NEUROLOGIX INC/DE
Form 10-K
March 26, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2009

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

Commission File Number 0-13347

NEUROLOGIX, INC.

DELAWARE	06-1582875
State or other jurisdiction of Incorporation or organization	I.R.S. Employer Identification No.
ONE BRIDGE PLAZA, FORT LEE, NEW JERSEY	07024
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code (201) 592-6451

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001 per share

(Title of Class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] 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 [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [ ] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer (Do not check if a smaller reporting company) [ ]	Smaller reporting company [X]

Indicate by checkmark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates was approximately $7,089,301, computed by reference to the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter.

As of March 12, 2010, there were outstanding 27,865,010 shares of the Registrant s common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of this Annual Report on Form 10-K is incorporated herein by reference to the registrant s Proxy Statement for its 2010 Annual Meeting of Stockholders, which Proxy Statement will be filed within 120 days after the Registrant s fiscal year ended December 31, 2009.

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FORWARD LOOKING STATEMENTS

This document includes certain statements of Neurologix, Inc. (the Company) that may constitute 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 (the Exchange Act) and which are made pursuant to the Private Securities Litigation Reform Act of 1995. These forward-looking statements and other information relating to the Company are based upon the beliefs of management and assumptions made by and information currently available to the Company. Forward-looking statements include statements concerning plans, objectives, goals, strategies, future events or performance, as well as underlying assumptions and statements that are other than statements of historical fact. When used in this document, the words expects, anticipates, estimates, plans, intends, projects, predict may, should, potential, continue and similar expressions are intended to identify forward-looking statements. These statements reflect the current view of the Company s management with respect to future events and are subject to numerous risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, among other things:

- the inability of the Company to raise additional funds, when needed, through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements.

- the inability of the Company to successfully commence and complete all necessary clinical trials for the commercialization of its product to treat Parkinson s disease.

Other factors and assumptions not identified above could also cause the actual results to differ materially from those set forth in the forward-looking statements. Additional information regarding factors which could cause results to differ materially from management s expectations is found in the section entitled Risk Factors starting on page 22. Although the Company believes these assumptions are reasonable, no assurance can be given that they will prove correct. Accordingly, you should not rely upon forward-looking statements as a prediction of actual results. Further, the Company undertakes no obligation to update forward-looking statements after the date they are made or to conform the statements to actual results or changes in the Company s expectations. In this annual report on Form 10-K, we , our and us refer to Neurologix, Inc., except as otherwise indicated or as the context otherwise requires.

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PART I

Item 1. Business

INTRODUCTION

The Company is a development stage company that is engaged in the research and development of proprietary treatments for disorders of the brain and central nervous system, using gene transfer and other innovative therapies. The Company s development efforts are currently focused on gene transfer for treating Parkinson s disease. The Company s core technology, which it refers to as NLX, is in the clinical development stages and was tested in the Phase 1 and Phase 2 clinical trials to treat Parkinson s disease. Although the Company s operations and resources will be primarily concentrated on its Parkinson s disease therapy, the Company intends to continue to develop therapies to treat other neurodegenerative and metabolic disorders, including therapies relating to epilepsy and Huntington s disease. Recent highlights include:

For the 12 months ended December 31, 2009, the Company reported a net loss of approximately $13.5 million versus a net loss of $6.3 million for the 12 months ended December 31, 2008. Cash and cash equivalents were $9.6 million at December 31, 2009.

On March 23, 2010, the Company extended the term of its consulting agreement with Dr. Martin Kaplitt, the Company s Chairman of the Board of Directors, from January 1, 2010 to December 31, 2010.

On March 23, 2010, the Company approved an extension of the term of its amended and restated consulting agreement with Dr. Michael Kaplitt, one of the Company s scientific co-founders and a member of its Scientific Advisory Board (the SAB), from April 30, 2010 to April 30, 2011.

Effective March 10, 2010, John E. Mordock resigned as a director and as President and Chief Executive Officer of the Company, with Clark A. Johnson, Vice Chairman of the Company s Board of Directors, being named his successor.

In February 2010, the Company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for intellectual property central to the Company s approach for the treatment of epilepsy. The patent allowance covers the treatment of seizures associated with temporal lobe epilepsy (TLE) by direct administration of an AAV (adeno-associated virus) vector encoding Neuropeptide Y (NPY) into the brain s temporal lobe. (See Business of the Company Patents and Other Proprietary Rights).

In January 2010, the USPTO expanded the intellectual property protections enabled by a previously issued patent that is central to the Company s Parkinson s disease program. The new allowances broaden the patent s coverage beyond Parkinson s disease to include the use of GAD65 in the treatment of other neurological and related disorders. (See Business of the Company Patents and Other Proprietary Rights).

In November 2009, the Company completed all planned surgeries in its Phase 2 clinical trial of the Company s gene transfer approach to the treatment of advanced Parkinson s disease. (See Business of the Company Parkinson s Disease).

On September 24, 2009, the Company entered into a third amendment to its Master Sponsored Research Agreement (the OSU Research Agreement), dated as of May 10, 2006, as amended, with The Ohio State University Research Foundation (OSURF), on behalf of Ohio State University. The third amendment,

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among other things, extended the term of the OSU Research Agreement to November 10, 2010.

On August 31, 2009, the Company extended the term of its consulting agreement with Dr. Matthew During, one of the Company s scientific co-founders and a member of the SAB, from September 30, 2009 to September 30, 2010.

On August 20, 2009, the Company entered into employment agreements with John E. Mordock, the Company s then President and Chief Executive Officer, and Marc L. Panoff, the Company s Chief Financial Officer, Treasurer and Secretary. The agreements replaced earlier agreements between the Company and the respective officers, each dated December 4, 2007. These new employment agreements extended the term of employment of each of the officers through December 4, 2010 and enhanced certain terms of each of the officers severance arrangements.

On July 23, 2009, the Company entered into Amendment No. 3 to its Clinical Study Agreement (the Clinical Study Agreement) with Cornell University for and on behalf of its Joan & Sanford I. Weill Medical College (Cornell). The Amendment extended the performance period of the sponsored research program and eliminated from the scope of work all research and activities relating to mechanisms by which certain gene therapy treatments may penetrate the blood-brain barrier.

On January 13, 2009, the Company entered into a License Agreement (the Cornell License Agreement) with Cornell, whereby Cornell granted the Company an exclusive license for the worldwide use of certain patents for the development of products and methods for the treatment of psychiatric conditions. The Company anticipates using these patents to develop a product for the treatment of depression. (See Business of the Company Other Neurodegenerative and Metabolic Disorders).

HISTORY

Arinco Computer Systems Inc. (formerly known as Change Technology Partners, Inc. and referred to herein as Arinco), the predecessor to the Company, was incorporated in New Mexico on March 31, 1978 for the principal purpose of serving its subsidiary operations, which included the sale of telecommunications equipment and services and the retail sales of computers. Arinco, which became a public company in 1982, did not have any business operations from 1985 to March 2000. At that time, an investor group acquired control of Arinco and commenced a new consulting business strategy focusing on internet, e-services and digital media solutions.

Thereafter, until approximately July 2001, the Company provided a broad range of consulting services, including e-services and technology strategy, online branding, web architecture and design, systems integration, systems architecture and outsourcing. However, the Company was not successful with its business strategy and therefore the Company s Board of Directors (the Board) voted to divest the Company of a majority of its then existing operations. On September 30, 2002, the Board adopted a plan of liquidation and dissolution in order to maximize stockholder value.

During the period from December 2001 through June 30, 2003, Canned Interactive, which designs and produces interactive media such as digital video discs (DVDs) and web sites, primarily for entertainment, consumer goods, sports and technology companies, was the Company s sole source of operating revenues. On June 30, 2003, the Company sold all of the issued and outstanding shares of Canned Interactive to a limited partnership of which Canned

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Interactive s managing director was the general partner. With the sale of Canned Interactive, the Company ceased to have any continuing operations.

On February 10, 2004, the Company completed a merger (the Merger) of a wholly-owned subsidiary with Neurologix Research, Inc. (formerly known as Neurologix, Inc. and sometimes referred to herein as NRI). Following the Merger, NRI became a wholly-owned subsidiary of the Company and stockholders of NRI received an aggregate number of shares of common stock of the Company (the Common Stock) representing approximately 68% of the total number of shares of Common Stock outstanding after the Merger.

Effective December 31, 2005, the Company completed a short-form merger whereby its operating subsidiary, NRI, was merged with and into the Company. Following the merger, NRI no longer existed as a separate corporation. As the surviving corporation in the merger, the Company assumed all of the rights and obligations of NRI. The short-form merger was completed for administrative purposes and did not have any material impact on the Company or its operations or financial statements.

