NeuroMetrix, Inc.
Form 10-K
March 29, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2006

OR

o 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	**04-3308180**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
62 Fourth Avenue Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	Zip Code

(781) 890-9989

(Registrant s Telephone Number, Including Area Code)

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

Title of each class	**Name of exchange on which registered**
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 o No x

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

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 x No o

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

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o

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

As of June 30, 2006 the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $267,896,949 based on the closing sale price of the common stock as reported on the NASDAQ Global Market on June 30, 2006. 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 21, 2007, there were 12,604,554 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for the registrant s 2007 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, 2006, are incorporated by reference into Part III of this Annual Report on Form 10-K.

NEUROMETRIX, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2006
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PART I

The statements contained in this annual report on Form 10-K, including under the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations and other sections of this annual report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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-lo statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled Risk Factors. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

ITEM 1. BUSINESS

Our Business

We design, develop and sell proprietary medical devices used to help physicians diagnose neuropathies and neurovascular disease. Neuropathies are diseases of the peripheral nerves and parts of the spine that frequently are caused by or associated with diabetes, low back pain and carpal tunnel syndrome, as well as other clinical disorders. We believe that our neuropathy diagnostic system, the NC-stat System, improves the quality and efficiency of patient care by offering all physicians the ability to diagnose patients with neuropathies at the point-of-service, that is, in the physician s office at the time the patient is examined, resulting in earlier and more accurate detection, greater patient comfort and convenience, and, in many cases, improved clinical and economic outcomes.

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

Neurovascular disease includes conditions such as retinopathy, an eye disease prevalent in patients with diabetes. We hold an exclusive sales and marketing license to a product known as the DigiScope®, which allows primary care physicians and endocrinologists to diagnose diabetic retinopathy and refer patients to the ophthalmologist for treatment if deemed necessary based on the results. It is recommended by the American Diabetes Association (ADA) that all patients with diabetes receive an annual dilated

eye examination 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 care physicians and endocrinologists offices could potentially lead to an increase in the level of testing and result in the earlier detection of eye diseases in patients with diabetes.

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies and neurovascular disease. To date, our primary focus has been on the diagnosis of neuropathies. We also believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. During the first half of 2007, we expect to enter the clinical stage of development of a drug delivery system to enable a broad base of primary care and specialist physicians to provide this type of minimally invasive neuropathy therapy at the point-of-service. We recently obtained an exclusive sales and marketing license to the DigiScope product for the diagnosis of diabetic retinopathy and launched our sales and marketing efforts for this product in the first quarter of 2007. We have built a sales force of over fifty regional sales managers and we may search for additional products that can be sold to the primary care physician and endocrinologist market by this direct sales force through licensing or acquisition opportunities.

All of our current products have received 510(k) clearance by the United States Food and Drug Administration, or FDA. The NC-stat System has been on the market since May 1999 and is presently used in over 4,900 physician s offices, clinics and other health care facilities. EyeTel Imaging, Inc. (EyeTel), the manufacturer of the DigiScope, for which we have an exclusive sales and marketing license for the U.S. primary care physician and endocrinologist market, has received a 510(k) clearance from the FDA for this product. We hold issued utility patents covering a number of important aspects of our NC-stat System. In 2006, we increased our revenues from the prior year by 61.1%, generating $55.2 million in revenues, compared with $34.3 million in 2005. Our gross margin percentage in 2006 was 75.5%, and 86.4% of our revenues were attributable to sales of the disposable biosensors that physicians use to perform tests with our NC-stat System. We recorded net income of approximately $4.3 million in 2006 and $249,000 in 2005 and incurred a net loss of approximately $4.7 million in 2004. Since our inception, more than 750,000 patients have been tested with the NC-stat System.

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 currently estimates that 60% to 70% of people with diabetes are affected by DPN, although a majority of these individuals are unaware of their nerve disease because they have no symptoms. Clinical studies have demonstrated that nerve conduction studies can detect DPN in cases where symptoms are not present. DPN, if left undiagnosed and unmanaged, can result in the development of lower extremity ulcers and, in severe cases, amputation. It is estimated by the ADA that over

75% of all foot amputations are in patients with diabetic peripheral neuropathy. Other neuropathies may be present in as many as 30% of patients with diabetes, including carpal tunnel syndrome, radiculopathy and chronic inflammatory demyelinating polyneuropathy, or CIDP.

