300, respectively; non-cash items of \$1.4 million and net income of \$249,300 were offset in part by increases in accounts receivable and inventory of \$1.7 million and \$1.4 million, respectively.

As a result of the decline in revenues and increase in operating expenses, we incurred a net loss in 2007 and we expect to incur increased net losses for 2008. This is expected to have an adverse impact on our cash flows from operating activities for 2008.

Our investing activities provided \$6.9 million of cash in 2007, used \$9.1 million of cash in 2006 and provided \$3.5 million of cash in 2005. In 2007, \$37.8 million in investment maturities provided cash which was offset in part by \$28.0 million in investment purchases, \$2.5 million used to fund our investment in Cyberkinetics, \$257,500 used to fund purchases of fixed assets, primarily related to computer equipment and tooling equipment for new products and \$175,000 used to fund the acquisition of substantially all of the assets of EyeTel. In 2006, \$42.1 million in investment purchases and \$620,500 used to fund purchases of fixed assets, primarily related to computer equipment, were partially offset by \$33.6 million in cash provided from investment maturities. In 2005, \$18.8 million in investment maturities provided cash which was offset by \$15.3 million in investment purchases, which was primarily reinvested in cash equivalents and \$475,100 used to fund purchases of fixed assets primarily related to leasehold improvements and tooling equipment for new products.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

During 2008, we expect to continue to maintain our cash and investments in money market funds and short-term investment vehicles. We currently have a commitment of approximately \$487,600 to purchase DigiScopes from our manufacturer in China. We expect that our capital expenditures will increase in 2008 compared with 2007 due to the purchases of DigiScopes. We anticipate a total capital investment for DigiScopes in 2008 of \$1.6 million to \$2.0 million, including the commitment referred to above. Additionally we have a potential commitment to purchase an additional \$1.25 million of Cyberkinetics common stock that we must exercise in certain circumstances.

In February 2008, our property lease, originally entered into at the beginning of January 2001 and which was scheduled to expire on March 31, 2009, was amended to extend the term of the lease for a period of an additional four years. In connection with this amendment, the amount of the irrevocable standby letter of credit, we are required to maintain, stating the lessor as the beneficiary, will be reduced from \$1,430,000 to \$400,000. The letter of credit must be secured by a certificate of deposit in an amount equal to 102% of the letter of credit as a security deposit. We expect that this reduction in the security deposit of approximately \$1.0 million will become available to us for our operating and working capital needs during the first half of 2008. The lease will now expire in March 2013. The certificate of deposit is renewable annually. This amount is classified as restricted cash in the balance sheet.

Our financing activities provided \$278,300, \$1.6 million and \$812,000 of cash in 2007, 2006 and 2005, respectively. Cash provided by financing activities in 2007, 2006 and 2005 represent the proceeds from the issuance of shares under our employee stock purchase plan and the exercise of stock options. In 2007, these proceeds were offset in part by payments on a capital lease.

During 2008, we plan to fund sales and marketing efforts for the DigiScope and continue our research and development programs, including the ADVANCE System. We plan to continue investing resources on the development of NAVIGATOR, a minimally invasive nerve localization system for regional anesthesia, pain control and the treatment of neuropathies such as CTS. We also expect to incur capital expenditures for computer hardware and software to support our business and the additional requirements of our customer base. We also continue to explore investment, licensing and acquisition opportunities that may expand our product offering in the physician office market and in the neurological sector.

We expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. Based upon our current plans, we believe that our existing capital resources, including cash and cash equivalents and short-term investments, as of December 31, 2007 are sufficient to finance our ongoing operations for twenty-four months, including the anticipated operating expenses and capital expenditures described above. However, our business is currently facing significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes in our estimates, future revenues, changes we make to our ongoing operating expenses, future changes in our business strategy, decisions we make regarding the size of our sales force and the magnitude of our sales and marketing programs, research and development spending plans, the outcome of the DOJ investigation that we are currently subject to, and other items affecting our level of expenditures and our use of existing cash and cash equivalents and short-term investments. Accordingly, we may need to raise additional funds to support our operating and capital needs. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities or other operations and potentially delay our product development efforts.

We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners or through additional credit lines or other debt financing sources to increase the funds we have available to us to fund our operations. However, there are no assurances that we will be able to secure such financing on favorable terms, if at all.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

As of December 31, 2007, we have federal and state net operating loss carryforwards available to offset future taxable income of \$37.0 million and \$21.1 million, respectively, and federal and state research and development credits of \$598,000 and \$544,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. The net operating loss and research and development credit carryforwards expire at various dates beginning in 2011 for federal and 2008 for state. Ownership changes in our company, as defined in the Internal Revenue Code, are expected to have a modest limitation on the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, based on an analysis of the provisions of Section 382 of the Internal Revenue Code. Subsequent changes in our ownership could further affect the limitation in future years.

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

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

As of December 31, 2007, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2007 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Payments due in					
	Total	2008	2009	2010	2011 & 2012	after 2012
Operating lease obligations	\$ 1,162,500	\$ 930,000	\$ 232,500	\$	\$	\$
Capital lease obligations	31,175	12,900	12,900	5,375		
Purchase order obligations	3,369,946	3,369,946				
<b>Total contractual obligations</b>	<b>\$ 4,563,621</b>	<b>\$ 4,312,846</b>	<b>\$ 245,400</b>	<b>\$ 5,375</b>	<b>\$</b>	<b>\$</b>

In connection with our investment in Cyberkinetics, we received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant, exercisable at \$0.46 per share, or approximately \$1.25 million, has a term of five years, and is required to be exercised by us if Cyberkinetics receives FDA approval of an HDE filing for the Andara OFS device for acute spinal cord injuries.

In February 2008, we entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics to develop and commercialize products for the treatment of peripheral nerve injury and formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with initial ownership of 50% held by us and 50% held by Cyberkinetics. Under the terms of the joint venture, we have agreed to fund the initial \$2.0 million in product development costs and have agreed to share equally in all costs in excess of the initial \$2.0 million.

In February 2008, we amended the Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and us for office and engineering laboratory space. The amendment extends the term of the lease, currently scheduled to expire on March 31, 2009, through March 31, 2013. Base rent for the period April 2009 through March 2013 will be reduced from the current level of \$930,000 annually to a range of \$675,000 to \$765,000 annually.

### **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 1 to our Financial Statements.

#### *Revenue Recognition*

Our revenue recognition policy is to recognize revenues from our NC-stat System monitors and biosensors upon shipment if the fee is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred and risk of loss has passed, collection of the resulting receivables is reasonably assured and product returns are reasonably estimable. Revenues from our docking station and access to the onCall Information System are considered one unit of accounting and are deferred and recognized over the shorter of the estimated customer relationship period or the estimated useful life of the product, currently three years. We record revenue on a net basis for product sales made to distributors, based upon the amount billed to the distributors, when the distributor accepts the responsibility for invoicing the customer and the responsibility for the risk of collections and product returns from the customer.

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

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

Certain product sales are made with a 30-day right of return. Since we can reasonably estimate future returns, we recognize revenues associated with product sales that contain a right of return upon shipment and at the same time reduce revenue by the amount of estimated returns under the provisions of SFAS No. 48, "*Revenue Recognition When Right of Return Exists.*"

Other revenues consist entirely of revenues relating to the DigiScope, including installation and training fees, per patient fees for eye scans performed using the DigiScope and monthly rental fees for the use of the DigiScope. Installation and training fees are deferred and recognized on a straight line basis over the non-cancelable term of the customer contract, currently one year. Revenues from fees charged for patient eye scans are recognized as the scans are performed. Fees for the rental of the DigiScope are recognized on a monthly basis. Under the terms of an exclusive sales and marketing license to the DigiScope from EyeTel, amounts due to EyeTel were recorded as cost of sales.

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

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts and determine the allowance based on an analysis of customer past payment history, product usage activity, and recent

communications between us and the customer. Past due balances over 90 days are reviewed individually for collectibility. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance sheet credit exposure related to our customers.

#### *Warranty Costs*

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

#### *Asset Valuation*

Asset valuation includes assessing the recorded value of certain assets, including short and long-term investments, accounts receivable, inventories and fixed assets. We use a variety of factors to assess valuation, depending upon the asset. Our investment portfolio is classified as held-to-maturity, and such investments are stated at amortized cost. In accordance with the provisions of SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*", or SFAS No. 115, our investment in Cyberkinetics is classified as available-for-sale and is carried at fair value, with any unrealized gains and losses, net of taxes, reported in accumulated other comprehensive loss, a separate component of stockholders' equity. Accounts receivable are evaluated based upon our historical experience, the age of the receivable and current market and economic conditions. 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 recoveries could be less than our estimates. The recoverability of our fixed assets and other long-lived assets are evaluated when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*", or SFAS No. 144.

#### *Accounting for Income Taxes*

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

Effective January 1, 2007, we adopted FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*", or FIN 48, which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 requires us to perform a two-step evaluation of all tax positions, ensuring that these tax return positions meet the "more-likely than not" recognition threshold and can be measured with sufficient precision to determine the benefit recognized in the financial statements. These evaluations provide us with a comprehensive model for how we should recognize, measure, present, and disclose in our financial statements certain tax

positions that we have taken or expect to take on income tax returns. Management estimated that as of December 31, 2006, there was an uncertain tax position totaling approximately \$100,000 relating to our tax credit carryforwards. As a result, we reduced our deferred tax assets and the associated valuation allowance by approximately \$100,000 as of January 1, 2007, the adoption date of FIN 48. There have been no other activities impacting FIN 48 reserves during the year ended December 31, 2007.