BUSINESS OF THE COMPANY

The Company is a development stage company that is engaged in the research and development of proprietary treatments for disorders of the brain and central nervous system, using gene transfer and other innovative therapies. These treatments are designed as alternatives to conventional surgical and pharmacological treatments.

The Company s scientific co-founders, Dr. Matthew J. During and Dr. Michael G. Kaplitt, have collaborated for more than ten years in working with central nervous system disorders. Their research spans from animal studies (for gene transfer in Parkinson s disease, epilepsy and other disorders of the central nervous system) to the Phase 2 clinical trial for the treatment of Parkinson s disease. They both remain as consultants to the Company and serve on the SAB.

From 1999 to 2002, the Company, through NRI, conducted its gene transfer research through sponsorship agreements with Thomas Jefferson University (TJU), the Rockefeller University (Rockefeller) and the University of Auckland in New Zealand (AUL). From October 2002 to April 2006, the Company staffed its own laboratory facilities at Columbia University s Audubon Biomedical Science and Technology Park in New York City to manufacture the gene transfer products required for its pre-clinical trials and to continue the research and development of additional gene transfer products.

Currently, the Company conducts basic and applied gene transfer research through research agreements with Cornell in a laboratory directed by Dr. Michael Kaplitt and one of the Company s scientists, and OSURF in a laboratory directed by Dr. During and five of the Company s scientists.

The Company currently outsources the manufacture of its materials and devices to third parties for use in its clinical trials. These third parties provide such materials and devices pursuant to directives from the Company.

Business Strategy

The Company s objective is to develop and commercialize innovative therapeutic treatments for disorders of the brain and central nervous system, primarily gene transfer therapy. Key elements of the Company s strategy include:

Focus resources on development of the Company s NLX technology. The Company intends to focus its research and development efforts on what it believes are achievable technologies having practical applications. Currently, the Company

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expects to allocate the majority of its resources and efforts to the development of its first-generation NLX product for the treatment of Parkinson s disease.

Focus on central nervous system disorders that are likely to be candidates for gene transfer. To attempt to reduce the technical and commercial risks inherent in the development of new gene therapies, the Company intends to pursue treatments for neurological diseases for which:

- the therapeutic gene function is reasonably well understood and has a physiological role;
- neurosurgical approaches are already established and standard;
- animal studies have indicated that gene transfer technology may be effective in treating the disease;
- specific clinical outcome is measurable;
- partial correction of the disease is expected to be clinically proven; and
- clinical testing can be conducted in a relatively small number of patients within a reasonably short time period.

Establish strategic relationships to facilitate research, product development and manufacturing. The Company continues to seek to establish collaborative research and manufacturing relationships with universities and companies involved in the development of gene transfer and other technologies. The Company believes that such relationships, if established, will make additional resources available to the Company for the manufacture of gene transfer products and for clinical trials involving such products. The Company may enter into joint ventures or strategic alliances with one or more pharmaceutical companies or other medical specialty companies to develop, manufacture and market its products. The Company may seek out companies that have extensive resources and knowledge to enable the Company to develop and commercialize its products. In February 2010, the Company retained MTS Health Partners, L.P. as a strategic advisor to complement and augment the Company s ongoing business development efforts, including efforts to seek strategic collaborations for the continued development and commercialization of its Parkinson s product. (See Manufacturing).

Funding Operations. The Company must continue to seek additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements, including joint ventures and strategic alliances. (See Risk Factors The Company Does Not Have Sufficient Funds to Continue its Operations in the Long Run or to Commercialize its Product Candidates , See Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Plan of Operation and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources).

Technology Overview

Deoxyribonucleic acid (DNA) is organized into segments called genes, with each gene representing the region of DNA that determines the structure of a protein, as well as the timing and location of such protein s production. Occasionally, the DNA for one or more genes can be defective, resulting in the absence or improper production of a functioning protein in the cell. This improper expression can alter a cell s normal function and may result in a disease. One goal of gene transfer is to treat these diseases by delivering DNA containing the corrected gene into

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the affected cells. Also, gene transfer can increase or decrease the synthesis of gene products or introduce new genes into a cell and thus provide new or augmented functions to that cell.

There are several different ways of delivering genes into cells. Each of the methods of delivery uses carriers, called vectors, to transport the genes into cells. Similar to the relationship between a delivery truck and its cargo, the vector (the truck) provides a mode of transport and the therapeutic agent (the cargo) provides the disease remedy. These carriers can be either man-made components or modified viruses. The use of viruses takes advantage of their natural ability to introduce DNA into cells. Gene transfer takes advantage of this property by replacing viral DNA with a payload consisting of a specific gene. Once the vector inserts the gene into the cell, the gene acts as a blueprint directing the cell to make the therapeutic protein.

For its first generation of products, the Company intends to utilize exclusively the adeno-associated virus (AAV) vector. In 1994, Drs. Michael Kaplitt and Matthew During demonstrated that AAV could be a safe and effective vehicle for gene transfer in the brain. Since that time, the AAV vector has been used safely in a variety of clinical gene transfer trials.

The Company believes that the benefits of AAV vector gene transfer technology include:

Safety. AAV vectors are based on a virus that, to the Company s knowledge, has not been associated with a human disease.

Efficiency of Delivery. AAV vectors are effective at delivering genes to cells. Once in the cell, genes delivered by AAV vectors in animal models have produced effective amounts of protein on a continuous basis, often for months or longer from a single administration.

Ability to Deliver Many Different Genes. The vast majority of the coding parts of genes (cDNA) fit into AAV vectors and have been successfully delivered to a wide range of cell types.

A Simpler and Safer Option than Standard Surgery. The Company intends to administer the AAV vector-based products in a procedure that is simpler and safer than other established neurosurgical procedures.

Parkinson s Disease

General. Parkinson s disease is a neurodegenerative disorder; it arises from the gradual death of nerve cells in the brain. Parkinson s disease is a progressive and debilitating disease that affects the control of bodily movement and is characterized by four principal symptoms:

tremor of the limbs,

rigidity of the limbs,

bradykinesia of the limbs and body evidenced by difficulty and slowness of movement, and

postural instability.

Physicians and patients have long recognized that this disease, or treatment complications, can cause a wide spectrum of other symptoms, including dementia, abnormal speech, sleep disturbances, swallowing problems, sexual dysfunction and depression.

Rigidity, tremor and bradykinesia result, primarily, from a loss of dopamine in two regions of the brain: the substantia nigra and striatum (caudate and putamen). Dopamine is a neurotransmitter, a chemical released from nerve cells (neurons), which helps regulate the flow of impulses from the substantia nigra to neurons in the caudate and putamen. Standard therapy for Parkinson s disease often involves use of levodopa, a drug that stimulates production of dopamine. However, over extended periods of time levodopa often declines in its effectiveness.

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In advanced stages of Parkinson s disease, as the disease becomes more and more debilitating, it becomes necessary to apply a riskier and potentially more invasive medical procedure to treat the disease. It is at this juncture that surgical procedures, including deep brain stimulators and lesioning, which target an area of the brain called the subthalamic nucleus (STN), are commonly advised.

The Company believes that the glutamic acid decarboxylase (GAD) gene can be used to selectively mimic normal physiology and alter the neural circuitry affected by Parkinson s disease. The Company s technology inserts a GAD gene into an AAV vector, and this packaged vector is introduced directly into the STN. The GAD gene is responsible for making gamma aminobutyric acid (GABA), which is released by nerve cells to inhibit or dampen activity. The loss of dopamine leads to a change in the activity of several brain structures that control movement. Central to this is the STN, which is overactive and does not receive adequate GABA, as well as targets of the STN, which are also hyperactive and also do not receive enough GABA. The goal of this therapy is to deliver GABA to the STN in order to re-establish the normal neurochemical balance and activity among these key structures.

The Company s gene transfer is therefore designed to reset the overactive brain cells to inhibit electrical activity and return brain network activity to more normal levels. This in turn reduces symptoms of Parkinson s disease, including tremors, rigidity and slowness of movement. The therapy is designed to be administered without destroying brain tissue and without implanting a permanent medical device.

According to the National Parkinson Foundation, there are over 1 million Parkinson s disease patients in America, with approximately 60,000 new cases diagnosed each year. While the peak onset of Parkinson s disease occurs after the age of 65, 15% of Parkinson s disease patients are less than 50 years of age.