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

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

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

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

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

- *Biosensors.* The biosensors are single use, self-adhesive, nerve-specific, electrode devices 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 device, biosensors convert nerve signals

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 carpal tunnel syndrome and for assessment of the nerve function in peroneal, tibial and sural nerves in the lower extremities for the diagnosis of diabetic peripheral neuropathy and low back conditions.

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

- *NC-stat device.* The NC-stat device is designed for efficient and easy 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, which is lightweight and slightly larger than a cordless telephone, customizes and calibrates the test for each patient, analyzes neurophysiological signals collected from the biosensor and displays the pertinent results on an LCD screen immediately at the conclusion of each nerve conduction study. It also stores data from multiple patients for optional transmission to the onCall Information System. We also sell optional related components that allow for the testing of long nerve segments, such as those between the elbow and wrist or the knee and foot. The monitor is powered for several months by two AA batteries. The NC-stat 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. A third generation diagnostic device, which we plan to market under the name ADVANCE , is currently in development and is expected to be introduced during 2007.

- *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 any available telephone line, such as those used by facsimile machines, to the onCall Information System that we maintain. The docking station has its own data storage so it does not lose data if the telephonic connection to the onCall Information System cannot be established for some time or is disrupted during transmission. The data is automatically processed by the onCall Information System and stored in a central database, and a detailed computer generated report is created for each patient that is then sent to the physician via facsimile or e-mail in three to four minutes on average. The report includes the raw waveform data, comparisons to an age- and height-adjusted normal range population, study reference table and text summaries of the study, which facilitate rapid and accurate diagnosis by the physician examining the patient. Although the study data presented in the onCall report can be generated manually by the physician using the numerical measurements displayed by the NC-stat device, the report is a convenient and fast adjunct. Whether using the information from the onCall 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 1.5 million individual nerve tests within the onCall information system database. We believe that this information provides us with the ability to continually improve our products and provide our customers with a very high level of customer service and value.

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

- *Facilitates performance of nerve conduction studies at the point-of-service.* The complexity and high capital cost of traditional diagnostic methods generally has limited their use to neurologists and physicians in related specialties. We believe the features of the NC-stat System facilitate the performance of nerve conduction studies within the offices of a wide range of physicians, 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 to a neurologist. 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 should reduce the cost to the patient and third-party payer of many nerve conduction studies. This belief is based on our observation that when these procedures are performed by the physician with primary clinical responsibility for the patient, the study is more directed so that generally fewer nerves are tested without compromising the accuracy of the diagnosis. As the cost to third-party payers for nerve conduction studies is typically based on the number of nerves tested, use of the NC-stat System can result in lower costs to patients and third-party payers. For example, a nerve conduction study for DPN using the NC-stat System would typically be performed by testing four nerves, whereas a nerve conduction study for the same indication performed by a neurologist upon referral could involve the testing of six nerves or more. 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 under $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 diagnostic result is accurate and reliable. We believe that, in combination, these features allow accurate and reliable nerve conduction studies to be performed in 15 to 30 minutes on average.

- *Patient-friendly, non-invasive procedure.* The NC-stat System allows for reduced patient discomfort during the nerve conduction study by minimizing the magnitude of the electrical stimulus to the nerve via a proprietary patient-specific calibration procedure. In most cases, the sophisticated signal

processing and automation capabilities of the NC-stat System provide sufficient diagnostic information to eliminate the need for an 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 Opthalmological Institute at Johns Hopkins for the risk assessment of retinopathy. 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 the primary care physicians or endocrinologists office 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 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 (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 the ease of use, accuracy and convenience provided by the NC-stat System position it to become a standard of care for the assessment of neuropathies at the point-of-service. We believe that the availability of point-of-service nerve conduction studies, through the NC-stat System, will result in earlier detection of neuropathies, leading to earlier therapeutic intervention and, in many cases, improved clinical and economic outcomes. We believe that use of traditional NCS/nEMG procedures is limited by the referral process and the resulting delay in availability of diagnostic information, the inconvenience and discomfort of these methods for the patient, and the expense to the patient and third-party payer. Our policy is to promote and support the utilization of nerve conduction studies in a manner strictly consistent with prevailing guidelines on the medically appropriate use of this diagnostic procedure. We estimate that there are approximately 2.0 million traditional NCS/nEMG procedures currently performed each year in the United States. Although the most common indication for which the NC-stat System has been used historically is carpal tunnel syndrome, we have since expanded our marketing efforts to include DPN and low back pain, as well as other indications. CTS represented approximately 40% of total nerve conduction testing by our customers in 2006, while DPN and low back pain represented approximately 27% and 33%, respectively. We anticipate that our future growth will be generated mainly from lower extremity testing for DPN and low back pain. Based on our analysis of current patient data, we estimate that the potential for point-of-service nerve conduction studies in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be greater than 9.5 million annual patient tests, estimated to be more than $1.0 billion annually for our disposable biosensors, in the United States. However, market size is difficult to predict, and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of a point-of-service product offering such as the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this potential market size. Additionally, although we have not yet quantified the size of the market, we believe a potential international market opportunity exists for the NC-stat System.