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

Effective January 1, 2006, we adopted SFAS No. 123(R) using the modified prospective method and began reflecting the stock-based compensation expense determined under fair value based methods in our statement of operations rather than as pro forma disclosure in our notes to the financial statements. Under this transition method, the compensation cost recognized beginning January 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation", or SFAS No. 123, and (ii) all share based payments granted or modified subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Compensation cost is generally recognized ratably over the requisite service period. Prior period amounts have not been restated. We use the Black-Scholes option pricing model for determining the fair value of our stock options and amortize our stock-based compensation expense using the straight-line method.

#### *Goodwill and Other Intangible Assets*

As result of our acquisition of substantially all of the assets of EyeTel on December 26, 2007, there was approximately \$5.8 million of goodwill and \$2.8 million of other intangible assets on our balance sheet at December 31, 2007. We will amortize intangible assets using the straight-line method over their estimated economic lives, which is currently estimated to be five years. Determining the economic lives of acquired intangible assets requires us to make significant judgment and estimates, and can materially impact our operating results.

SFAS No. 142, "Goodwill and Other Intangible Assets", or SFAS No. 142, requires us to assess the realizability of goodwill annually, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. The Company's ability to realize the value of the goodwill will depend on the future cash flows of the business. If the Company is not able to realize the value of goodwill, the Company may be required to incur material charges relating to the impairment of goodwill.

We are required to perform impairment tests under SFAS No. 142 annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For the acquisition, various analyses, assumptions and estimates were made at the time of the acquisition specifically regarding product development, market conditions and expected cash flows that were used to determine the valuation of goodwill and intangibles.

When we perform impairment tests in future years, changes in forecasts and estimates from those used at the acquisition date could result in impairment charges.

#### *Other Long-Lived Assets*

We periodically evaluate long-lived assets for potential impairment under SFAS No. 144. We plan to perform these evaluations whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. If we believe an indicator of potential impairment exists, we test to determine whether the impairment recognition criteria in SFAS No. 144

have been met. In evaluating long-lived assets for potential impairment, we will make several significant estimates and judgments, including:

determining the appropriate grouping of assets at the lowest level for which cash flows are available;

estimating future cash flows associated with the asset or group of assets; and

determining an appropriate discount rate to use in the analysis.

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

### **New Accounting Pronouncements**

In December 2007, the Financial Accounting Standards Board, or FASB, issued SFAS No. 141 (Revised 2007), "*Business Combinations*", or SFAS No. 141R. SFAS No. 141R will significantly change the accounting for business combinations. Under SFAS No. 141R, an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS No. 141R will change the accounting treatment for certain specific acquisition related items including: (1) expensing acquisition related costs as incurred; (2) valuing noncontrolling interests at fair value at the acquisition date; and (3) expensing restructuring costs associated with an acquired business. SFAS No. 141R also includes a substantial number of new disclosure requirements. SFAS No. 141R is to be applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. We expect SFAS No. 141R will have an impact on our accounting for future business combinations once adopted but the effect is dependent upon the acquisitions that are made in the future.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*", or SFAS No. 159. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS No. 159 does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We believe that our adoption of SFAS No. 159 will not have a material impact on our financial position, results of operations or cash flows.

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



**Subsequent Events**

**Joint Venture with Cyberkinetics**

In February 2008, we entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics to develop and commercialize products for the treatment of peripheral nerve injury and formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with 50% ownership held by us and 50% ownership held by Cyberkinetics.

Under the terms of the joint venture, we have agreed to fund the initial \$2.0 million in product development costs and have agreed to share equally in all costs in excess of the initial \$2.0 million. Cyberkinetics has agreed to contribute technology, know-how and intellectual property, primarily relating to their Andara OFS technology, to the joint venture.

We obtained sales and marketing rights and Cyberkinetics obtained commercial manufacturing rights to any products commercialized under the joint venture. Each party will charge the joint venture at cost for all expenses incurred in connection with their respective commercialization activities. Based on the initial ownership of the joint venture, we will equally split profits and losses realized from the joint venture with Cyberkinetics.

**Lease Agreement**

In February 2008, we amended the Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and us for office and engineering laboratory space. The amendment extends the term of the lease, currently scheduled to expire on March 31, 2009, through March 31, 2013. Base rent for the period April 2009 through March 2013 will be reduced from the current level of \$930,000 annually to a range of \$675,000 to \$765,000 annually.

In connection with the amendment of the lease, the amount of the irrevocable letter of credit required to be maintained by us for the benefit of the lessor will be reduced from \$1,430,000 to \$400,000. The letter of credit must be secured by a certificate of deposit in an amount equal to 102% of the letter of credit as security.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments with a maturity of 12 months or less and maintain an average maturity of twelve months or less. We do not believe that a notional or hypothetical 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

**Item 8. Financial Statements and Supplementary Data**

The information required by this item may be found on pages F-1 through F-30 of this Form 10-K with the exception of the unaudited quarterly financial information which is presented below:

**Year Ended December 31, 2007**

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenues	\$ 11,757,786	11,475,509	11,290,004	\$ 10,098,912	\$ 44,622,211
Gross margin	\$ 8,663,168	8,407,874	8,241,990	\$ 7,247,381	\$ 32,560,413
Net loss attributable to common shareholders	\$ (1,377,282)	(1,290,991)	(3,570,925)	\$ (2,139,276)	\$ (8,378,474)
Net loss per common share:					
Basic	\$ (0.11)	(0.10)	(0.28)	\$ (0.17)	\$ (0.66)
Diluted	\$ (0.11)	(0.10)	(0.28)	\$ (0.17)	\$ (0.66)
Weighted average shares used to compute net loss per common share:					
Basic	12,605,431	12,611,880	12,624,465	12,693,209	12,628,310
Diluted	12,605,431	12,611,880	12,624,465	12,693,209	12,628,310

**Year Ended December 31, 2006**

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenues	\$ 11,823,275	\$ 13,970,050	\$ 15,261,251	\$ 14,195,140	\$ 55,249,716
Gross margin	\$ 8,943,362	\$ 10,592,584	\$ 11,525,299	\$ 10,630,417	\$ 41,691,662
Net income (loss) attributable to common shareholders	\$ (102,662)	\$ 1,233,700	\$ 2,104,630	\$ 1,032,138	\$ 4,267,806
Net income (loss) per common share:					
Basic	\$ (0.01)	\$ 0.10	\$ 0.17	\$ 0.08	\$ 0.34
Diluted	\$ (0.01)	\$ 0.09	\$ 0.16	\$ 0.08	\$ 0.33
Weighted average shares used to compute net income (loss) per common share:					
Basic	12,414,479	12,485,205	12,539,709	12,583,825	12,501,742
Diluted	12,414,479	13,137,867	13,095,430	12,926,449	13,097,891

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

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

**Item 9A. Controls and Procedures**

(a)

**Evaluation of disclosure controls and procedures.**

Our management carried out an evaluation, with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2007. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and

communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures.

Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that our disclosure controls and procedures are effective, as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to the issuer's management, including its principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosures. We continue to review and document our disclosure controls and procedures, including our internal controls over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b)

**Management's Report on Internal Control Over Financial Reporting.**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 based on the criteria in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under the framework in *Internal Control Integrated Framework* issued by the COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

Management has excluded EyeTel from our assessment of internal control over financial reporting as of December 31, 2007 because it was acquired by us in a purchase business combination during the year ended December 31, 2007. The total assets and total revenues related to the acquisition of EyeTel represent 4% and 0%, respectively, of the related financial statement amounts as of and for the year ended December 31, 2007.

The effectiveness of our internal control over financial reporting as of December 31, 2007, has been audited by PricewaterhouseCoopers LLP, an independent registered accounting firm, as stated in their report which is included herein.

(c)

**Changes in internal control over financial reporting.**

There have been no changes to the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The response to this item is contained in our Proxy Statement relating to our 2008 Annual Meeting of Stockholders (the "Proxy Statement") and is incorporated herein by reference.