Product Development and Operations. In October 2006, the Company announced that it had completed its Phase 1 clinical trial of gene transfer for Parkinson s disease. The results indicated that the treatment, which was confined to only one side of the brain, appeared to be safe and well-tolerated in patients with advanced Parkinson s disease, with no evidence of adverse effects or immunologic reaction related to the study treatment. The trial also yielded statistically significant clinical efficacy and neuro-imaging results. Such results were published in 2007 in two leading peer-reviewed medical and scientific journals: *The Lancet* and *Proceedings of the National Academy of Sciences.*

A Phase 1 clinical trial is primarily designed to test the safety, as opposed to the efficacy, of a proposed treatment. The clinical trial was conducted by Drs. Michael Kaplitt and Matthew During. As part of this clinical trial, twelve patients with Parkinson s disease underwent surgical gene transfer at The New York Presbyterian Hospital/Weill Medical College of Cornell University. All patients were evaluated both pre- and post-operatively with Positron Emission Tomography (PET) scans and with graded neurological evaluations by Drs. Andrew Feigin and David Eidelberg of North Shore University Hospital. The Phase 1 clinical trial was an open-label dose-escalation study with four patients in each of three escalating dose cohorts. The third cohort of four patients received 10 times the dose of the first cohort. The 12 patients who participated in the trial were diagnosed with severe Parkinson s disease of at least five years duration and were no longer adequately responding to current medical therapies.

Following this Phase 1 clinical trial, the Company designed its protocol for a Phase 2 clinical trial. On December 3, 2007, the Company reviewed its Phase 2 protocol with the National Institutes of Health s Office of Biotechnology Activities Recombinant DNA Advisory Committee (the RAC) in a public forum.

On December 13, 2007, the Company announced that the U.S. Food and Drug Administration (the FDA) granted Fast Track Designation for the Company s treatment of

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Parkinson s disease. Under the FDA Modernization Act of 1997, Fast Track Designation may facilitate the development and expedite the review of a drug candidate that is intended for the treatment of a serious life-threatening condition and demonstrates the potential to address an unmet medical need for such a condition. Fast Track Designation will provide various means to expedite the development and review of the Company s gene transfer procedure for Parkinson s disease, including the facilitation of meetings and other correspondence with FDA reviewers, consideration for priority review and the ability to submit portions of a Biologic License Application (BLA) early for review as part of a rolling submission. The receipt of Fast Track Designation does not, however, assure the approval of any of the Company s study protocols or the ultimate approval of any BLA that may be submitted by the Company to the FDA for marketing approval.

Under a manufacturing and development agreement, the Company and Medtronic, Inc. (Medtronic) have co-developed a new catheter infusion device to infuse the Company s gene transfer product into the brain with respect to the treatment of Parkinson s disease. (See Manufacturing). The FDA reviewed and approved the use of this device in connection with the Company s Phase 2 clinical trial for its Parkinson s disease product under the Company s investigational new drug application (IND). The use of such a catheter facilitates the delivery of the Company s gene transfer treatment by neurosurgeons and simplifies the procedures for infusing the gene product into the brain. In order for the Company to market its products, Medtronic must obtain the FDA s approval for the commercialization of such catheter infusion device, and the Company must obtain sufficient quantities of the catheter infusion device whether from Medtronic or another manufacturer. (See Risk Factors).

The Company initiated its Phase 2 clinical trial for the treatment of advanced Parkinson s disease in December 2008 and completed all 44 of the planned surgeries associated with the trial in November 2009. The Company will be evaluating the 44 trial participants that were enrolled across seven medical center sites. Half of the trial participants were randomly selected to receive an infusion of the gene-based treatment bilaterally and the other half were randomly selected to receive a sterile saline solution (the Control Participants). Trial participants are being assessed for safety and for treatment effects by standardized Parkinson s disease ratings at multiple time points both pre and post-procedure. The primary endpoint for the trial will be a clinical assessment of motor function at 6 months using the Unified Parkinson s Disease Rating Scale (UPDRS). The Company expects to receive initial results, based on these assessments, of its Phase 2 clinical trial at the end of the 6-month period following the completion of the last participant s surgical procedure. All participants in the trial will continue to be monitored for safety for 12 months following their respective surgical procedures. If such initial efficacy results are significantly positive and if the 12-month safety data is acceptable, then those Control Participants who continue to meet all entry, medical and surgical criteria for the trial will be offered the opportunity to participate in the open label arm of the trial to receive a bilateral infusion of the gene-based treatment.

In December 2009, the Data Monitoring Committee (the DMC), a group of independent medical experts, selected by the Company, who are responsible for reviewing and evaluating the safety data generated from the Company s Phase 2 clinical trial, recommended no modifications to the clinical trial. This recommendation was based on the DMC s review of all safety data from the first 20 patients enrolled in the clinical trial with at least one month of data.

The Company is currently taking steps to move toward a pivotal trial for the treatment of Parkinson s disease, and hopes to be in a position to file its protocol with the FDA in 2010 or 2011. The Company s conduct of such a trial will require, among other things, approval by the FDA and adequate funding. Currently, the Company estimates that the pivotal trial could be completed in 2013 and the estimated total direct costs to reach that milestone are expected to be between $20 million and $40 million. (See Risk Factors and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations).

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Epilepsy

General. Epilepsy, a group of diseases associated with recurrent seizures, is caused by periodic episodes of repetitive, abnormal electrochemical disturbance in the central nervous system, beginning in the brain. Generalized seizures happen when massive bursts of electrical energy sweep through the entire brain at once, causing loss of consciousness, falls, convulsions or intense muscle spasms. Partial or focal seizures happen when the disturbance occurs in only one part of the brain, affecting the physical or mental activity controlled by that area of the brain. Seizures may also begin as partial or focal seizures and then generalize.

According to the Epilepsy Foundation (USA) (the EF), epilepsy affects more than 3 million Americans of all ages and backgrounds, making it one of the most common neurological diseases in this country. Approximately 200,000 new cases of seizures and epilepsy occur each year, with approximately 80% of epileptic Americans below age 65. Despite optimal medical (drug) treatment, as many as 30% to 40% of people with epilepsy continue to have seizures and are potential candidates for surgery, including gene transfer.

Product Development and Operations. Over the past several years, the Company has completed multiple pre-clinical trials in rodents and two non-human primate studies to evaluate the toxicity and efficacy of using its gene transfer technology in the brain for the treatment of epilepsy. The Company s approach is based on the use of the non-pathogenic AAV vector, delivered using standard neurosurgical techniques. Other studies have demonstrated that NPY, a 36-amino acid peptide which acts to dampen excessive excitatory activity and prevents seizures in multiple animal models, had efficacy in preventing the development of spontaneous seizures that occur after a prolonged episode of status epilepticus, a life-threatening condition in which the brain is in a state of persistent seizure. The Company s proposed treatment uses gene transfer technology to deliver genes into the brain which restore the chemical balance, but only in the areas in which the disease process is occurring.

In December 2006, the Company submitted an IND to the FDA for permission to begin a Phase 1 clinical trial in TLE. The proposed clinical protocol for this study was presented to the RAC on September 23, 2004 and was reviewed favorably.

On December 4, 2007, the Company announced the receipt of a grant from the Epilepsy Research Foundation, a joint venture of three non-profit epilepsy organizations the Epilepsy Therapy Project, EF, and Finding a Cure for Epilepsy and Seizures formed to identify and accelerate the development of promising epilepsy research. The grant will help fund the Company s clinical epilepsy research.

In January 2008, the Company announced that as a result of comments from, and discussions with, the FDA, the Company would need to conduct an additional pre-clinical trial in non-human primates prior to commencing a Phase 1 clinical trial. The non-human primate study would be designed to confirm the safety of the administration and use of the AAV containing NPY.

In February 2010, the Company received a Notice of Allowance from the USPTO for intellectual property covering the use of NPY for the treatment of TLE. The Company believes that this Notice of Allowance will protect the Company s intellectual property rights with respect to the use of NPY for the treatment of TLE.

The Company s timetable for commencement of a Phase 1 clinical trial for its TLE product has been delayed, with any such commencement being subject to, among other things, the successful completion of the additional pre-clinical trial, the availability of funding, approval by the FDA and procurement of certain intellectual property licenses. (See Risk Factors). The Company cannot predict the timing for the conduct of additional trials or for a filing for the FDA s approval of the epilepsy product.

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Huntington s Disease

General. Huntington s disease is a devastating, hereditary, degenerative brain disorder for which there is, at present, no effective treatment or cure. Huntington s disease slowly diminishes the affected individual s ability to walk, think, talk and reason. Early symptoms of Huntington s disease may affect cognitive ability or mobility and include depression, mood swings, forgetfulness, clumsiness, involuntary twitching and lack of coordination. As the disease progresses, concentration and short-term memory diminish and involuntary movements of the head, trunk and limbs increase. Walking, speaking and swallowing abilities deteriorate and eventually a person is unable to care for himself or herself. Ultimately, death occurs due to complications such as choking, infection or heart failure.