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 at the point of care for the early detection of diabetic retinopathy. There are estimated to be 21 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 created an opportunity for such testing to be performed in the primary care physician or endocrinologist office since these patients are routinely seeing their primary care physician or endocrinologist.

Market Size

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

- *We estimate the potential DPN market for a point-of-service product offering such as the NC-stat System could be over six million annual patient tests*. The number of individuals with diabetes in the United

States was estimated to be 21.0 million, or 7.0% of the population. Among this group, approximately 6.0 million were undiagnosed. According to the CDC, there are about 26 million annual patient visits to office-based physicians for diabetes. We anticipate that the increasing focus on early detection and prevention of the chronic complications of diabetes will lead to increased nerve conduction studies for DPN. We believe that the estimated 50% rate of annual foot examinations in patients known to have diabetes is a reasonable estimate for the addressable testing market in diabetes. If these examinations were replaced by a nerve conduction study, or a nerve conduction study were added to the examination, the diabetes arena would represent an opportunity for over six million annual NC-stat System patient tests. The number of Americans with diabetes is projected to more than double over the next 40 to 50 years. At the present time, there are no currently marketed pharmaceuticals targeted specifically at DPN, and therefore nerve conduction studies are performed on a selective basis in order to address specific clinical issues. If a targeted therapy for DPN were successfully developed and marketed, we believe the rate of testing would further increase. Based on current clinical trial activity, we anticipate that drugs for the treatment of DPN will eventually become available in the marketplace, accelerating the need to detect DPN at its earliest stages to allow for earlier therapeutic intervention and a decrease in the adverse clinical and economic outcomes associated with DPN.

- *We estimate the potential low back pain market for a point-of-service product offering such as the NC-stat System could be as great as three million annual patient tests*. Low back pain is one of the most common medical conditions in the United States. Over 63 million people report experiencing at least one day of serious low back pain in the prior year. Furthermore, back disorders account for over one-quarter of all nonfatal occupational injuries and illnesses that result in days away from work. According to the CDC, there are about nine million annual patient visits to office-based physicians specifically for low back symptoms. The CDC further estimates that about one-third of office visits are initial visits, at which time we believe utilization of the NC-stat System is most likely. We thus anticipate that there may be as many as approximately three million testing opportunities for nerve conduction testing related to low back pain for a point-of-service product offering such as the NC-stat System. We believe that the number of testing opportunities may be even higher, as there are many patients that visit physicians for symptoms and medical conditions that must be differentiated from sciatica, such as leg and foot symptoms, rheumatoid arthritis and diabetes.

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

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

We estimate that the size of the market for a point-of-service product such as DigiScope 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 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, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this market size. Additionally, although we have not yet quantified the size of the market, we believe a potential international market opportunity exists for the NC-stat System. 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.

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 carpal tunnel syndrome. 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 carpal tunnel release 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 diabetic peripheral neuropathy.

- 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.

- 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.

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

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.

- 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. 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, 2006, we had over 4,900 active customers. No single customer accounted for more than 10% of our revenues in 2006, 2005 or 2004.

Currently, there are approximately over 100 customers using the DigiScope, primarily representing the existing customer base of EyeTel at the time we signed an exclusive sales and marketing license with them for the sale of the DigiScope into the U.S. primary care and endocrinologist market. We launched our sales and marketing efforts for this product in the first quarter of 2007.

Geographic Information

All of our assets, revenues and expenses for the years ended December 31, 2006, 2005 and 2004 were located at or derived from operations in the United States.

Sales, Marketing and Distribution

Currently, we employ 53 regional sales managers and 5 sales directors who sell directly to physician practices and also manage the activities of more than 100 independent regional sales agencies employing a total of more than 1,200 independent sales agents. The independent sales agencies we work with include small to medium sized regional firms as well as national firms such as Physician Sales & Service (PS&S) and Henry Schein, Inc. (Henry Schein .) The majority of the 1,200 independent sales agents are employed by PS&S and Henry Schein. At present, our products are marketed and distributed solely within the United States. We select our sales agencies based on their expertise and experience calling on primary care or specialist physicians, their reputation within the targeted physician community and their sales coverage. Each sales agency is assigned a sales territory for the NC-stat System and is subject to periodic performance reviews. Typically, our independent sales representatives identify potential customers for us and assist in monitoring our existing customer accounts, and our regional sales managers complete sales to these customers. Our independent sales agencies do not act as distributors of our products.