**Item 11. Executive Compensation**

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

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

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

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

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

**Item 14. Principal Accountant Fees and Services**

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

## PART IV

**Item 15. Exhibits and Financial Statement Schedules**

(a)

1. *Financial Statements*

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

2. *Financial Statement Schedule*

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

3. *Exhibit Index:*

Exhibit Number	Description
2.1	Asset Purchase Agreement by and among NeuroMetrix, Inc., EyeTel Imaging, Inc. and EyeTel Reading Center, LLC, dated as of December 26, 2007 (9)
3.1	Second Amended and Restated By-laws of NeuroMetrix, Inc. (10)
3.2	Third Amended and Restated Certificate of Incorporation of NeuroMetrix, Inc. (10)
3.3	Certificate of Designations for Series A Junior Cumulative Preferred Stock, par value \$0.001 per share (7)
3.4	Amendment No. 1 to Second Amended and Restated Bylaws of NeuroMetrix, Inc. (8)
4.1	Specimen certificate for shares of common stock (1)
4.2	Shareholder Rights Agreement, dated as of March 7, 2007, between NeuroMetrix, Inc. and American Stock Transfer & Trust Company, as Rights Agent (7)
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	Amended and Restated 2004 Stock Option and Incentive Plan (2)
10.6	2004 Employee Stock Purchase Plan (1)
10.7	Form of Indemnification Agreement between NeuroMetrix, Inc. and each of its directors (1)
10.8	Employment Agreement, dated June 21, 2004, by and between NeuroMetrix, Inc. and Shai N. Gozani, M.D., Ph.D. (1)
10.9	Letter Agreement, dated June 19, 2002, by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
10.10	NeuroMetrix, Inc. Stock Option Agreements (1998 Plan) dated as of July 1, 2002 and April 8, 2004 by and between NeuroMetrix, Inc. and Gary L. Gregory (1)
10.11	NeuroMetrix, Inc. Confidentiality and Non-Compete Agreement, dated as of June 28, 2002, by and between Gary L. Gregory and NeuroMetrix, Inc. (1)
10.12	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement dated as of June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D. and NeuroMetrix, Inc. (1)
10.13	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004, by and between Shai N. Gozani M.D., Ph.D., and NeuroMetrix, Inc. (1)
10.14	Second Amendment to Amended and Restated 1998 Equity Incentive Plan (1)
10.15	NeuroMetrix, Inc. Non-Statutory Stock Option Agreement (1998 Plan) dated as of June 21, 2004 by and between Gary Gregory and NeuroMetrix, Inc. (1)
10.16	Indemnification Agreement dated June 21, 2004, by and between Shai N. Gozani, M.D., Ph.D., and NeuroMetrix, Inc. (1)
10.17	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of May 1, 2000, by and between Michael Williams and NeuroMetrix, Inc. (1)

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

10.18	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of October 13, 1998, by and between Guy Daniello and NeuroMetrix Inc. (1)
10.19	Form of Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (3)
10.20	Form of Non-Qualified Stock Option Agreement For Company Employees, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (3)
10.21	Form of Non-Qualified Stock Option Agreement For Non-Employee Directors, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan (3)
10.22	Letter Agreement, dated February 7, 2005, by and between NeuroMetrix, Inc. and W. Bradford Smith (4)
10.23	Form of Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option and Incentive Plan, by and between NeuroMetrix, Inc. and W. Bradford Smith (4)
10.24	NeuroMetrix, Inc. Confidentiality & Non-Compete Agreement, dated as of February 7, 2005, by and between W. Bradford Smith and NeuroMetrix, Inc. (4)
10.25	Director Compensation Arrangements (5)
10.26	Manufacturing and Supply Agreement, dated as of August 2, 2006, by and between Parlex Polymer Flexible Circuits, Inc. and NeuroMetrix, Inc. (6)
*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 (Registration No. 333-115440).
- (2) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on May 26, 2006 (File No. 000-50856).
- (3) Incorporated herein by reference to NeuroMetrix, Inc.'s Quarterly Report on Form 10-Q filed on November 15, 2004 (File No. 000-50856).
- (4) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on February 11, 2005 (File No. 000-50856).
- (5) Incorporated herein by reference to NeuroMetrix, Inc.'s Annual Report on Form 10-K filed on March 16, 2006 (File No. 000-50856).
- (6) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on August 2, 2006 (File No. 000-50856).
- (7) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on March 8, 2007 (File No. 000-50856).
- (8) Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on September 17, 2007 (File No. 000-50856).

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

(9)

Incorporated herein by reference to NeuroMetrix, Inc.'s Current Report on Form 8-K filed on December 28, 2007 (File No. 000-50586).

(10)

Incorporated herein by reference to NeuroMetrix, Inc.'s Registration Statement on Form S-8 (Registration No. 333-118059).



SIGNATURES

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

NEUROMETRIX, INC.

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

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

Date: March 14, 2008

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 14, 2008 in the capacities indicated below.

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

INDEX TO FINANCIAL STATEMENTS

NeuroMetrix, Inc.

Years ended December 31, 2007, 2006 and 2005

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Financial Statements</u>	
<u>Balance Sheets</u>	F-4
<u>Statements of Operations</u>	F-5
<u>Statements of Changes in Stockholders' Equity</u>	F-6
<u>Statements of Cash Flows</u>	F-7
<u>Notes to Financial Statements</u>	F-8
<u>Schedule II Valuation and Qualifying Accounts</u>	S-1
	F-1

---

**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying balance sheets and the related statements of operations, statements of changes in stockholders' equity, and statements of cash flows present fairly, in all material respects, the financial position of NeuroMetrix, Inc. at December 31, 2007 and December 31, 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 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. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## Edgar Filing: NeuroMetrix, Inc. - Form 10-K

As described in Management's Report on Internal Control over Financial Reporting, management has excluded EyeTel Imaging, Inc. from its assessment of internal control over financial reporting as of December 31, 2007 because it was acquired by the Company in a purchase business combination during the year ended December 31, 2007. We have also excluded EyeTel Imaging, Inc. from our audit of internal control over financial reporting. Total assets and total revenues related to the acquisition of EyeTel Imaging, Inc. represent 4.0% and 0.0%, respectively, of the related financial statement amounts as of and for the year ended December 31, 2007.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 14, 2008

F-3

---

## NeuroMetrix, Inc.

## Balance Sheets

	December 31,	
	2007	2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,097,239	\$ 7,909,778
Short-term held-to-maturity investments	22,621,741	32,410,685
Restricted cash	45,000	
Accounts receivable, net of allowance for doubtful accounts of \$906,000 and \$900,000 at December 31, 2007 and 2006, respectively	5,731,697	7,698,550
Inventories	5,354,338	3,633,389
Prepaid expenses and other current assets	710,159	761,400
Current portion of deferred costs	464,061	370,013
	<hr/>	<hr/>
Total current assets	42,024,235	52,783,815
Restricted cash	1,458,598	1,458,598
Fixed assets, net	2,973,718	1,115,436
Long-term available-for-sale investment	1,058,255	
Goodwill	5,833,464	
Other intangible assets	2,800,000	
Deferred costs	226,304	348,430
	<hr/>	<hr/>
Total assets	\$ 56,374,574	\$ 55,706,279
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,627,889	\$ 2,766,650
Accrued compensation	2,127,546	2,460,328
Accrued expenses	2,308,563	4,275,983
Current portion of deferred revenue	1,643,026	1,386,867
Current portion of capital lease obligation	12,900	
	<hr/>	<hr/>
Total current liabilities	8,719,924	10,889,828
Deferred revenue	891,958	1,335,138
Capital lease obligation net of current portion	18,275	
Other long-term liabilities	14,546	72,727
	<hr/>	<hr/>
Total liabilities	9,644,703	12,297,693
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding		
Common stock, \$0.0001 par value; 50,000,000 authorized; 13,690,134 and 12,601,224 shares issued and outstanding at December 31, 2007 and 2006, respectively	1,369	1,260
Additional paid-in capital	110,235,835	97,205,145
Deferred compensation		(110,705)
Accumulated deficit	(62,065,588)	(53,687,114)
Accumulated other comprehensive loss	(1,441,745)	
	<hr/>	<hr/>
Total stockholders' equity	46,729,871	43,408,586
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 56,374,574	\$ 55,706,279
	<hr/>	<hr/>

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

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

F-4

---

## NeuroMetrix, Inc.

## Statements of Operations

	Years Ended December 31,		
	2007	2006	2005
<b>Revenues:</b>			
Diagnostic device	\$ 4,254,011	\$ 7,538,320	\$ 4,221,311
Biosensor	39,413,265	47,711,396	30,076,822
Other	954,935		
<b>Total revenues</b>	<b>44,622,211</b>	<b>55,249,716</b>	<b>34,298,133</b>
Cost of revenues	12,061,798	13,558,054	8,858,094
<b>Gross margin</b>	<b>32,560,413</b>	<b>41,691,662</b>	<b>25,440,039</b>
<b>Operating expenses:</b>			
Research and development	4,891,937	5,010,513	3,820,624
Sales and marketing	22,963,840	22,013,682	14,150,157
General and administrative	14,834,073	11,805,062	8,021,783
<b>Total operating expenses</b>	<b>42,689,850</b>	<b>38,829,257</b>	<b>25,992,564</b>
<b>Income (loss) from operations</b>	<b>(10,129,437)</b>	<b>2,862,405</b>	<b>(552,525)</b>
Interest income	1,750,963	1,598,401	838,825
Interest expense			(2,042)
<b>Income (loss) before provision for income taxes</b>	<b>(8,378,474)</b>	<b>4,460,806</b>	<b>284,258</b>
Provision for income taxes		193,000	35,000
<b>Net income (loss)</b>	<b>\$ (8,378,474)</b>	<b>\$ 4,267,806</b>	<b>\$ 249,258</b>
<b>Net income (loss) per common share:</b>			
Basic	\$ (0.66)	\$ 0.34	\$ 0.02
Diluted	\$ (0.66)	\$ 0.33	\$ 0.02
<b>Weighted average shares used to compute net income (loss) per common share:</b>			
Basic	12,628,310	12,501,742	12,152,139
Diluted	12,628,310	13,097,891	12,986,365
<b>Comprehensive income (loss):</b>			
Net income (loss)	\$ (8,378,474)	\$ 4,267,806	\$ 249,258
Unrealized loss on available-for-sale investment	(1,441,745)		
<b>Comprehensive income (loss)</b>	<b>\$ (9,820,219)</b>	<b>\$ 4,267,806</b>	<b>\$ 249,258</b>