According to the Huntington s Disease Society of America, Huntington s disease is recognized as one of the more common genetic disorders. More than a quarter of a million Americans have Huntington s disease or are at risk of inheriting the disease from an affected parent. Huntington s disease typically begins in mid-life, between the ages of 30 and 50 and affects males and females equally. Each child of a person with Huntington s disease has a 50 percent chance of inheriting the fatal gene. Everyone who carries the gene will develop the disease.

Product Development and Operations. In November 2005, the Company announced findings from pre-clinical studies which showed that a form of the gene XIAP (X-linked Inhibitor of Apoptosis Protein or dXIAP) may prevent the progression of Huntington s disease. The Company further investigated the neuroprotective effects of dXIAP by injecting pre-symptomatic rodents with AAV vectors encoding dXIAP into the striatum, an area of the brain normally affected in patients with Huntington s disease. In the study, rodents injected with this vector experienced significant reversal of motor dysfunction to the motor function level of normal rodents, while there was no improvement in the motor function of rodents treated with a control vector. dXIAP also improved the function of the diseased neurons in culture. Furthermore, no adverse effects due to dXIAP overproduction were observed.

In August 2008, the Company entered into a license agreement with Aegera Therapeutics Inc. (Aegera) (the Aegera License Agreement) whereby the Company was granted an exclusive license for the worldwide rights, excluding China, for the use of dXIAP for therapeutic or prophylactic purposes in the treatment of Huntington s disease.

In September 2009, the Company received orphan drug designation from the FDA for its Huntington s disease product.

The Company s development of this therapy for Huntington s disease is currently in the pre-clinical phase. The Company reviewed and analyzed its initial pre-clinical results and determined that additional pre-clinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this therapy. The timing of such trial is subject to the completion of additional pre-clinical testing, the availability of funding, the availability of the AAV vector and an infusion system and to receipt of applicable regulatory approvals. (See Risk Factors The Company Cannot Ensure that it will be Able to Pursue Further Trials for its Product Candidates or the Timing of any Future Trials).

Other Neurodegenerative and Metabolic Disorders

The Company has also undertaken efforts to develop gene transfer for the treatment of other neurodegenerative and metabolic disorders, including depression and metabolic syndrome or genetically-based obesity. The Company is also continuing its research and development of gene transfer for the treatment of these disorders. Since the Company s primary focus remains the development of its product for the treatment of Parkinson s disease, the Company expects

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that these other treatment candidates will remain in research and pre-clinical phases for the next several years.

In January 2009, the Company and Cornell entered into the Cornell License Agreement which resulted from the ongoing research and development relationship between the Company and Cornell under the Clinical Study Agreement. Pursuant to the terms of the Cornell License Agreement, Cornell granted the Company an exclusive license for the worldwide use of certain patents for the development of products and methods for the treatment of psychiatric conditions.

Patents and Other Proprietary Rights

The Company believes that its success depends upon its ability to develop and protect proprietary products and technology. Accordingly, whenever practicable, the Company applies for patents in the United States (and, in some instances, foreign patents as well) covering those developments that it believes are innovative, technologically significant and commercially attractive to its field of operations. At present, it holds the license to 17 issued U.S. patents and 8 foreign patents, as well as more than 20 pending U.S. and foreign patent applications. In addition, the Company owns 2 issued U.S. patents, 11 U.S. pending patent applications and 10 foreign patent applications. All of the above patents cover gene transfer technologies and delivery mechanisms for gene transfer.

Exclusive patent licenses were granted by Rockefeller and TJU pursuant to research agreements that the Company had with these institutions and by Aegera pursuant to the Aegera License Agreement and Cornell pursuant to the Cornell License Agreement. Non-exclusive patent licenses were granted pursuant to agreements the Company has with Rockefeller, Yale University and Diamyd Therapeutics AB (Diamyd).

All of such licenses granted to the Company cover patent rights and technical information relating to its gene transfer products and its NLX technology. Under the licenses granted by Rockefeller, TJU, the Rockefeller-Yale Agreement (as defined below) and Cornell, Drs. Michael Kaplitt and Matthew During, the Company s founders, are entitled to receive, and have received, certain amounts out of the payments made by the Company to Rockefeller, TJU, Yale University and Cornell pursuant to such licenses. (See Note 3 to Financial Statements).

In August 2002, the Company entered into a license agreement with Rockefeller and Yale University (the Rockefeller-Yale Agreement) whereby the universities granted to the Company a nonexclusive license to certain patent rights and technical information. An initial fee of $20,000 was paid to each of the two universities pursuant to the agreement, and the Company pays an annual maintenance fee of $5,000 per year to each university. In addition, the Company must make additional payments upon reaching certain milestones. The Company has the right to terminate the agreement at any time on 3 months notice. (See Note 10 to Financial Statements).

On July 2, 2003, the Company entered into the Clinical Study Agreement with Cornell to sponsor the Company s Phase 1 clinical trial for the treatment of Parkinson s disease. Under this agreement, the Company paid Cornell $36,000 when each patient commenced treatment and $23,000 annually for the services of a nurse to assist in the clinical trial. The Company fulfilled its obligation under this portion of the agreement in May 2006 when the last patient to participate in the Phase 1 clinical trial completed its one-year follow-up. On September 24, 2004, the parties amended the Clinical Study Agreement to provide for research covering the development of gene transfer approaches to neurodegenerative disorders, including Parkinson s disease, Huntington s disease, Alzheimer s disease and epilepsy (the Scientific Studies). On March 2, 2007, the parties entered into Amendment No. 2 to the Clinical Study Agreement, among other things, to extend the agreement until August 31, 2008 and to further expand the scope of work to cover research and activities relating to mechanisms by which certain gene therapy treatments may penetrate the blood-brain barrier (Blood-Brain Barrier Research). On July 23, 2009, the

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parties entered into Amendment No. 3 to the Clinical Study Agreement to eliminate all Blood-Brain Barrier Research from the scope of work and to extend the performance period of the sponsored research program until terminated by the Company upon 30 days prior written notice or by Cornell if circumstances beyond Cornell s reasonable control preclude continuation of the Scientific Studies.

This sponsored research under the Clinical Study Agreement is funded by the Company and is being conducted in Cornell s Laboratory of Molecular Neurosurgery under the direction of Dr. Michael Kaplitt. The Company is required to pay Cornell $135,000 per year for the duration of the Scientific Studies. (See Note 10 to Financial Statements). Pursuant to the terms of the Cornell License Agreement, the Company agreed to continue to provide research support to Cornell under the Clinical Study Agreement until the expiration of the Cornell License Agreement.

Effective May 2006, the Company entered into a Sponsored Research Agreement (Research Agreement) with OSURF which provides for research covering the development of gene transfer approaches to neurodegenerative disorders, including Parkinson s disease, epilepsy, Huntington s disease and Alzheimer s disease, as well as gene transfer approaches to pain, stroke, neurovascular diseases and other research. The Company has first right to negotiate with OSURF, on reasonably commercial terms, for an exclusive, worldwide right and license for commercial products embodying inventions conceived under the Research Agreement if there is involvement from employees of OSURF. The term of the Research Agreement, as amended in September 2009, runs through November 10, 2010.

The Company entered into a Sublicense Agreement, effective as of August 4, 2006, with Diamyd (the Sublicense Agreement). Pursuant to the Sublicense Agreement, Diamyd granted to the Company a non-exclusive worldwide license to certain patent rights and technical information for the use of a gene version of GAD 65 in connection with the Company s gene transfer treatment for Parkinson s disease. The Company paid Diamyd an initial fee of $500,000 and will pay annual license maintenance fees and certain milestone and royalty payments to Diamyd, as provided for in the Sublicense Agreement. The Sublicense Agreement will terminate upon the last to occur of: (a) expiration of the last to expire patent covered by the Sublicense Agreement; (b) such time as any claims under a properly filed patent application have been fully prosecuted; or (c) 17 years. However, either party may terminate earlier pursuant to the terms of the Sublicense Agreement.

On August 28, 2008, the Company entered into the Aegera License Agreement whereby Aegera granted the Company an exclusive license for the worldwide rights, excluding China, for the use of the XIAP gene (x-linked inhibitor of apoptosis protein) for therapeutic or prophylactic purposes in the treatment of Huntington s disease. Under the terms of the Aegera License Agreement, the Company paid Aegera an initial fee and, during the term of the Aegera License Agreement, the Company will pay to Aegera an annual license maintenance fee and certain milestone and royalty payments, as provided for in the Aegera License Agreement. The Company may terminate the Aegera License Agreement upon 90 days written notice to Aegera.