We recently launched our sales and marketing efforts for the DigiScope product for the detection of diabetic retinopathy. This product will be sold directly to primary care physicians and endocrinologists by our regional sales managers who are also selling the NC-stat System. We do not intend to use our independent sales agency network for the DigiScope product. Our initial target market for the DigiScope will be our installed base of NC-stat System customers. We obtained an exclusive sales and marketing license to the DigiScope from EyeTel in the fourth quarter of 2006.

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

We 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 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, our customer accrual efforts and market adoption for our products.

We generally invoice products purchased by our customers directly to physician offices and other customers. We currently have a relationship with one distributor that directly invoices the physician practice and we invoice the distributor at list price less a negotiated discount. With the exception of the DigiScope, we ship all products directly to the customer even in cases where we are selling through a distributor. The DigiScope is manufactured and shipped by EyeTel while we are responsible for

installation, training and service. The independent regional sales agencies and their sales representatives are compensated by commissions. Our regional managers are compensated by a combination of base salary, commissions and goal-based bonus compensation.

Our success is highly dependent on our ability to maintain our direct sales force and independent sales agency network. We may be unable to enter into agreements with additional qualified independent sales agencies and representatives 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 additional independent sales agencies, these parties may not commit the necessary resources to effectively market and sell our products or ultimately be successful in selling our products. Promotion and sales of medical devices are also highly regulated not only by the FDA, but also by the Federal Trade Commission, and are subject to federal and state fraud and abuse enforcement activities.

Manufacturing and Supply

We rely on outside contractors for the manufacture and servicing of our products and their components, and we do not currently maintain alternative manufacturing sources for the NC-stat monitor, docking station or biosensors or any other finished goods products. In outsourcing, we target companies that meet FDA, International Organization for Standardization, or ISO, and other quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring all product requirements are met or exceeded. We believe these manufacturing relationships minimize our capital investment, provide us with manufacturing expertise and help control costs.

Following the receipt of products or product components from our third-party manufacturers, we conduct the necessary inspection and packaging and labeling at our corporate headquarters facility. We may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so. We currently have no plans to manufacture any products or product components internally.

We seek to obtain products from our manufacturers in order to maintain sufficient inventory to satisfy our customer obligations. We did not experience any significant inventory shortages on any established products in 2006. We occasionally experience transient inventory shortages, typically lasting less than one month, on new products during the initial production ramp-up phase. If our third-party manufacturers are unable to manufacture our products to keep up with demand, we would not meet expectations for growth of our business.

Parlex Polymer Flexible Circuits, Inc., which was previously known as PolyFlex Circuits, Inc., a wholly owned subsidiary of the Parlex Corporation, or Parlex, has been manufacturing NC-stat biosensors 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 is in the process of validating manufacturing of our biosensors at a second site located in the U.K.

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 at a facility in Massachusetts and they are producing the initial production runs of the ADVANCE System.

The DigiScope is manufactured by EyeTel, the company from which we obtained an exclusive sales and marketing license for the sale of the DigiScope to the primary care physician and endocrinologist market.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. Our products are cleared for market within the United States and Canada, and are also approved for distribution in the European Union, although to date we have sales only in the United States. Our facility and the facilities of our manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. We 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 developing new biosensors, as well as designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. Our research and development staff consists of 26 people, including 6 who hold Ph.D. degrees. Our research and development group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors and information systems. These individuals work closely with our marketing group, our clinical support group (led by a board-certified neurologist), our scientific advisors and our customers to design products that are intended to improve clinical and economic outcomes.

Devices for the Treatment of Neuropathy

In pursuit of our objective to develop medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies, we are seeking to expand our product base beyond the diagnostic and into the treatment arena. We believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. In particular, we believe that neuropathies that are focal, or localized, in nature can be safely and effectively treated if drugs can be delivered near the disease site without damaging the nerve in the process. Some of these types of treatments are performed today, but they are performed manually by a limited number of physicians. Our product development program includes the design of a product that we believe will reduce the risk involved in providing these treatments. During the first half of 2007, we expect to enter the clinical stage of development of a drug delivery system to enable a broad base of primary care and specialist physicians to provide this type of minimally invasive neuropathy therapy at the point-of-service.