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

## NeuroMetrix, Inc.

## Statements of Changes in Stockholders' Equity

	Common Stock					Accumulated Other Comprehensive Loss	Total
	Number of Shares	Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit		
Balance at December 31, 2004	12,034,650	\$ 1,203	\$ 92,278,379	\$ (745,086)	\$ (58,204,178)		33,330,318
Issuance of stock upon exercise of stock options and warrants	317,361	32	512,825				512,857
Compensation expense associated with stock options			120,272				120,272
Adjustment to deferred compensation associated with terminated employees			(33,405)	33,405			
Amortization of deferred compensation				286,058			286,058
Issuance of common stock under employee stock purchase plan	23,265	3	299,297				299,300
Income tax effect of the exercise of stock options			35,000				35,000
Net income					249,258		249,258
Balance at December 31, 2005	12,375,276	1,238	93,212,368	(425,623)	(57,954,920)		34,833,063
Issuance of stock upon exercise of stock options	202,808	20	1,180,637				1,180,657
Stock-based compensation expense			2,403,222				2,403,222
Adjustment to deferred compensation associated with terminated employees			(65,503)	65,503			
Amortization of deferred compensation				249,415			249,415
Issuance of common stock under employee stock purchase plan	23,140	2	394,621				394,623
Income tax effect of the exercise of stock options			79,800				79,800
Net income					4,267,806		4,267,806
Balance at December 31, 2006	12,601,224	1,260	97,205,145	(110,705)	(53,687,114)		43,408,586
Issuance of stock upon exercise of stock options	5,957	1	24,099				24,100
Stock-based compensation expense			2,976,059				2,976,059
Adjustment to deferred compensation associated with terminated employees			(15,674)	15,674			
Amortization of deferred compensation				95,031			95,031
Issuance of common stock under employee stock purchase plan	32,656	3	261,763				261,766
Issuance of common stock to complete the acquisition of EyeTel	1,050,297	105	9,784,443				9,784,548
Unrealized loss on long-term investment						(1,441,745)	(1,441,745)
Net loss					(8,378,474)		(8,378,474)



Edgar Filing: NeuroMetrix, Inc. - Form 10-K

**Common Stock**

---

Balance at December 31, 2007	13,690,134	\$	1,369	\$	110,235,835	\$	(62,065,588)	\$	(1,441,745)	\$	46,729,871
------------------------------	------------	----	-------	----	-------------	----	--------------	----	-------------	----	------------

---

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

F-6

---

## NeuroMetrix, Inc.

## Statements of Cash Flows

	Years Ended December 31,		
	2007	2006	2005
<b>Cash flows for operating activities:</b>			
Net income (loss)	\$ (8,378,474)	\$ 4,267,806	\$ 249,258
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	422,938	380,655	278,932
Compensation expense associated with stock options	3,071,090	2,652,637	406,330
Provision for doubtful accounts	358,141	946,850	281,684
Amortization of premium on investments	(41,811)	184,163	439,734
Income tax effect of the exercise of stock options		79,800	35,000
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	1,643,712	(4,102,061)	(1,698,458)
Inventories	(1,720,949)	(949,980)	(1,399,148)
Prepaid expenses and other current assets	267,241	(147,231)	58,801
Accounts payable	(7,340)	1,068,067	799,292
Accrued expenses and compensation	(3,386,539)	2,147,762	1,925,923
Other long-term liabilities	(58,181)	(58,182)	(58,182)
Deferred revenue and deferred costs	(158,943)	827,617	588,924
Net cash provided by (used in) operating activities	(7,989,115)	7,297,903	1,908,090
<b>Cash flows for investing activities:</b>			
Purchases of fixed assets	(257,520)	(620,540)	(475,124)
Purchases of investments	(27,959,957)	(42,141,626)	(15,290,120)
Maturities of investments	37,790,712	33,628,724	18,840,191
Purchase of Cyberkinetics common stock	(2,500,000)		
Acquisition of EyeTel	(175,000)		
Release of restricted cash			438,602
Net cash provided by (used in) investing activities	6,898,235	(9,133,442)	3,513,549
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options	24,100	1,180,657	512,857
Proceeds from issuance of common stock under employee stock purchase plan	261,766	394,623	299,300
Payments on long-term debt	(7,525)		
Net cash provided by financing activities	278,341	1,575,280	812,157
Net increase (decrease) in cash and cash equivalents	(812,539)	(260,259)	6,233,796
Cash and cash equivalents, beginning of year	7,909,778	8,170,037	1,936,241
Cash and cash equivalents, end of year	\$ 7,097,239	\$ 7,909,778	\$ 8,170,037
<b>Supplemental disclosure of cash flow information:</b>			
Equipment acquired under capital lease	\$ 38,700	\$	\$
Fair value of EyeTel assets acquired	10,914,464		
Fair value of common stock issued to EyeTel	9,784,548		
EyeTel liabilities assumed	804,916		

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



**NeuroMetrix, Inc.**

**Notes to Financial Statements**

**1. Business and Summary of Significant Accounting Policies**

**Business**

NeuroMetrix, Inc. (the "Company"), a Delaware corporation, was founded in June 1996. The Company designs, develops and markets proprietary medical devices used to help physicians diagnose and treat diseases of the nervous system such as neuropathies, which are disorders of the peripheral nerves and parts of the spine, and neurovascular disorders such as diabetic retinopathy. The Company also develops medical devices designed to be used to provide regional anesthesia and pain control. Our focus to date has been on products that help physicians with the diagnosis of neuropathies and neurovascular disorders. We have two products lines cleared by the United States Food and Drug Administration ("FDA") that are currently being marketed to physicians, including the NC-stat System and the DigiScope.

In November 2007, the Company made an investment of \$2.5 million for the purchase of approximately 5.4 million shares of common stock of Cyberkinetics Neurotechnology Systems, Inc. ("Cyberkinetics"), representing approximately 13% of Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share. The Company also received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant is exercisable at \$0.46 per share and has a term of five years, but will be required to be exercised if Cyberkinetics receives FDA approval of a Humanitarian Device Exemption ("HDE") filing for the Andara OFS (Oscillating Frequency Stimulation) ("Andara OFS") device for acute spinal cord injuries.

On December 26, 2007, the Company acquired substantially all of the assets of EyeTel Imaging, Inc., ("EyeTel") for an aggregate purchase price of 1,050,297 shares of the Company's common stock, \$175,000 in cash and the assumption of certain specified liabilities totaling \$804,916. EyeTel was engaged in the design, development, and commercialization of proprietary medical devices, including the DigiScope, a device that helps physicians detect eye disorders such as diabetic retinopathy, the leading cause of blindness in patients with diabetes. The DigiScope, developed in collaboration with the Wilmer Eye Institute at Johns Hopkins University, is an FDA cleared diagnostic device that primary care physicians and endocrinologists can use for the early detection of diabetic retinopathy. The Company had previously entered into an exclusive licensing agreement with EyeTel pursuant to which the Company had sales and marketing rights to the DigiScope in the primary diabetes care physician market. The acquisition is intended to further diversify the Company's proprietary medical device product offering and expand sales into additional markets such as the optometry market. The Company's balance sheet at December 31, 2007, includes the acquired assets and assumed liabilities of EyeTel (Note 3). There was no material impact to the Company's statement of operations for the year ended December 31, 2007 subsequent to the acquisition.

**Significant Accounting Policies**

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

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of ninety days or less to be cash equivalents. Cash equivalents are recorded at cost which approximates fair value. The

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

Company invests cash primarily in a money market account and other investments which management believes are subject to minimal credit and market risk.

***Held-to-Maturity Investments***

The Company's investment portfolio is classified as held-to-maturity, and such investments are stated at amortized cost. Interest earned on investments held-to-maturity is included in interest income. The amortized cost of investments held-to-maturity is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income.

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

In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*", ("SFAS No. 115"), the Company's investment in Cyberkinetics is classified as available-for-sale and is carried at fair value, with any unrealized gains and losses, net of taxes, reported in accumulated other comprehensive income (loss), a separate component of stockholders' equity.

***Restricted Cash***

At December 31, 2007, the Company held short-term restricted cash in the amount of \$45,000 in connection with certain liabilities assumed with the acquisition of EyeTel on December 26, 2007. The Company maintained long-term restricted cash in the amount of \$1,458,598 at December 31, 2007 and 2006, respectively, associated with a facility lease. See Note 9 Commitments and Contingencies and Note 11 Subsequent Events.

***Concentration of Credit Risk***

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

The Company distributes its products through its own regional sales managers, who had managed independent sales agencies through the end of 2007. At December 31, 2007 and 2006 and for the years ended December 31, 2007, 2006 and 2005, no single customer accounted for more than 10% of accounts receivable or revenue.

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

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

*Inventories*

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

*Fair Value of Financial Instruments*

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, short-term investments, long-term investments, accounts receivable, accounts payable and accrued expenses, approximate their fair value at December 31, 2007 and 2006.

*Revenue Recognition*

The Company recognizes revenue when the following criteria have been met: persuasive evidence of an arrangement exists, delivery has occurred and risk of loss has passed, the seller's price to the buyer is fixed or determinable and collection is reasonably assured. The Company recorded revenue on a net basis for product sales made to independent sales agencies or distributors, based upon the amount billed to the distributors, when the distributor accepts the responsibility for invoicing the customer and the responsibility for the risk of collections and product returns from the customer. During 2007, the Company terminated its relationships with all independent sales agencies and focused selling efforts exclusively through the direct sales force.

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

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 or determinable, evidence of a persuasive arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable and no continuing obligations exist. The revenues from the sale of a NC-stat docking station and access to the onCall Information System are considered one unit of accounting and deferred and recognized on a straight line basis over the estimated period of time the Company provides the service associated with the onCall Information System, which is the shorter of the estimated customer relationship period or the estimated useful life of the docking station, currently three years. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet.