On January 13, 2009, the Company entered into the Cornell License Agreement whereby Cornell granted the Company an exclusive license for the worldwide use of certain patents for the development of products and methods for the treatment of psychiatric conditions. Under the terms of the Cornell License Agreement, the Company paid Cornell an initial fee and, during the term of the Cornell License Agreement, will pay to Cornell an annual license maintenance fee and certain milestone and royalty payments as provided for in the Cornell License Agreement. The Cornell License Agreement will terminate on the expiration date of the longest-lived patent rights covered thereunder unless earlier terminated by Cornell or the Company pursuant to the terms thereof. In addition, the Company agreed to continue to provide research support to Cornell under the Clinical Study Agreement during the term of the Cornell License Agreement.

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In addition to patents, the Company relies on trade secrets, technical know-how and continuing technological innovation to develop and maintain its competitive position. The Company requires all of its employees to execute confidentiality and assignment of invention agreements. These agreements typically provide that (i) all materials and confidential information developed or made known to the individual during the course of the individual s relationship with the Company are to be kept confidential and not disclosed to third parties except in specific circumstances and (ii) all inventions arising out of the relationship with the Company shall be the Company s exclusive property. While the Company takes these and other measures to protect its trade secrets, such measures do not ensure against the unauthorized use and/or disclosure of its confidential information.

In February 2010, the Company received a Notice of Allowance from the USPTO for intellectual property covering the use of NPY for the treatment of TLE. The Company believes that this Notice of Allowance will protect the Company s intellectual property rights with respect to the use of NPY for the treatment of TLE.

In January 2010, the USPTO expanded the intellectual property protections enabled by a previously issued patent that is central to the Company s Parkinson s disease program. The new allowances to the U.S. Patent entitled Glutamic acid decarboxylase (GAD) based delivery systems, broaden the patent s coverage beyond Parkinson s disease to include the use of a gene called GAD65 in the treatment of other neurological and related disorders.

The Company s intellectual property rights may be called into question, subject to litigation or forfeited in certain situations. (See Risk Factors The Company s Intellectual Property Rights may be Called into Question or Subject to Litigation and Risk Factors If the Company Fails to Meet Certain Milestones Related to its Intellectual Property Licenses with Third Parties, the Company Could Forfeit License Rights That Are Important to its Business).

Manufacturing

The Company, or third parties retained by it, will need to have available, or develop, capabilities for the manufacture of components and delivery systems utilized in the Company s products, including all necessary equipment and facilities. In order to receive approval by the FDA and commercialize its product candidates, the Company must develop and implement manufacturing processes and facilities that comply with governmental regulations, including the FDA s Good Manufacturing Practices (GMP). As discussed below, the Company manufactured its own AAV and other components for its Phase 1 clinical trial for Parkinson s disease and contracted and oversaw a third party manufacturer for the production of its Phase 2 clinical trial for Parkinson s disease and its previously planned Phase 1 clinical trial for epilepsy. All products have been reviewed by the Company and the third party manufacturer and subsequently were submitted to the FDA for review. The large scale manufacture and development of components and systems will require both time and significant funding. (See Risk Factors The Company Does Not Have any Experience in Manufacturing Product for Commercial Sale and Risk Factors The Company s Ability to Manufacture Product Depends upon FDA Approval and Access to Third-Party Manufacturing Facilities).

The Company s adeno-associated virus glutamic acid decarboxylase (the AAVGAD) for Parkinson s disease, as well as other product candidates for its other therapies, is a biological product requiring manufacture in specialized facilities. As the Company s development programs advance through the phases of clinical development, the regulatory requirements increase for manufacture of these products. The Company is planning to continue manufacturing product consistent with current GMP as defined by the FDA and commensurate with the clinical phase of development and commercial release. The Company does not currently own any such facilities, and it is evaluating whether it will seek to establish such capabilities on its own or instead will contract with third parties for such manufacturing.

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The Company contracted with Cincinnati Children s Hospital Medical Center (CCHMC) for the production of the AAV viral vectors to be used in the Company s Phase 2 clinical trial for Parkinson s disease and Phase 1 clinical trial for epilepsy. The agreement required CCHMC to produce such vectors in accordance with current GMP for the corresponding clinical phase of development. The products have been released by CCHMC and the Company, and the products have been filed with the FDA in connection with the Company s submitted clinical protocols. The AAV vector for the Phase 2 clinical trial for Parkinson s disease was produced and was supplied by CCHMC as approved by the FDA. The Company does not expect that CCHMC will manufacture the AAV viral vectors for a Phase 3 clinical trial for Parkinson s disease.

Currently, there is no commercial product available for infusion of gene therapeutics or other biological agents into the brain and all clinical trials to date, including the Company s Phase 1 clinical trial for Parkinson s disease, have utilized either experimental devices created specifically for the particular trial or have used technologies which were not designed for use in the brain. Under a manufacturing and development agreement with Medtronic (the Manufacturing and Development Agreement), the Company s scientists, along with Medtronic s engineers, developed a novel catheter infusion device for infusing gene therapies into the brain. The Company used this device in its Phase 2 clinical trial for Parkinson s disease and plans to use it in follow-on clinical studies. In order for the Company to market its products, the FDA s approval is required for use of such catheter infusion device. As of December 31, 2009, the Company had paid $850,000 to Medtronic under the Manufacturing and Development Agreement and purchased the catheter infusion devices used in its Phase 2 clinical trial for Parkinson s disease pursuant to an addendum to the Manufacturing and Development Agreement. While Medtronic is not obligated to manufacture and supply such device for a Phase 3 clinical trial for Parkinson s disease or for commercialization of the Parkinson s product, Medtronic has indicated its intent to manufacture and supply such device for a Phase 3 clinical trial for Parkinson s disease, subject to the execution and delivery of a definitive agreement satisfactory to Medtronic. If Medtronic does not elect to manufacture and supply the device for such Phase 3 clinical trial, the Company will have to utilize alternative manufacturers and suppliers for such device. (See Risk Factors The Company s Ability to Manufacture Products Depends upon FDA Approval and Access to Third-Party Manufacturing Facilities).

The Manufacturing and Development Agreement provides Medtronic with rights of first offer and first refusal involving the distribution or commercialization of any of the Company s gene therapies for Parkinson s disease or TLE. These rights granted to Medtronic will have an impact on the Company s negotiations with respect to strategic collaborations for the further development and funding of the Company s Parkinson s product, including the conduct of a Phase 3 clinical trial and the future manufacture and marketing of a commercial product. (See Risk Factors The Company Does Not Have Sufficient Funds to Continue its Operations in the Long Run or to Commercialize its Product Candidates).

The Company continues to seek manufacturing capabilities for its AAV vectors and catheter infusion devices in connection with a potential pivotal trial for the treatment of Parkinson s disease and for use in its other gene therapy products. At the present time, the Company is evaluating whether it will seek to establish such capabilities on its own or instead will contract with third parties for such manufacturing. (See Risk Factors The Company Does Not Have any Experience in Manufacturing Products for Commercial Sale).

Competition

The Company is aware of other companies currently conducting clinical trials of gene transfer products in humans to treat Parkinson s disease, and recognizes that it faces intense competition from pharmaceutical companies, biotechnology companies, universities, governmental entities and other healthcare providers developing alternative treatments for Parkinson s

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disease, Huntington s disease and epilepsy. At this time, the Company is not aware of any new developments with respect to these trials or with respect to the trials described below. Alternative treatments include surgery, deep brain stimulator implants and the use of pharmaceuticals. The Company may also face competition from companies and institutions involved in developing gene transfer and cell therapy treatments for other diseases, whose technologies may be adapted for the treatment of central nervous system disorders. Some companies, such as Genzyme Corp. (Genzyme), Cell Genesys, Inc., and Targeted Genetics Corporation, have significant experience in developing and using AAV vectors to deliver gene transfer products.

Oxford Biomedica (Oxford), a gene therapy company using the lentivirus to deliver therapeutic genes, announced results from the first six patients in its Phase 1/2 trial of its proprietary gene therapy, ProSavin, for the treatment of Parkinson s disease. Oxford indicated that all six patients showed improved motor function at six months and that the safety profile of ProSavin had been maintained at six months with no evidence of adverse events or immunologic reactions to the treatment. Oxford is in the first stage of its clinical trial in France, an open-label dose escalation study designed to evaluate at least two dose levels of ProSavin in cohorts of three patients each. If such trial is successful, Oxford has stated it will commence a Phase 3 clinical trial.

Ceregene, Inc. (Ceregene), an affiliate company of Cell Genesys, Inc., announced, in November 2008, that its Phase 2 clinical trial for Parkinson s disease failed to demonstrate an appreciable difference between patients treated with AAV expressing the neurturin gene (a nerve growth factor) versus those in the control group. In May 2009, Ceregene reported additional findings from the trial and in September 2009 commenced a new Phase 1/2 clinical trial for Parkinson s disease administering the same gene into an additional target in the brain. In June 2007, Ceregene announced that it had entered into a partnership with Genzyme for the development and commercialization of its Parkinson s indication. Under this partnership, Genzyme gained all marketing rights outside of the U.S. and Canada to Ceregene s Parkinson s indication. The Company is unaware of Ceregene s future plans with regard to this indication.