NCS/nEMG Systems

We have an ongoing program of making enhancements and improvements to the NC-stat System. We are developing new biosensors and associated software for the medically appropriate testing of additional nerves. We have also developed a third generation diagnostic device, the ADVANCE System, that will

allow our customers to perform more complex analyses of diagnostic data. We submitted a 510(k) filing to the FDA in the first quarter of 2007 for the ADVANCE System.

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

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

- 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. Consistent with the current NC-stat System, this user interface provides for real-time data review including waveforms.

- Compatibility with existing biosensors and with new nerve conduction biosensors that we develop in the future.

- The ADVANCE System will also support the performance of nEMG studies.

NEUROMetrix®, NC-stat®, ADVANCE and onCall are trademarks of ours.

During 2006, 2005 and 2004, we spent $5.0 million, $3.8 million and $3.3 million, respectively, on research and development.

Competition

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

There are a number of companies that sell traditional NCS/nEMG equipment, typically to neurologists. These companies include Viasys Healthcare Inc., Cadwell Laboratories, Inc and Xltec, Inc. Viasys Healthcare has substantially greater financial resources than we do, and they have established reputations as worldwide distribution channels for medical instruments to neurologists and other physicians. Xltec 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.

Currently, we believe that our most direct competitors are certain specialist physicians, such as neurologists, who perform traditional nerve conduction studies and may view the NC-stat System as competitive with or a threat to their business. Because of the level of automation and the ease of use of the NC-stat System, the NC-stat System facilitates the performance of nerve conduction studies within the

offices of a wider range of physicians. Accordingly, neurologists, including a professional society representing a subset of neurologists who most frequently perform traditional nerve conduction studies, have competed and may continue to compete with us by advancing positions that are adverse to the NC-stat System. We believe this competition has come, and is most likely to continue to come, through the advancement of positions challenging the effectiveness and accuracy of the NC-stat System and the ability of non-specialist physicians to perform nerve conduction studies and accurately diagnose neuropathies. Because specialist physicians and professional societies may be viewed as authoritative, without regard to their potential economic motives, and may have connections to or influence with various regulatory bodies and third-party payers, they may have a competitive advantage over us and their positions may lead to or be reflected in actions taken by these regulatory bodies and third-party payers that are adverse to our business. In this respect, we seek to respond to these positions by supporting and making reference to past and future clinical studies substantiating the effectiveness of the NC-stat System, including those described above in the section titled Clinical Studies and Clinical Validation.

Intellectual Property

We rely on a combination of patents, trademarks, copyrights, trade secrets and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary technology, intellectual property rights and know-how. We hold issued utility patents covering a number of important aspects of our NC-stat System. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2006, we had 12 issued U.S. patents, 7 issued foreign patents and 45 pending patent applications, including 23 U.S. applications, 1 International PCT application and 21 foreign national applications. We also hold an exclusive license to 2 issued U.S. patents and 2 issued foreign patents. The issued and pending patents that we own and license cover, among other things:

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

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

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

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

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

Trademarks

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

Third-Party Reimbursement

We anticipate that sales volumes and prices of our products will continue to be dependent in large part on the availability of reimbursement for our customers from third-party payers and on policies issued by governmental agencies. Third-party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers compensation plans. These organizations may deny coverage and refuse reimbursement for a diagnostic procedure or specific product such as the NC-stat System if they determine that the diagnostic test or product was not medically appropriate, 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 place limitations on the types of physicians that can perform specific types of diagnostic procedures. Also, third-party payers are increasingly challenging the prices charged for medical products and services. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted payment ceilings on specific product lines and procedures. We cannot assure you that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that procedures performed using our products will be reimbursed as separate procedures under existing CPT

codes, that an adequate level of reimbursement will be available or that the third-party payers coverage and reimbursement policies will not adversely affect our ability to sell our products profitably.

A key component in the reimbursement decision by most private insurers and CMS, which administers Medicare, is the assignment of a CPT code. This code is used in the submission of claims to insurers for reimbursement for medical services. CPT codes are assigned, maintained and revised by the CPT Editorial Panel administered by the American Medical Association, or AMA. According to present Medicare guidelines, nerve conduction studies must be performed or supervised by medical doctors, or M.D.s, and doctors of osteopathic medicine, or D.O.s, and are reimbursable under the three CPT codes: 95900, 95903, and 95904. We believe that the nerve conduction measurements performed by the NC-stat System meet the requirements stipulated in the code descriptions published by the AMA and that these codes are currently used by physicians to obtain reimbursement for the performance of nerve conduction studies with the NC-stat System, except, as described below, in cases where they are seeking reimbursement from Medicare in a jurisdiction where the local insurance carrier processing Medicare claims has determined that physicians must submit these claims using a miscellaneous CPT code (95999). If the CPT codes that apply to the procedures performed using our products are changed, or determined not to apply to tests performed with the NC-stat System, reimbursement for performances of these procedures may be adversely affected.