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

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

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

Certain product sales are made with a 30-day right of return. Since the Company can reasonably estimate future returns, the Company recognizes revenues associated with product sales that contain a right of return upon shipment and at the same time reduces revenue by the amount of estimated returns under the provisions of SFAS No. 48, "*Revenue Recognition When Right of Return Exists*".

Other revenues consist entirely of revenues relating to the DigiScope sold under a license agreement with EyeTel. Revenue was recognized on a gross basis and comprised of installation and training fees, per patient fees for eye scans performed using the DigiScope and monthly rental fees for the use of the DigiScope. Installation and training fees are deferred and recognized on a straight line basis over the non-cancelable term of the customer contract, currently one year. Revenues from fees charged for patient eye scans are recognized as the scans are performed. Fees for the rental of the DigiScope are recognized on a monthly basis. Under the terms of the exclusive sales and marketing license to the DigiScope from EyeTel, amounts due to EyeTel were recorded as cost of revenues.

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

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company reviews its allowance for doubtful accounts and determines the allowance based on an analysis of customer past payment history, product usage activity, and recent communications between the Company and the customer. Past due balances over 90 days are reviewed individually for collectibility. Account balances are charged off against the allowance when the Company feels it is probable the receivable will not be recovered. The Company does not have any off-balance sheet credit exposure related to its customers.

***Income Taxes***

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company's financial statements contain certain deferred tax assets, which have arisen primarily as a result of operating losses, as well as other temporary differences between financial and tax accounting. SFAS No. 109 "*Accounting for Income Taxes*," requires the Company to establish a valuation allowance if the likelihood of realization of the deferred tax assets is reduced based on an evaluation of objective verifiable evidence. Significant management judgment is required in determining the Company's provision for income taxes, the Company's deferred tax assets and liabilities and any valuation allowance recorded against those net deferred tax assets. The Company evaluates the weight of all available evidence to determine whether it is more likely than not that some portion or all of the net deferred income tax assets will not be realized.

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes - an interpretation of SFAS No. 109*" ("FIN 48"). FIN 48 requires management to perform a two-step evaluation of all tax positions, ensuring that these tax return positions meet the "more-likely than not" recognition threshold and can be measured with sufficient precision to determine the benefit recognized in the financial statements. These evaluations provide management with a comprehensive model for how a company should recognize, measure,

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 1. Business and Summary of Significant Accounting Policies (Continued)

present, and disclose in its financial statements certain tax positions that the Company has taken or expects to take on income tax returns. Management estimated that as of December 31, 2006, there was an uncertain tax position totaling approximately \$100,000 relating to the Company's tax credit carryforwards. As a result, the Company reduced its deferred tax assets and the associated valuation allowance by approximately \$100,000 as of January 1, 2007, the adoption date of FIN 48. There have been no other activities impacting FIN 48 reserves during the year ended December 31, 2007.

*Research and Development*

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

*Product Warranty Costs*

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

The following is a rollforward of the Company's accrued warranty liability for the years ended December 31, 2007, 2006 and 2005:

	Years Ended December 31,		
	2007	2006	2005
Balance at beginning of period	\$ 231,725	\$ 124,852	\$ 116,779
Accrual for warranties	749,078	688,234	314,117
Settlements made	(728,855)	(581,361)	(306,044)
Balance at end of period	\$ 251,948	\$ 231,725	\$ 124,852

*Fixed Assets and Long-Lived Assets*

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

The Company periodically evaluates the recoverability of its fixed assets and other long-lived assets, including intangibles, when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". This periodic review may result in an adjustment of estimated depreciable lives or an asset impairment. When indicators of impairment are present, the carrying values of the asset are evaluated in relation to the assets operating performance and future undiscounted cash flows of the underlying assets. If the future undiscounted cash flows are less than their book value, an impairment



NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

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 impairments were identified in the years ended December 31, 2007, 2006 and 2005.

***Goodwill and Other Intangible Assets***

As result of the acquisition of substantially all of the assets of EyeTel on December 26, 2007, the Company identified approximately \$5.8 million of goodwill and \$2.8 million of other intangible assets on its balance sheet at December 31, 2007. The Company will amortize intangible assets using the straight-line method over their estimated economic lives, which is estimated to be 5 years, or using the economic use method if that method results in significantly greater amortization than the straight-line method. Determining the economic lives of acquired intangible assets requires us to make significant judgment and estimates, and can materially impact the Company's operating results.

In accordance with the provisions of SFAS No. 142, "*Goodwill and Other Intangible Assets*" ("SFAS No. 142"), the Company will assess the realizability of goodwill annually, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. The Company's ability to realize the value of the goodwill will depend on the future cash flows of the business. If the Company is not able to realize the value of goodwill, the Company may be required to incur material charges relating to the impairment of goodwill.

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

In December 2004, the FASB issued SFAS No. 123(R), "*Share Based Payment*" ("SFAS No. 123(R)"), which requires that the expense resulting from all share-based payment transactions be recognized in the financial statements. SFAS No. 123(R) revises SFAS No. 123 "*Accounting for Stock-Based Compensation*" ("SFAS No. 123") and supersedes Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB No. 25") and SFAS No. 148, "*Accounting for Stock Based Compensation Transition and Disclosure an amendment of Financial Accounting Standards Board Statement No. 123*" ("SFAS No. 148".) As a result, beginning January 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective method and has begun reflecting the stock-based compensation expense determined under fair value based methods in the statement of operations rather than as pro forma disclosure in the notes to the financial statements. Under this transition method, the compensation cost recognized beginning January 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123, and (ii) all share based payments granted or modified subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Compensation cost is generally recognized ratably over the requisite service period. Prior period amounts have not been restated. The Company uses the Black-Scholes option pricing model for determining the fair value of its stock options and amortizes its stock-based compensation expense using the straight-line method.

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 1. Business and Summary of Significant Accounting Policies (Continued)

Prior to the adoption of SFAS No. 123(R), the Company accounted for stock options granted to employees in accordance with APB No. 25 and provided the disclosures required under SFAS No. 148 only in the notes to our financial statements. Accordingly, compensation expense was recorded for options issued to employees to the extent that the fair market value of the Company's common stock exceeded the exercise price of the option at the date granted and all other criteria for fixed accounting were met. All stock-based awards granted to non-employees were accounted for at their fair value and the resulting compensation expense was generally recognized over the period of service.

*Net Income (Loss) Per Common Share*

The Company accounts for and discloses net income (loss) per common share in accordance with SFAS No. 128, "Earnings Per Share". Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants (using the treasury stock method.)

	Years Ended December 31,		
	2007	2006	2005
<b>Basic:</b>			
Net income (loss)	\$ (8,378,474)	\$ 4,267,806	\$ 249,258
Weighted average shares	12,628,310	12,501,742	12,152,139
Basic income (loss) per common share	\$ (0.66)	\$ 0.34	\$ 0.02
<b>Diluted:</b>			
Net income (loss)	\$ (8,378,474)	\$ 4,267,806	\$ 249,258
Weighted average shares	12,628,310	12,501,742	12,152,139
Effect of stock options		596,149	821,254
Effect of warrants			12,972
Weighted average shares, as adjusted	12,628,310	13,097,891	12,986,365
Diluted income (loss) per common share	\$ (0.66)	\$ 0.33	\$ 0.02

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

	Years Ended December 31,		
	2007	2006	2005
Options	1,661,427	366,618	45,400

*Advertising and Promotional Costs*

Advertising and promotional costs are expensed as incurred. Advertising and promotion expense was \$718,650, \$547,441 and \$280,034 in the years ended December 31, 2007, 2006 and 2005, respectively.

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

*Accumulated Other Comprehensive Loss*

SFAS No. 130, "Reporting Comprehensive Income" establishes standards for reporting and displaying comprehensive income and its components in a full set of general-purpose financial statements. In November 2007, the Company entered into a strategic alliance with Cyberkinetics, a medical device company focused on neurological conditions. The Company made an investment of \$2.5 million in shares of Cyberkinetics common stock and is accounting for this investment as an available-for-sale security under the provisions of SFAS No. 115. Accordingly, at December 31, 2007, the Company has recorded the decrease in fair value of this investment within other comprehensive loss. For the years ended December 31, 2006 and 2005, the Company had no components of other comprehensive income or loss other than net income (loss).

*Segments*

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

*Use of Estimates*

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

*Risks and Uncertainties*

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

*Reclassification*

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

*Recent Accounting Pronouncements*

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), "Business Combinations" ("SFAS No. 141R"). SFAS No. 141R will significantly change the accounting for business combinations. Under SFAS No. 141R, an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS No. 141R will change the accounting treatment for certain specific acquisition related items including: (1) expensing acquisition related costs as incurred; (2) valuing noncontrolling interests at fair value at the acquisition date; and (3) expensing restructuring costs associated with an acquired business. SFAS

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**1. Business and Summary of Significant Accounting Policies (Continued)**

No. 141R also includes a substantial number of new disclosure requirements. SFAS No. 141R is to be applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The Company expects SFAS No. 141R will have an impact on accounting for future business combinations once adopted but the effect is dependent upon if any acquisitions are made in the future.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115.*" ("SFAS No. 159") SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS No. 159 does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company does not believe that the adoption of SFAS No. 159 will have a material impact on its financial position, results of operations or cash flows.