Genzyme purchased the AAV gene transfer assets of Avigen, Inc. (Avigen) in December 2005, including Avigen s AV201, an AAV vector containing the gene for AADC (aromatic amino acid decarboxylase) which is delivered directly to the part of the brain that requires dopamine to control movement. In August 2004, Avigen announced that the FDA had authorized it to initiate a Phase 1/2 clinical trial of gene transfer for the treatment of Parkinson s disease using AV201. Avigen commenced such trial, with its first patient undergoing gene transfer surgery in December 2004, and Genzyme has since taken over the control of the study. In May 2008, Genzyme published interim results of the trial in *Neurology.* According to the conclusions of the publication, Genzyme s gene therapy approach has been well tolerated thus far and shows PET evidence that the AADC gene is evident in the brain. This study is separate and distinct from Ceregene s study discussed above.

Many of the Company s competitors have significantly greater research and development, marketing, manufacturing, financial and/or managerial resources than the Company enjoys. Moreover, developments by others may render the Company s products or technologies noncompetitive or obsolete.

Government Regulation

All of the Company s potential products must receive regulatory approval before they can be marketed. Human therapeutic products are subject to rigorous pre-clinical and clinical testing and other pre-market approval procedures administered by the FDA and similar authorities in foreign countries. In accordance with the Federal Food, Drug and Cosmetics Act, the FDA exercises regulatory authority over, among other things, the development, testing, formulation, manufacture, labeling, storage, record keeping, reporting, quality control,

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advertising, promotion, export and sale of the Company s potential products. Similar requirements are imposed by foreign regulatory agencies. In some cases, state regulations may also apply.

Gene transfer is a relatively new technology that has not been extensively tested or shown to be effective in humans. The FDA reviews all product candidates for safety at each stage of clinical testing. Safety standards must be met before the FDA permits clinical testing to proceed to the next stage. Also, efficacy must be demonstrated before the FDA grants product approval. The approval process and ongoing compliance with applicable regulations after approval is time intensive and involves substantial risk and expenditure of financial and other resources. (See Risk Factors The Company is Subject to Stringent Regulation; FDA Approvals).

Pre-clinical trials generally require studies in the laboratory or in animals to assess the potential product s safety and effectiveness. Pre-clinical trials include laboratory evaluation of toxicity; pharmacokinetics, or how the body processes and reacts to the drug; and pharmacodynamics, or whether the drug is actually having the expected effect on the body. Pre-clinical trials must be conducted in accordance with the FDA s Good Laboratory Practice regulations and, before any proposed clinical testing in humans can begin, the FDA must review the results of these pre-clinical trials as part of an IND.

If pre-clinical trials of a product candidate, including animal studies, demonstrate safety, and laboratory test results are acceptable, then the potential product may undergo clinical trials to test the therapeutic agent in humans. Human clinical trials are subject to numerous governmental regulations that provide detailed procedural and administrative requirements designed to protect the trial participants. Each institution that conducts human clinical trials has an Institutional Review Board or Ethics Committee charged with evaluating each trial and any trial amendments to ensure that the trial is ethical, subjects are protected and the trial meets the institutional requirements. These evaluations include reviews of how the institution will communicate the risks inherent in the clinical trial to potential participants, so that the subjects may give their informed consent. Clinical trials must be conducted in accordance with the FDA s Good Clinical Practices regulations and the protocols established by the Company to govern the trial objectives, the parameters to be used for monitoring safety, the criteria for evaluating the efficacy of the potential product and the rights of each participant with respect to safety. FDA regulations require the Company to submit these protocols as part of the application. FDA review or approval of the protocols, however, does not necessarily mean that the trial will successfully demonstrate safety and/or efficacy of the potential product. (See Risk Factors The Company is Subject to Stringent Regulation; FDA Approvals).

Institutions that receive National Institutes of Health (NIH) funding for gene transfer clinical trials must also comply with the NIH Recombinant DNA Guidelines, and the clinical trials are subject to a review by the RAC. The outcome of this review can be either an approval to initiate the trial without a public review or a requirement that the proposed trial be reviewed at a quarterly committee meeting. A clinical trial will be publicly reviewed when at least three of the committee members or the Director of the Office of Biotechnology Activities recommends a public review. The review by the RAC may also delay or impede the Company s clinical trials. (See Risk Factors The Company s Research Activities are Subject to Review by the RAC). On December 3, 2007, the Company reviewed its Parkinson s disease Phase 2 protocol with the RAC in a public forum. In December 2008, the Company initiated its Phase 2 clinical trial for the treatment of advanced Parkinson s disease.

Clinical trials are typically conducted in three phases and may involve multiple studies in each phase. In Phase 1, clinical trials generally involve a small number of subjects, who may or may not be afflicted with the target disease, to determine the preliminary safety profile of the treatment. In Phase 2, clinical trials are conducted with larger groups of subjects afflicted with the target disease in order to establish preliminary effectiveness and optimal dosages and to

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obtain additional evidence of safety of the treatment. In Phase 3, large-scale, multi-center, comparative clinical trials are conducted with subjects afflicted with the target disease in order to provide enough data for the statistical proof of efficacy and safety of the treatment required by the FDA and other regulatory agencies for market approval. The Company reports its progress in each phase of clinical testing to the FDA, which may require modification, suspension or termination of the clinical trial if it deems that patient risk is too high. The length of the clinical trial period, the number of trials conducted and the number of enrolled subjects per trial vary, depending on the Company s results and the FDA s requirements for the particular clinical trial. Although the Company and other companies in its industry have made progress in the field of gene transfer, it cannot predict what the FDA will require in any of these areas to establish to its satisfaction the safety and effectiveness of the product candidate. (See Risk Factors The Company is Subject to Stringent Regulation; FDA Approvals).

If the Company successfully completes clinical trials for a product candidate, it must obtain FDA approval or similar approval required by foreign regulatory agencies, as well as the approval of several other governmental and nongovernmental agencies, before it can market the product in the United States or in foreign countries. Current FDA regulations relating to biologic therapeutics require the Company to submit an acceptable BLA to the FDA to receive the FDA s approval before the Company may commence commercial marketing. The BLA includes a description of the Company s product development activities, the results of pre-clinical trials and clinical trials and detailed manufacturing information. Unless the FDA gives expedited review status (which the Company has been granted by the FDA with regards to Parkinson s disease), this stage of the review process generally takes at least one year. Should the FDA have concerns with regard to the potential product s safety and efficacy, it may request additional data, which could delay product review or approval. The FDA may ultimately decide that the BLA does not satisfy its criteria for approval and might require the Company to do any or all of the following:

modify the scope of its desired product claims;

add warnings or other safety-related information; and/or

perform additional testing.

Because the FDA has not yet approved any gene transfer products, it is not clear what, if any, unforeseen issues may arise during the approval process. The Company expects the FDA s regulatory approach to product approval, and its requirements with respect to product testing, to become more predictable as its scientific knowledge and experience in the field of gene transfer increases. Adverse events in the field of gene transfer or other biotechnology-related fields, however, could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of gene transfer products. (See Risk Factors Events in the General Field of Gene Transfer may Affect the Company s Ability to Develop its Products).

Once approved by the FDA, marketed products are subject to continual review by the FDA, which could result in restrictions on marketing a product or in its withdrawal from the market, as well as potential criminal penalties or sanctions. (See Risk Factors Once Approved by the FDA, the Company s Products Would Remain Subject to Continual FDA Review and Risk Factors The Company May Face Liability Due to its Use of Hazardous Materials).

Employees

As of December 31, 2009, the Company had twelve full-time employees, of which eight are directly involved in its research and development activities, including product development, manufacturing, regulatory affairs and clinical affairs. Four of the Company s employees have Ph.D. degrees, with expertise in virology, protein chemistry and molecular biology. The

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Company s employees are not subject to any collective bargaining agreements, and the Company regards its relations with its employees to be good.

Scientific Advisory Board

The Company has assembled the SAB to advise the Company on the selection, implementation and prioritization of its research programs. The SAB, which currently consists of the following seven scientists, did not meet in 2009 and met one time in 2008.