For Medicare, 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 early 2007, five local Medicare carriers covering a total of twenty states 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 CPT codes for conventional nerve conduction studies (95900, 95903 and 95904), which provide for levels of reimbursement fixed by CMS, but rather that physicians must submit claims for reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers may determine the level of reimbursement to be paid, if any. We do not know what success our customers will have in obtaining reimbursement under the miscellaneous code or what level of reimbursement they may receive if they are successful. If physicians do not receive adequate reimbursement under the miscellaneous CPT code from those local carriers, our existing customers may 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 CPT Editorial Panel has formed a committee which is expected to examine the reimbursement coding of automated nerve conduction studies, including the NC-stat System and other electrodiagnostic equipment from additional manufacturers. The findings of this committee may affect which CPT codes Medicare carriers and commercial payers require from physicians who perform procedures with the NC-stat System. 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. These 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. Such requirements could potentially impact the use of the NC-stat System and could potentially have an adverse impact on our revenues.

Additionally, 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 an nEMG 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 are relatively new and they do appear to be targeted at limiting access to perform and/or reimbursement for nerve conduction studies. These LCDs could be interpreted or implemented in a manner that limits the ability of physicians to receive reimbursement under Medicare for nerve conduction studies performed using the NC-stat System, which could adversely affect our business.

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.

FDA and Other Governmental Regulation

FDA Regulation

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

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

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

- Class III, requiring general controls and pre-market approval.

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

510(k) Pre-Market Notification Process

To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use, safety and effectiveness to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not yet required the submission of a pre-market approval application. In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. It generally takes three months from the date of 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 significant change in its intended use, requires a new 510(k) clearance or could require *de novo* classification or pre-market approval. The FDA allows each

company to make this determination, but the FDA can review the decision. If the FDA disagrees with a company s decision not to seek FDA authorization, the FDA may retroactively require the company to seek 510(k) clearance, *de novo* classification or pre-market approval. The FDA also can require the company to cease marketing and/or recall the medical device in question until 510(k) clearance, *de novo* classification or pre-market approval is obtained or take other action.

De Novo Review Process

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

Pre-Market Approval Process

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for clearance through the *de novo* review process, a company must file a pre-market approval application. The pre-market approval process generally requires more extensive pre-filing testing than is required in the 510(k) pre-market notification process and is more costly, lengthy and uncertain. The pre-market approval process can take one to three years or longer. The pre-market approval process requires the company to prove the safety and effectiveness of the device to the FDA s satisfaction through extensive submissions, including pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before granting pre-market approval, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA s quality system regulations. After any pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication, or its manufacturing process.

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;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

- regular, unannounced, 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.

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 August 2006. The NC-stat System has the following intended use, as stated in the most recent 510(k) approval:

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

Furthermore, Section 6 (Basis for Substantial Equivalence) of the 510(k) Summary states:

Clinical data submitted in the 510(k) demonstrates that nerve conduction measurements obtained using the NC-stat are comparable to those obtained using conventional nerve conduction measurement equipment.

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

During the fourth quarter of 2006, we submitted a 510(k) filing for an updated version of the onCall Information System, and we are currently in the process of responding to a request for additional information from the FDA related to this filing. Prior versions of the onCall Information System were included in the 510(k) filings for the NC-stat System. During the first quarter of 2007, we also submitted a 510(k) filing for the ADVANCE System.

DigiScope

The DigiScope received a 510(k) clearance (K990205) as a Class II medical device in 1999 and the intended use language is as follows:

The DigiScope is intended to capture and store images of the retina taken by a fundus camera. The DigiScope has the same intended use and indications as the predicate devices, fundus cameras and computer hardware/software intended to capture, store and transmit images of the fundus.

Manufacturing Facilities

We currently have three contract manufacturing facilities, of which one has 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 shortcomings, we could be subject to fines, recalls or requirements to halt manufacturing.