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

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

**Stock Option Plans**

During 1996, the Company adopted the 1996 Stock Option/Restricted Stock Plan (the "1996 Stock Plan"). The 1996 Stock Plan provides for the granting of incentive and non-qualified stock options and stock bonus awards to officers, directors and employees of the Company. The maximum number of shares that may be issued pursuant to the 1996 Stock Plan is 156,250. All of the outstanding options under the 1996 Stock Plan are fully vested and terminate 10 years after the grant date, or earlier if the option holder is no longer an executive officer, employee, consultant, advisor or director, as applicable, of the Company. As of December 31, 2006, all shares had been issued under the 1996 Stock Plan.

During 1998, the Company adopted the 1998 Equity Incentive Plan (the "1998 Stock Plan"). The 1998 Stock Plan also provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 1998 Stock Plan generally vest over three or four years and terminate 10 years after the grant date, or earlier if the

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

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

option holder is no longer an executive officer, employee, consultant, advisor or director, as applicable, of the Company. As of December 31, 2007, 1,250,000 shares of common stock were authorized for issuance under the 1998 Stock Plan, of which 546,731 shares had been issued and 607,739 shares were subject to outstanding options at a weighted average exercise price of \$7.17 per share. The 1998 Stock Plan was closed to any future grants at the time of the Company's Initial Public Offering ("IPO") and therefore the Company will not make any additional grants under the 1998 Stock Plan.

During 2004, the Company adopted the 2004 Stock Option and Incentive Plan, as amended and restated in 2006 (the "2004 Stock Plan"). The 2004 Stock Plan also provides for granting of incentive and nonqualified stock option and stock bonus awards to officers, employees and outside consultants. Outstanding options under the 2004 Stock Plan generally vest over three or four years and terminate 10 years after the grant date, or earlier if the option holder is no longer an executive officer, employee, consultant, advisor or director, as applicable, of the Company. As of December 31, 2007, 1,946,022 shares of common stock were authorized for issuance under the 2004 Stock Plan, of which 92,963 shares had been issued, 1,241,153 shares were subject to outstanding options at a weighted average exercise price of \$14.25 per share and 611,906 shares were available for future grant. In March 2006, the Company's Board of Directors voted to discontinue the provision of the 2004 Stock Plan which automatically increased the number of options available for grant under the 2004 Stock Plan based on the net increase in the total number of outstanding shares of common stock during the year.

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

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

In June 2004, the Company adopted the 2004 Employee Stock Purchase Plan ("ESPP"). All of our employees who have been employed by the Company for at least 60 days and whose customary employment is for more than 20 hours per week and for more than five months in any calendar year are eligible to participate and any employee who owns 5% or more of the voting power or value of our stock is not eligible to participate. An employee may purchase no more than \$25,000 worth of common stock, valued at the start of the purchase period, in any calendar year. The ESPP authorizes the issuance of up to a total of 375,000 shares of our common stock to participating employees.

Under the ESPP, participating employees can authorize the Company to withhold up to 10% of their earnings during consecutive six-month payment periods for the purchase of the shares. At the conclusion of each period, participating employees can purchase shares at 85% of the lower of their fair market value at the beginning or end of the period. The ESPP is regarded as a compensatory plan according to the provisions of SFAS No. 123(R). Under this plan, the Company has issued 32,656,

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 2. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)

23,140 and 23,265 shares of its common stock during the years ended December 31, 2007, 2006 and 2005, respectively.

A summary of activity under the Company's 1996, 1998 and 2004 Stock Plans for the year ended December 31, 2007 is presented below:

	Number of Shares	Exercise Price Range	Weighted Average Exercise Price
<b>Stock Option Awards</b>			
Outstanding at December 31, 2006	1,215,094	0.40 38.96	14.66
Granted at fair value	906,700	7.36 14.91	9.62
Exercised	(12,207)	0.40 10.40	2.08
Forfeited	(260,695)	1.35 38.96	17.14
Outstanding at December 31, 2007	1,848,892	\$ 0.40 38.96	\$ 11.92

The aggregate intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was \$99,034, \$5,304,033 and \$6,713,552, respectively.

The following table summarizes information about stock options outstanding at December 31, 2007:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
\$0.40 7.36	93,989	5.3	\$ 2.54
\$7.52 8.00	528,250	6.6	7.99
\$8.13 9.50	223,808	9.1	9.05
\$9.52 9.52	514,300	9.2	9.52
\$9.61 30.10	405,620	7.9	19.32
\$30.26 38.96	82,925	7.8	34.02
	1,848,892	7.9	\$ 11.92

The following table summarizes information about stock options exercisable at December 31, 2007:

Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price
\$0.40 7.36	81,737	\$ 2.52
\$7.52 8.00	446,812	8.00
\$8.13 9.50	43,432	9.17
\$9.52 9.52		
\$9.61 30.10	153,335	20.28
\$30.26 38.96	37,985	34.07
	763,301	\$ 11.24



## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 2. Stock Option Plans, Stock-Based Compensation and Common Stock (Continued)

The weighted average remaining contractual life for stock options exercisable at December 31, 2007 was 7.9 years. The aggregate intrinsic value for stock options outstanding and exercisable at December 31, 2007 was \$1,305,157 and \$1,088,300 respectively.

## Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based compensation plans in accordance with the provisions of APB No. 25, as permitted by SFAS No. 123, and accordingly did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the fair value at the date of grant. The following table illustrates the effect on net income (loss) and net income (loss) per common share for the year ended December 31, 2005 had the Company applied the fair value based method as prescribed by SFAS No. 123:

	2005
Net income attributable to common stockholders, as reported	\$ 249,258
Add employee stock-based compensation expense included in reported net income	406,330
Less employee stock-based compensation expense determined under fair value method	(1,432,031)
Net loss pro forma	\$ (776,443)
Net income (loss) per common share (basic and diluted):	
As reported	\$ 0.02
Pro forma	\$ (0.06)

The weighted average grant-date fair value used in the calculation of stock-based compensation expense in the accompanying statement of operations for the years ended December 31, 2007, 2006 and 2005 and the pro forma net income (loss) and net income (loss) per common share information presented above is calculated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years Ended December 31,					
	2007		2006		2005	
Risk-free interest rate	3.3%	5.1%	4.3%	5.2%	3.5%	4.6%
Expected dividend yield						
Expected option term	5 years		5 years		5 years	
Volatility	60.0%	70.0%	50.0%	75.0%	52.6%	
Weighted average fair value of options granted at fair value	\$5.76		\$14.76		\$7.23	
Weighted average fair value of options granted below fair value	\$		\$		\$	

The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a five year term (corresponding to the expected option term) on the date the option was granted. The expected dividend yield is zero because the Company does not currently pay dividends nor expects to do so during the expected option term. The expected option term of five years is



NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

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

estimated based on an analysis of actual option exercises and a review of comparable medical device companies. The volatility assumption is based on weekly historical volatility during the time period that corresponds to the expected option term, a review of comparable medical device companies and expected future stock price volatility. The pre-vesting forfeiture rate is based on the historical and projected average turnover rate using four classifications of employees.

The Company uses the Black-Scholes option pricing model for determining the fair value of shares of common stock issued or to be issued under the ESPP. The following assumptions are used in determining fair value: The risk-free interest rate assumption is based on the United States Treasury's constant maturity rate for a six month term (corresponding to the expected option term) on the date the option was granted. In 2007 and 2006, the Company used a risk-free interest rate assumption that ranged from 3.5% to 5.1% and 5.1% to 5.2%, respectively. The expected dividend yield is zero because the Company does not currently pay dividends nor expects to do so during the expected option term. An expected term of six months is used based on the duration of each plan offering period. The volatility assumption is based on stock price volatility over the most recent period of time corresponding to the expected term and is also based on expected future stock price volatility. In 2007 and 2006, the expected future stock price volatility ranged from 60.0% to 70.0% and 50.0% to 90.0%, respectively.

The Company recorded stock-based compensation expense of \$3,071,090, \$2,652,637 and \$406,330 for the years ended December 31, 2007, 2006 and 2005, respectively. Included in the stock-based compensation expense recorded by the Company for the years ended December 31, 2007 and 2006 is (a) \$2,902,662 and \$2,265,556, respectively, in compensation expense relating to stock options granted to employees subsequent to the Company's July 2004 IPO that are accounted for according to the provisions of SFAS No. 123(R); (b) \$37,752 and \$53,471, respectively, in reductions of compensation expense related to stock options granted to non-employees that are accounted for according to the provisions of Emerging Issues Task Force ("EITF") Issue No. 96-18 "*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*" ("EITF No. 96-18"); (c) \$94,325 and \$159,480, respectively, in compensation expense related to the ESPP and accounted for under the provisions of SFAS No. 123(R); (d) \$95,031 and \$249,415, respectively in compensation expense relating to stock options granted to employees prior to the Company's IPO that are being accounted for using the intrinsic value method according to the provisions of SFAS No. 123(R) and (e) \$16,824 and \$31,657, respectively in compensation expense related to modifications to pre-IPO option grants. Compensation expense recorded by the Company for the modification of stock options for the year ended December 31, 2005 was \$35,790.

The additional costs incurred as a result of the implementation of SFAS No. 123(R) reflected in income before provision of income taxes and net income attributable to common stockholders for the years ended December 31, 2007 and 2006 was \$2,996,987 and \$2,425,036, respectively. The effect on basic and diluted earnings per share for the years ended December 31, 2007 and 2006 was \$0.24 and \$0.19, respectively.