Paul Greengard, Ph.D. Dr. Greengard has been a member and the chairman of the SAB since July 2003. Dr. Greengard receives an annual fee of $25,000 for his participation in the SAB. Dr. Greengard is the Vincent Astor Professor and Chairman of the Laboratory of Molecular and Cellular Neuroscience at Rockefeller. Dr. Greengard was awarded the 2000 Nobel Prize in Physiology or Medicine. Dr. Greengard received a Ph.D. in biophysics from Johns Hopkins University. Prior to joining Rockefeller in 1983, Dr. Greengard was the director of biochemical research at the Geigy Research Laboratories and simultaneously Professor of Pharmacology and Professor of Psychiatry at the Yale University School of Medicine. Dr. Greengard is an elected member of the U.S. National Academy of Sciences and its Institute of Medicine and of the American Academy of Arts and Sciences. He is also a foreign member of the Royal Swedish Academy of Sciences and a member of the Norwegian Academy of Science and Letters.

Andrew J. Brooks, Ph.D. Dr. Brooks has been a member of the SAB since January 2002. Dr. Brooks receives an annual fee of $12,000 for his participation in the SAB. Dr. Brooks is currently the Director of the Bionomics Research and Technology Center (BRTC) at the Environmental and Occupational Health Science Institute of the University of Medicine and Dentistry of New Jersey (UMDNJ). He is also the Associate Director of Technology Development at Rutgers University s Cell and DNA Repository and an Associate Professor of Environmental Medicine and Genetics at UMDNJ. Dr. Brooks is a molecular neuroscientist whose research focuses on deciphering the molecular mechanisms that underlie memory and learning. These studies investigate gene-environment interactions in the context of aging, neurodegenerative disease and neurotoxicant exposure. Previously, Dr. Brooks was the Director of the Center for Functional Genomics in the Aab Institute for Biomedical Science at the University of Rochester from which he also received his Ph.D.

Matthew J. During, M.D., D.Sc. Dr. During, one of the Company s scientific co-founders, has been a member of the SAB since October 1999. Dr. During receives an annual fee of $175,000 as a consultant to the Company (see Notes 3 and 10 to Financial Statements), but does not receive an additional fee for his participation in the SAB. Dr. During is currently Professor of Molecular Virology, Immunology and Medical Genetics, Neuroscience and Neurosurgery at the Ohio State Medical School where he directs neuroscience and neurosurgical gene transfer programs. He is also a Professor of Molecular Medicine and Pathology at AUL. From June 2004 to February 2006 he was the Research Lab Director of the Department of Neurological Surgery at Cornell University. He served as Director of the CNS Gene Therapy Center and Professor of Neurosurgery at Jefferson Medical College from 1998 through 2002. From 1989 through 1998, Dr. During was an Assistant then Associate Professor of Neurosurgery at Yale University where he directed a translational neuroscience program and headed Yale s first gene transfer protocol. Dr. During received his M.D. and D.Sc. from the AUL School of Medicine and did further postgraduate training at M.I.T. from 1985 to 1987, Massachusetts General Hospital and Harvard Medical School from 1986 to 1989 and Yale University from 1988 to 1989.

Michael G. Kaplitt, M.D., Ph.D. Dr. Kaplitt, one of the Company s scientific co-founders, has been a member of the SAB since October 1999. Dr. Kaplitt receives an annual fee of $175,000 as a consultant to the Company (see Notes 3 and 10 to Financial Statements), but

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does not receive an additional fee for his participation in the SAB. Dr. Kaplitt is Associate Professor and Vice-Chairman for Research, Department of Neurological Surgery at Weill Medical College of Cornell University. He is also a Clinical Associate Attending, Department of Neurosurgery at Memorial-Sloan Kettering Cancer Center, and Adjunct Faculty at Rockefeller University. Dr. Kaplitt graduated magna cum laude with a Bachelor s degree in Molecular Biology from Princeton University. He received a Ph.D. in Molecular Neurobiology from Rockefeller in 1993 and his M.D. from Cornell University School of Medicine in 1995. He completed his neurosurgical residency training at the New York Hospital Cornell Medical Center in 2000 and a Fellowship in Stereotactic and Functional Neurosurgery at the University of Toronto, Toronto Ontario, Canada in 2001. Dr. Kaplitt is the son of Dr. Martin Kaplitt.

Daniel H. Lowenstein, M.D. Dr. Lowenstein has been a member of the SAB since January 2005. Dr. Lowenstein receives an annual fee of $12,000 for his participation in the SAB. Dr. Lowenstein is Professor and Vice Chairman in the Department of Neurology at the University of California, San Francisco (UCSF), Director of the UCSF Epilepsy Center and Director of Physician-Scientist Training Programs for the UCSF School of Medicine. He received his M.D. degree from Harvard Medical School in 1983. Dr. Lowenstein established the UCSF Epilepsy Research Laboratory, and was the Robert B. and Ellinor Aird Professor of Neurology from 1998 to 2000. He then joined Harvard Medical School as the Dean for Medical Education and Carl W. Walter Professor of Neurology for two and a half years, and in 2003, moved back to UCSF in his current position. During 2004, he served as the President of the American Epilepsy Society. His research interests have included the molecular and cellular changes in neural networks following seizure activity and injury, and the clinical problem of status epilepticus. More recently, he has turned his attention to the genetics of epilepsy, and he is leading the Epilepsy Phenome/Genome Project, a large, national study aimed at identifying the genes responsible for the more common forms of epilepsy. Dr. Lowenstein has received several national awards for excellence in teaching and numerous academic honors and awards, including the American Epilepsy Society s 2001 Basic Research Award. Among his numerous publications, he has authored approximately 80 papers in peer-reviewed journals, 80 research abstracts and 43 review articles, editorials and book chapters.

Andres M. Lozano, M.D., Ph.D. Dr. Lozano has been a member of the SAB since April 2001. Dr. Lozano receives an annual fee of $25,000 for his participation in the SAB. He is currently Professor of Neurosurgery and holds the Ronald Tasker Chair in Stereotactic and Functional Neurosurgery at The University of Toronto. Dr. Lozano received his M.D. from the University of Ottawa and a Ph.D. from McGill University. He completed a residency in Neurosurgery at the Montreal Neurological Institute prior to joining the staff at the University of Toronto. Dr. Lozano is the Past President of each of the American Society for Stereotactic and Functional Neurosurgery and the World Society for Stereotactic and Functional Neurosurgery.

Eric J. Nestler, M.D., Ph.D. Dr. Nestler has been a member of the SAB since May 2004. Dr. Nestler receives an annual fee of $12,000 for his participation in the SAB. Dr. Nestler s research focuses on better understanding the molecular mechanisms of addiction and depression in animal models, and using this information to develop improved treatments for these disorders. He has authored or edited seven books and published more than 375 articles and reviews relating to the field of neuropsychopharmacology. From 1992-2000, he was Director of the Abraham Ribicoff Research Facilities and of the Division of Molecular Psychiatry at Yale University. From 2000-2008, he served as Professor and Chairman of the Department of Psychiatry at The University of Texas Southwestern Medical Center at Dallas. In 2008, he moved to the Mount Sinai School of Medicine in New York, where he is now Chairman of the Department of Neuroscience and Director of the Mount Sinai Brain Institute. Dr. Nestler s awards and honors include the Pfizer Scholars Award (1987), Sloan Research Fellowship (1987), McKnight Scholar Award (1989), Efron Award of the American College of Neuropsychopharmacology (1994), Pasarow Foundation Award for Neuropsychiatric Research (1998), Fondation Ipsen

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Prize in Neural Plasticity (2008), and the Patricia Goldman-Rakic Award from NARSAD (2008). He is a member of the Institute of Medicine (elected 1998) and a fellow of the American Academy of Arts and Sciences (elected 2005).

Item 1A. Risk Factors

RISK FACTORS

The following sets forth some of the business risks and challenges facing the Company as it seeks to develop its business:

The Company is Still in the Development Stage and Has Not Generated any Revenues.

From inception through December 31, 2009, the Company has incurred net losses of approximately $47.8 million and negative cash flows from operating activities of approximately $36.6 million. Because it takes years to develop, test and obtain regulatory approval for a gene-based therapy product before it can be sold, the Company likely will continue to incur significant losses and cash flow deficiencies for the foreseeable future. Accordingly, it may never be profitable and, if it does become profitable, it may be unable to sustain profitability.

The Company Does Not Have Sufficient Funds to Continue its Operations in the Long Run or to Commercialize its Product Candidates.

The Company s existing resources are not sufficient to enable it to obtain the regulatory approvals necessary to commercialize its current or future product candidates. The Company will, from time to time, need to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. Availability of financing depends upon a number of factors beyond the Company s control, including market conditions and interest rates. The Company does not know whether additional financing will be available when needed, or, if available, whether any such financing will be on terms acceptable or favorable to the Company.