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. Our business practices could be subject to scrutiny and challenge by federal or state enforcement officials or others under these laws. This type of challenge could have a material adverse effect on our business, financial condition and results of operations. We are currently subject to an investigation by the Office of Inspector General (OIG) within the Department of Health and Human Services based on a subpoena served to us in the second quarter of 2006. We are cooperating with the OIG with their informational request. In addition, we have recently become aware that we are the subject of an investigation by the United States Department of Justice. We have not yet been informed of the subject of this investigation or received any formal request for information relating to it.

Employees

As of December 31, 2006, we had a total of 123 employees. Of the total employees, 26 were in research and development, 72 in sales and marketing and 25 in general and administrative services. Two employees hold both M.D. and Ph.D. degrees, 5 additional employees hold Ph.D. degrees and 1 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 as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information on our Investor Relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the public may read and copy any materials that we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission s Electronic Data Gathering, Analysis and Retrieval system at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

ITEM 1A. RISK FACTORS

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

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

The extent of our future operating income or losses is highly uncertain, and we may not be able to sustain profitability. We have incurred significant cumulative net losses since our inception, including net losses of approximately $4.9 million in 2002, $3.9 million in 2003 and $4.7 million in 2004. In 2005 and 2006, we recorded net income of $249,000 and $4.3 million, respectively. At December 31, 2006, we had an accumulated deficit of approximately $53.7 million. We cannot assure you that we will be able to sustain the profitability achieved in 2005 and 2006.

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.

In particular, we note that as our presence in the market expands and the use of the NC-stat System increases, we are experiencing 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. At any point in time, a number of third-party payers may take positions adversely affecting reimbursement, including taking the position of not reimbursing our customers for their use of the NC-stat System. During the second half of 2006 and early 2007, five local Medicare carriers covering a total of twenty states issued draft LCDs, final LCDs or coding articles particularly addressing coverage and reimbursement policies for nerve conduction studies that could adversely impact the reimbursement of 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 CPT codes for conventional nerve conduction studies (95900, 95903 and 95904), which provide for levels of reimbursement fixed by CMS, but rather that physicians must submit claims for reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers will determine the level of reimbursement to be paid, if any. We do not know what success our customers will have in obtaining reimbursement under the miscellaneous code or what level of reimbursement they may receive if they are successful. The AMA CPT Editorial Panel has formed a committee which is expected to examine the reimbursement coding of automated nerve conduction studies, including the NC-stat System and other traditional equipment. The findings of this committee may affect which CPT codes Medicare carriers require from physicians who perform procedures with the NC-stat System. 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. These 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. Such requirements could potentially impact the use of the NC-stat System and could potentially have a material and adverse impact on our revenues.

Additionally, 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 an nEMG 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 for medically necessary nerve conduction studies performed using the NC-stat System. However, these LCDs are relatively new and they do appear targeted at limiting access to perform and/or reimbursement for nerve conduction studies. These LCDs could be interpreted or implemented in a manner that limits the ability of physicians to receive reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

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, our existing customers in those areas 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. For example, in the fourth quarter of 2006, we experienced a decline in revenues from the third quarter of 2006, which we believe primarily resulted from the uncertainty created by the issuance of the draft LCDs, final LCDs and coding articles issued by local Medicare carriers that are described above. 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.

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

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

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

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

- unfavorable experiences by physicians using the NC-stat System;

- physicians reluctance to alter their existing practices; and

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

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

We may not be able to accurately predict the size of the market for our 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 the NC-stat System will significantly increase the number of nerve conduction studies performed. Based on our analysis of current data, we estimate that the potential market size for the NC-stat System in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be greater than 9.5 million annual patient tests. This represents a significant increase in the size of the market for nerve conduction studies and is based upon a number of assumptions and estimates, which themselves may not be accurate. For example, we have assumed that all initial office visits for low back pain may represent an opportunity for use of the NC-stat System, and we have estimated that an annual testing rate of 50% for all individuals diagnosed with diabetes represents the potential addressable market in diabetes. 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 and specialist physicians, our ability to increase our revenues will be limited.

We are focusing our sales and marketing efforts for the NC-stat System and the DigiScope on primary care and specialist physicians. As these physicians 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 two single source manufacturers to produce the NC-stat System, and any change in our relationship with either of these manufacturers could prevent us from delivering products to our customers in a timely manner and may materially 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. In the event that either of our manufacturers ceases to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate an alternate manufacturer. Additionally, if either of our manufacturers experiences a failure in its production process, is unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fails to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products, particularly our NC-stat biosensors, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have entered into an exclusive manufacturing and supply agreement with Parlex for the manufacture of the NC-stat biosensors, and currently rely on a single manufacturer, Sunburst, for the manufacture of our NC-stat monitors and docking stations. 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 growth could be limited and our business could be harmed.