Stock options granted to non-employees are recorded at fair value and adjusted to market over the vesting period according to the provisions of EITF No. 96-18. The Company determines fair value using the Black-Scholes option pricing model, an expected term equal to the option term, a risk-free interest rate corresponding to the expected term, an expected volatility of 60% 70% and a dividend yield of zero.

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

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

Deferred compensation was recorded in connection with stock option grants made prior to the Company's IPO. The deferred compensation represents the difference between the estimated market value of common stock on the date of grant and the exercise price associated with the stock options. All remaining deferred compensation has been amortized to expense over the vesting period of the related stock options.

Total unrecognized stock-based compensation costs related to non-vested stock options was approximately \$8,211,907 which related to approximately 1,085,591 shares with a per share weighted fair value of \$7.56 as of December 31, 2007. This unrecognized cost is expected to be recognized over a weighted average period of approximately 2.3 years.

As of December 31, 2007, there were 1,731,089 stock options vested and expected to vest with a weighted average exercise price of \$11.92 per share, a weighted average contractual remaining life of 7.9 years and an aggregate intrinsic value of \$1,305,157. Expected to vest options are determined by applying the pre-vesting forfeiture rate to the total outstanding options. Aggregate intrinsic value represents the total pre-tax intrinsic value (the aggregate difference between the closing stock price of the Company's common stock as of December 31, 2007, as applicable, and the exercise price for the in-the-money options) that would have been received by the option holders if all the in-the-money options had been exercised on December 31, 2007.

**Common Stock**

As of December 31, 2007, the Company had 50,000,000 shares of common stock authorized and 13,690,132 shares issued and outstanding. There were no treasury shares outstanding at December 31, 2007 and 2006, 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.

At December 31, 2007, the Company has reserved authorized shares of common stock for future issuance as follows:

Outstanding stock options	1,848,892
Possible future issuance under stock option plans	611,906
Possible future issuance under employee stock purchase plan	286,407
	<hr/>
Total	2,747,205
	<hr/>

On March 7, 2007, the Company's Board of Directors adopted a Shareholder Rights Plan and declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's common stock to shareholders of record as of the close of business on March 8, 2007.

**3. Acquisition**

On December 26, 2007, the Company acquired substantially all of the assets of EyeTel for an aggregate purchase price of 1,050,297 shares of the Company's common stock, \$175,000 in cash and the assumption of certain specified liabilities totaling \$804,916. EyeTel was engaged in the design, development, and commercialization of proprietary medical devices, including the DigiScope, a device

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 3. Acquisition (Continued)

that helps physicians detect eye disorders such as diabetic retinopathy, the leading cause of blindness in patients with diabetes. The Company had previously entered into an exclusive licensing agreement with EyeTel pursuant to which the Company had sales and marketing rights to the DigiScope in the primary diabetes care physician market. The acquisition is intended to further diversify the Company's proprietary medical device product offering and expand sales into additional markets such as the optometry market.

In accordance with the provisions of SFAS No. 141, "*Business Combinations*" the assets acquired and liabilities assumed have been recorded at their estimated fair value. A total of \$2.8 million was allocated to intangible assets, representing the fair value of existing technology, which is being amortized on a straight line basis over the estimated life of five years. The fair value of the intangible assets was determined primarily through assessments by the Company's management and the fair value of the tangible assets acquired and liabilities assumed approximated their carrying values. Goodwill totaling \$5.8 million was recorded in connection with the acquisition, representing the excess of the purchase price over the estimated fair value of the acquired tangible assets, intangible assets and assumed liabilities.

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

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

## Pro Forma Financial Summary (Unaudited)

The following unaudited pro forma financial summary is presented as if the acquisition of substantially all of the assets of EyeTel was completed as of the beginning of each period presented. The pro forma combined results are not necessarily indicative of the actual results that would have

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 3. Acquisition (Continued)

occurred had the acquisition been consummated on that date, or of the future operations of the combined entities.

	Years Ended December 31,	
	2007	2006
Total revenues	\$ 44,814,865	\$ 56,455,840
Net loss	\$ (19,760,624)	\$ (3,096,033)
Basic and diluted loss per common share	\$ (1.44)	\$ (0.23)
Basic and diluted weighted average shares used to compute net loss per common share	13,678,607	13,552,039

## 4. Inventories

At December 31, 2007 and 2006, inventories consist of the following:

	December 31,	
	2007	2006
Purchased components	\$ 1,216,758	\$ 345,852
Finished goods	4,137,580	3,287,537
	\$ 5,354,338	\$ 3,633,389

## 5. Investments

## Short-Term Held-to-Maturity

Held-to-maturity investments as of December 31, 2007 and 2006 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>2007</b>				
Commercial paper and bank notes	\$ 964,900	\$ 9,960	\$	\$ 974,860
Corporate bonds	21,656,841	5,049	(25,807)	21,636,083
	\$ 22,621,741	\$ 15,009	\$ (25,807)	\$ 22,610,943
<b>2006</b>				
Commercial paper and bank notes	\$ 3,895,713	\$ 104,287	\$	\$ 4,000,000
U.S. agency obligations	997,752	998		998,750
Corporate bonds	27,517,220	1,983	(17,656)	27,501,547

Edgar Filing: NeuroMetrix, Inc. - Form 10-K

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	\$ 32,410,685	\$ 107,268	\$ (17,656)	\$ 32,500,297

The following table shows the gross unrealized losses and fair value of the Company's held-to-maturity investments with unrealized losses that are not deemed to be other-than-temporarily

F-23

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 5. Investments (Continued)

impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2007 and 2006:

	12 Months or less		Greater than 12 Months		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
<b>2007</b>						
Corporate bonds	\$ 15,701,223	\$ (25,807)	\$	\$	\$ 15,701,223	\$ (25,807)
<b>2006</b>						
Corporate bonds	\$ 24,478,947	\$ (17,656)	\$	\$	\$ 24,478,947	\$ (17,656)

Corporate bonds At December 31, 2007, the Company held 13 corporate bonds in an unrealized loss position which was primarily the result of higher market interest rates since the date of purchase, rather than a decline in credit quality of these investments. The contractual terms of these investments do not permit the issuers to settle the securities at a price less than the face value of the investment. Each of the bonds maintains a Standard & Poor's rating of A or higher and has made each of their scheduled interest payments. Therefore, it is not expected that the bonds would be settled at a price less than the amortized cost of the investment. Because the Company has the ability and intent to hold these investments until maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2007.

The amortized cost and fair value of fixed maturity securities at December 31, 2007 and 2006, by contractual maturity, are shown below:

	December 31,			
	2007		2006	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less	\$ 22,621,741	\$ 22,610,943	\$ 32,410,685	\$ 32,500,297

## Long-Term Available-for-Sale Investment

In November 2007, the Company made an investment of \$2.5 million for the purchase of approximately 5.4 million shares of common stock of Cyberkinetics, representing approximately 13% of the Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share. The Company also received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant is exercisable at \$0.46 per share and has a term of five years, but will be required to be exercised if Cyberkinetics receives FDA approval of an HDE filing for the Andara OFS device for acute spinal cord injuries.

In accordance with SFAS No. 115, the investment in Cyberkinetics common stock and warrants is being accounted for as available-for-sale and has been recorded at an estimated value of \$1.1 million as of December 31, 2007. The adjustment to the carrying value of the investment in Cyberkinetics to estimated value as of December 31, 2007 has been recorded in accumulated other comprehensive loss within stockholders' equity. The Company will review the carrying value of this investment quarterly to

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 5. Investments (Continued)

determine whether an other than temporary decline in market value exists. The Company considers factors such as the length of time the value of the investment has been below its original purchase price, the financial condition of the investee and near-term prospects for the investee's recovery to original purchase price and the Company's intent with regard to the underlying investment. Based on the Company's assessment as of December 31, 2007, and taking into consideration the volatility of Cyberkinetics' common stock and the time period the investment has been in an unrealized loss position, the Company does not believe that the decline in value of the investment is other than temporary in nature.

In connection with the investment in Cyberkinetics, the Company also received certain rights, including a right of first negotiation for the acquisition of Cyberkinetics, or any other change of control transaction, and a right of first negotiation for the commercialization of the Andara OFS device for the treatment of acute spinal cord injuries. In addition, the Company received a seat on the Cyberkinetics Board of Directors. Dr. Shai Gozani M.D. Ph.D., the Company's Chief Executive Officer and President, has been named as the initial designee.

In February 2008, The Company entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics to develop and commercialize products for the treatment of peripheral nerve injury and formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with initial ownership of 50% held by the Company and 50% held by Cyberkinetics. (See Note 11. Subsequent Events)

## 6. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Life (Years)	December 31,	
		2007	2006
Computer and laboratory equipment	3	\$ 1,908,750	\$ 1,746,322
Furniture and equipment	3	411,116	350,678
DigiScope equipment	5	1,985,000	
Production equipment	7	665,267	665,266
Construction in progress		288,829	215,476
Leasehold improvements	*	150,097	150,097
		<u>5,409,059</u>	<u>3,127,839</u>
Less accumulated depreciation		<u>(2,435,341)</u>	<u>(2,012,403)</u>
		<u>\$ 2,973,718</u>	<u>\$ 1,115,436</u>

\*

Lesser of life of lease or estimated useful life.

Depreciation expense was \$422,938, \$380,655 and \$278,932 for the years ended December 31, 2007, 2006 and 2005, respectively.

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

**6. Fixed Assets (Continued)**

DigiScope equipment acquired, in conjunction with the Company's December 26, 2007 acquisition of substantially all of the assets of EyeTel, consists of equipment and sub-assemblies leased to customers.

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

**7. Accrued Expenses**

Accrued expenses consist of the following for the years ended December 31, 2007 and 2006:

	December 31,	
	2007	2006
Professional services	\$ 706,952	\$ 401,186
Sales taxes	489,555	2,851,307
Other	1,112,056	1,023,490
	\$ 2,308,563	\$ 4,275,983

**8. Income Taxes**

The income tax provision consists of the following for the years ended December 31, 2007, 2006 and 2005:

	Years Ended December 31,		
	2007	2006	2005
Federal tax expense	\$	\$ 193,000	\$ 35,000
State tax expense			
Total	\$	\$ 193,000	\$ 35,000

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2007, 2006 and 2005.

	Years Ended December 31,		
	2007	2006	2005
Federal tax provision (benefit) rate	34.0%	34.0%	34.0%
State tax provision, net of federal provision (benefits)	4.6	7.6	9.9
Permanent items	(1.1)	11.1	56.3
Research and development tax credits	0.5	(4.2)	(54.5)
Alternative minimum tax		4.3	12.3
Alternative minimum tax credit		(2.7)	
Valuation allowance	(38.0)	(45.8)	(45.7)
Effective income tax rate		%	4.3%
			12.3%



Years Ended December 31,

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

F-26

\_\_\_\_\_

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

## 8. Income Taxes (Continued)

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

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,797,528	\$ 9,373,722
Research and development credit carryforwards	957,221	978,653
Alternative minimum tax credit	120,490	120,195
Accrued expenses	1,713,220	2,808,024
Other	1,650,107	522,822
Total gross deferred tax assets	16,238,566	13,803,416
Valuation allowance	(16,238,566)	(13,803,416)
Net deferred tax assets	\$	\$

At December 31, 2007, the Company has federal and state net operating loss carryforwards ("NOL") of approximately \$37.0 million and \$21.1 million, respectively, as well as federal and state tax credits of \$598,000 and \$544,000, respectively, which may be available to reduce future taxable income and the related taxes thereon. This amount includes tax benefits of \$3.8 million and \$71,000 attributable to NOL and tax credit carryforwards, respectively, that result from the exercise of employee stock options. The tax benefit of these items will be recorded as a credit to additional paid-in capital upon realization of the deferred tax asset or reduction in income taxes payable. The federal NOLs begin to expire in 2019 and the state NOLs begin to expire in 2008.

As required by SFAS No. 109 "Accounting for Income Taxes" ("SFAS No. 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 \$16.2 million and \$13.8 million has been established at December 31, 2007 and 2006, respectively.

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

In June 2006, the FASB issued FIN 48. FIN 48 requires management to perform a two-step evaluation of all tax positions, ensuring that these tax return positions meet the "more-likely than not" recognition threshold and can be measured with sufficient precision to determine the benefit recognized in the financial statements. These evaluations provide management with a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements certain tax positions that the Company has taken or expects to take on income tax returns. Management estimated that as of December 31, 2006, there was an uncertain tax position totaling approximately \$100,000 relating to the Company's tax credit carryforwards. As a result, the Company reduced its deferred tax assets and the associated valuation allowance by approximately \$100,000 as of

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

**8. Income Taxes (Continued)**

January 1, 2007, the adoption date of FIN 48. There have been no other activities impacting FIN 48 reserves during the year ended December 31, 2007.

**9. Commitments and Contingencies****Cyberkinetics**

In connection with the Company's investment in Cyberkinetics, the Company received a warrant to purchase up to approximately 2.7 million shares of Cyberkinetics common stock. The warrant, exercisable at \$0.46 per share, or approximately \$1.25 million, has a term of five years, and is required to be exercised if Cyberkinetics receives FDA approval of an HDE filing for the Andara OFS device for acute spinal cord injuries.

In February 2008, the Company entered into a Collaboration Agreement and Operating Agreement with Cyberkinetics to develop and commercialize products for the treatment of peripheral nerve injury and formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture with 50% ownership held by the Company and 50% ownership held by Cyberkinetics. Under the terms of the joint venture, the Company has agreed to fund the initial \$2.0 million in product development costs and has agreed to share equally in all costs in excess of the initial \$2.0 million. Cyberkinetics has agreed to contribute technology, know-how and intellectual property, primarily relating to their Andara OFS technology, to the joint venture.

**Operating Leases**

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

Future minimum lease payments under noncancelable operating leases as of December 31, 2007 are as follows:

2008	\$	930,000
2009		232,500
		<hr/>
Total minimum lease payments	\$	1,162,500
		<hr/>

Total recorded rent expense was \$871,819 for each the years ended December 31, 2007, 2006 and 2005. 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, 2007 and 2006 of \$72,727 and \$130,909, respectively on the accompanying balance sheets. See Note 11 Subsequent Events Lease Agreement.

**Capital Lease**

In June 2007, the Company entered into a non-cancelable capital lease for copiers located at our corporate headquarters valued at \$38,700. The lease expires in May 2010.

## NeuroMetrix, Inc.

## Notes to Financial Statements(Continued)

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

Future minimum lease payments under the capital lease as of December 31, 2007, are as follows:

2008	\$	12,900
2009		12,900
2010		5,375
Total capital lease payments	\$	31,175

**Restricted Time Deposit**

In connection with the Company's facility lease, the Company is required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary over the term of the lease, which is secured by a certificate of deposit in an amount equal to 102% of the letter of credit, as security. The lease expires in March 2009. The certificate of deposit is renewable annually. At December 31, 2007 and 2006, the Company has \$1,458,598 recorded as restricted cash associated with this lease on the accompanying balance sheet. See Note 11 Subsequent Events Lease Agreement.

**Legal Matters**

In the second quarter of 2006, the Company received a subpoena from the Office of Inspector General ("OIG"), of the Department of Health and Human Services requesting documents in connection with an investigation of potential violations of the federal anti-kickback statute and False Claims Act. In addition, on June 21, 2007, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents in connection with an investigation by the United State Department of Justice ("DOJ"). The DOJ is investigating various aspects of the Company's practices relating to the NC-stat System, including sales and marketing practices. The Company is cooperating with both investigations. During 2007, the Company formed a Special Committee of its Board of Directors to provide oversight of an ongoing independent review of the Company's sales and marketing practices and of the Company's continuing cooperation with the DOJ and OIG investigations. The Company cannot predict the ultimate outcome of these investigations. The Company is unable to determine when these matters will be resolved, whether any additional areas of inquiry will be opened, or any outcome of this matter. Any negative findings in this matter could result in fines, penalties, or program exclusions, which could have a material adverse effect on the Company's financial condition, results of operations, and cash flows.

**10. 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, 2007, 2006 and 2005 the Company made no contributions to the plan.

**11. Subsequent Events****Joint Venture with Cyberkinetics**

In February 2008, the Company and Cyberkinetics formed PNIR (Peripheral Nerve Injury Repair) LLC, a joint venture incorporated in Delaware, and entered into a Collaboration Agreement

NeuroMetrix, Inc.

Notes to Financial Statements(Continued)

**11. Subsequent Events (Continued)**

and Operating Agreement to develop and commercialize products for the treatment of peripheral nerve injury. The joint venture is initially 50% owned by the Company and 50% owned by Cyberkinetics. Under the terms of the joint venture, the Company has agreed to fund the initial \$2.0 million in product development costs and the Company and Cyberkinetics have agreed to share equally in all costs in excess of the initial \$2.0 million. Cyberkinetics has agreed to contribute technology, know-how and intellectual property, primarily relating to their Andara OFS technology, to the joint venture.

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

**Lease Agreement**

In February 2008, the Company amended the Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and the Company for office and engineering laboratory space. The amendment extends the term of the lease, currently scheduled to expire on March 31, 2009, through March 31, 2013. Base rent for the period April 2009 through March 2013 will be reduced from the current level of \$930,000 annually to a range of \$675,000 to \$765,000 annually.

In connection with the amendment of the lease, the amount of the irrevocable letter of credit required to be maintained by the Company for the benefit of the lessor will be reduced from \$1,430,000 to \$400,000. The letter of credit must be secured by a certificate of deposit in an amount equal to 102% of the letter of credit as security.

## NeuroMetrix, Inc.

## Schedule II Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Additions		Deductions (Describe)	Balance at End of Period
		Charged to costs and expenses	Charged to other accounts (Describe)(1)		
<b>December 31, 2007</b>					
Allowance for Doubtful Accounts	\$ 900,000	\$ 358,141	\$ 195,875	\$ (548,016)(2)	\$ 906,000
Deferred Tax Asset Valuation Allowance	13,803,416	2,642,021		(206,871)(3)	16,238,566
<b>December 31, 2006</b>					
Allowance for Doubtful Accounts	400,000	946,850	74,539	(521,3897)(2)	900,000
Deferred Tax Asset Valuation Allowance	16,081,539	2,226,513		(4,504,636)(3)	13,803,416
<b>December 31, 2005</b>					
Allowance for Doubtful Accounts	300,000	281,684	78,143	(259,8277)(2)	400,000
Deferred Tax Asset Valuation Allowance	14,235,366	1,846,173			16,081,539

- (1) Recoveries.
- (2) Write-offs.
- (3) Utilization and expiration of Federal and State Net Operating Loss Carryforwards.