In order for us successfully to expand our business within the United States and internationally, our contract manufacturers must be able to provide us with 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 anticipated growth may strain the ability of our manufacturers to deliver an increasingly large supply of products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed.

We currently rely entirely on EyeTel for the production and supply of the DigiScope to customers and on the Wilmer Eye Institute for the analysis of eye scans performed by our customers. Any interruption in supply of the DigiScope systems from EyeTel or any interruption in the services provided by the Wilmer Eye Institute could significantly reduce our ability to generate revenues.

EyeTel is the sole manufacturer of the DigiScope and they serve as the only source of supply of systems to customers. If there were any interruption in the manufacturing and supply capabilities of EyeTel, our ability to generate revenues from the DigiScope could be adversely impacted. The Wilmer Eye Institute receives digital scans from customers using the DigiScope and eye specialists employed by the Wilmer Eye Institute analyze the images and within 24-48 hours after receipt 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 materially adversely impacted.

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

We introduced the NC-stat System to the market in May 1999. We derive all of our revenues from sales of the products that comprise the NC-stat System, and we expect that sales of these products will continue to constitute the substantial majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is entirely reliant on our ability to market and sell the products that comprise the NC-stat System, particularly the disposable biosensors, sales of which accounted for approximately 86.4%, 87.7% and 87.6% of our total revenues in 2006, 2005 and 2004, respectively. Our sales of these products may be negatively impacted by many factors, including:

- changes or proposed changes in reimbursement rates or policies relating to our products by third-party payers;
- the failure of the market to accept our products;
- manufacturing problems;
- claims that our products infringe on patent rights or other intellectual property rights owned by other parties;
- adverse regulatory or legal actions relating to our products;
- competitive pricing and related factors; and
- results of clinical studies relating to our products or our competitors products.

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

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

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. Our patent position is generally uncertain and involves complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

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

- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and
- other companies may design around technologies we have patented, licensed or developed.

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

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, nondisclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. In particular, we have sought no patent protection for the technology and algorithms we use in our onCall Information System, and we rely on trade secrets to protect this information. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur:

- the agreements may be breached;
- we may have inadequate remedies for any breach;
- trade secrets and other proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

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

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

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

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

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

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

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

We are subject to extensive regulation by the 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 either 510(k) clearance, grant of a *de novo* classification or pre-marketing approval from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance or *de novo* classification or pre-market approval for significant post-market modifications to our products. Each of these processes can be expensive and lengthy. The FDA s process for 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. The process for obtaining pre-market approval is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occur, 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.

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 and medical device 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, consent decrees and civil penalties;
- requiring repair, replacement, refunds, recall or seizure of our products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

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

If we or 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 unannounced 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 force a suspension or shutdown of our packaging and labeling operations, the operations of the manufacturers of our products or a recall of our products. If any of these events occurs, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

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

We are subject to the medical device reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would be likely to have caused or contributed to a death or serious injury. The FDA and similar governmental bodies in other countries have the authority to require the recall of our products if we or the manufacturers of our products fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of our products. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving the NC-stat System would be particularly harmful to our business and financial results because the products that comprise the NC-stat System 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. Several Medicare carriers, however, have developed articles or proposed LCDs suggesting or imposing coverage, coding or billing guidelines that are not consistent with coding information we have provided based on then-existing guidelines. There is a growing debate over how certain types of nerve conduction tests, including those performed using the NC-stat System, would be billed and assessed in connection with Medicare claims. Accordingly, we cannot predict how the government would regard what it might allege to be billing or coding errors made with respect to services rendered using our products and cannot predict whether the government might assert that any such errors were not inadvertent and therefore potentially subject to the federal civil Federal Claims Act or other laws that could be potentially applicable to us. 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.

We note that in the second quarter of 2006, we received a subpoena from the 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. We are cooperating with the OIG with their information request and there are presently no actions against us of which we are aware.

We are the subject of an investigation by the United States Department of Justice, which could cause adverse publicity, be costly to respond to or lead to civil or criminal charges against us or our employees, any of which could materially adversely affect our business.

We have recently become aware that we are the subject of an investigation by the United States Department of Justice. We have not yet been informed of the subject matter of this investigation or received any formal requests for information relating to it. This investigation could cause adverse publicity, be costly to respond to or lead to civil or criminal charges against us or our employees, any of which could adversely affect our business.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal pen