The Company may need to seek funds through arrangements with collaborative partners or others that require the Company to relinquish rights to technologies or product candidates that the Company would otherwise seek to develop or commercialize itself. These arrangements could harm the Company s business, results of operations, financial condition, cash flow or future prospects. The Company may not be successful in entering into collaborative partnerships on favorable terms, if at all. The failure to enter into new corporate relationships may harm the Company s business. (See Business of the Company Manufacturing).

The Company is currently seeking to raise funds sufficient to finance its ongoing operations through 2010. If the Company is not able to raise funds in a timely manner, the Company may not be able to continue to operate its business or continue as a going concern by the end of its current fiscal year.

The Company s independent registered public accounting firm has expressed substantial doubt about the Company s ability to continue as a going concern in the audit report on the Company s audited financial statements for the fiscal year ended December 31, 2009 included herein. (See Management s Discussion and Analysis of Financial Condition and Results of Operations).

If the Clinical Trials for Parkinson s Disease are Unsuccessful, it Would Likely Have a Material Adverse Effect on the Company s Operations.

In November 2009, the Company completed all of the planned surgeries in its Phase 2 clinical trial for Parkinson s disease. At this time, the Company cannot determine whether such

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Phase 2 clinical trial will yield successful safety results or efficacy results that would warrant the conduct of a pivotal trial.

If the results of the Phase 2 clinical trial for Parkinson s disease do not warrant the conduct of a pivotal trial, future operations and the potential for profitability will be significantly adversely affected and the business may not succeed. (See Business of the Company Parkinson s Disease).

The Company Has Not Demonstrated that it Can Establish Many Necessary Business Functions.

The Company has not demonstrated that it can:

obtain the regulatory approvals necessary to commercialize product candidates that it may develop in the future;

manufacture, or arrange for third parties to manufacture, future product candidates in a manner that will enable the company to be profitable;

attract, retain and manage a large, diverse staff of physicians and researchers;

establish sales, marketing, administrative and financial functions;

develop relationships with third-party collaborators to assist in the marketing and/or distribution of the technologies that the Company may develop;

make, use and sell future product candidates without infringing upon third party intellectual property rights;

secure meaningful intellectual property protection covering its future product candidates; or

respond effectively to competitive pressures.

The Company will need to establish or otherwise arrange for performance of such functions in order to operate in the long term.

The Company Cannot Ensure that it will be Able to Pursue Further Trials for its Product Candidates or the Timing of any Future Trials.

The Company s ability to conduct further trials for its product candidates depends upon a number of factors beyond the Company s control, including, but not limited to, regulatory reviews of trials, procurement of licenses from third parties and access to third party manufacturing facilities. Accordingly, the Company is unable to assure that it will be able to pursue further trials for any of its product candidates or the timing of any such trials. As previously stated, the Company has experienced delays in the commencement of its Phase 1 clinical trials for epilepsy. (See Business of the Company Epilepsy). As described directly below, the Company s ability to pursue further trials also depends upon the Company s ability to retain its current key physicians and researchers. As described above under The Company Does Not Have Sufficient Funds to Continue its Operations in the Long Run or To Commercialize its Product Candidates , the Company will be required to raise additional capital in order to fund further trials.

The Company s Future Success Depends Upon Key Physicians and Researchers.

The Company s future success depends, to a significant degree, on the skills, experience and efforts of its current key physicians and researchers, including Dr. Matthew During and Dr. Michael Kaplitt. If either of Dr. During or Dr. Kaplitt were unable or unwilling to continue his present relationship with the Company, it is likely that the Company s business, financial

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condition, operating results and future prospects would be materially adversely affected. Dr. During and Dr. Kaplitt are not employees of the Company, and they devote their attention to other projects and ventures in addition to the services that they render to the Company.

The Company is Subject to Stringent Regulation; FDA Approvals.

The industry in which the Company competes is subject to stringent regulation by certain regulatory authorities. The Company may not obtain regulatory approval for any future product candidates that it develops. To market a pharmaceutical product in the United States requires the completion of rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA. Satisfaction of regulatory requirements typically takes several years, depends upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. The Company may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or prevent the marketing of its product candidates. The Company may encounter delays or rejections in the regulatory approval process resulting from additional governmental regulation or changes in policy during the period of product development, clinical trials and FDA regulatory review. In addition, the regulatory requirements governing gene transfer product candidates and commercialized products are subject to change.

Additionally, the Company must have access to an FDA approved catheter infusion device that has been tested and found compatible to infuse the Company s gene transfer product into the brain. Currently, the Company is using a catheter infusion device that was developed by Medtronic in collaboration with the Company. To date, such device has not received regulatory approval.

To the Company s knowledge, neither the FDA nor any other regulatory agency has approved a gene transfer product for sale in the United States.

The Company s Research Activities are Subject to Review by the RAC.

As noted above, institutions that receive NIH funding for gene transfer clinical trials are subject to a review by the RAC. The outcome of this review can be either an approval to initiate the trial without a public review or a requirement that the proposed trial be reviewed at a quarterly committee meeting. Should the RAC require a public hearing, the start of the trial must be delayed until after the hearing date. Although the NIH guidelines do not have regulatory status, the RAC review process can impede the initiation of the trial, even if the FDA has reviewed the trial and approved its initiation. Before any gene transfer clinical trial can be initiated, the Institutional Biosafety Committee of each site must perform a review of the proposed clinical trial and ensure there are no safety issues associated with the trial.

The Company May Face Substantial Penalties if it Fails to Comply with Regulatory Requirements.

Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against the Company s future product candidates or the Company itself. Outside the United States, the ability to market a product is also contingent upon receiving clearances from appropriate foreign regulatory authorities. The non-U.S. regulatory approval process includes risks similar to those associated with the FDA s clearance.

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The Company Will Need to Conduct Significant Additional Research and Testing Before Conducting Clinical Trials Involving Future Product Candidates.

Before the Company can conduct clinical trials involving future product candidates, the Company will need to conduct substantial research and animal testing, referred to as pre-clinical testing. It may take many years to complete pre-clinical testing and clinical trials and failure could occur at any stage of testing. Acceptable results in early testing or trials may not be repeated in later tests. Whether any products in pre-clinical testing or early stage clinical trials will receive approval is unknown. Before applications can be filed with the FDA for product approval, the Company must demonstrate that a particular future product candidate is safe and effective. The Company s failure to adequately demonstrate the safety and efficacy of future product candidates would prevent the FDA from approving such products. The Company s product development costs will increase if it experiences delays in testing or regulatory approvals or if it becomes necessary to perform more or larger clinical trials than planned. If the delays are significant, they could negatively affect the Company s financial results, ability to raise capital and the commercial prospects for future product candidates.

The Company s Future Success Depends Upon Acceptance of its Products by Health Care Administrators and Providers.

The Company s future success depends upon the acceptance of its products by health care administrators and providers, patients and third-party payors (including, without limitation, health insurance companies, Medicaid and Medicare). Market acceptance will depend on numerous factors, many of which are outside the Company s control, including:

the safety and efficacy of future product candidates, as demonstrated in clinical trials;

favorable regulatory approval and product labeling;

the frequency of product use;

the availability, safety, efficacy and ease of use of alternative therapies;

the price of future product candidates relative to alternative therapies; and

the availability of third-party reimbursement.

Events in the General Field of Gene Transfer May Affect the Company s Ability to Develop its Products.

Patient complications that may occur in gene-based clinical trials conducted by the Company and other companies and the resulting publicity surrounding them, as well as any other serious adverse events (SAE) in the field of gene transfer that may occur in the future, may result in greater governmental regulation of future product candidates and potential regulatory delays relating to the testing or approval of them. Even with the requisite approval, the commercial success of the Company s product candidates will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human disease. Public attitudes may be influenced by claims that gene transfer is unsafe, and gene transfer may not gain the acceptance of the public or the medical community. Negative public reaction to gene transfer could result in greater governmental regulation, stricter clinical trial oversight and commercial product labeling requirements of gene therapies and could negatively affect demand for any products the Company may develop.

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Side Effects, Patient Discomfort, Defects or Unfavorable Publicity May Affect the Company s Ability to Commercialize its Products.

The Company s results for its Phase 1 clinical trial for Parkinson s disease and its preliminary indications from its Phase 2 clinical trial for Parkinson s disease suggest that this treatment appears to be safe and well-tolerated in participants with advanced Parkinson s disease, with no evidence of adverse effects or immunologic reaction related to the study treatment. However, the Company cannot assure that it will not discover unanticipated side effects, patient discomfort or product defects in connection with its Phase 2 clinical trial or additional trials for Parkinson s disease or its trials for any other product candidates. Unanticipated side effects, patient discomfort, or product defects discovered in connection with the Company s Phase 2 clinical trial or future trials may significantly impact the Company s ability to commercialize its products or achieve market acceptance. Commercialization could also be materially affected by unfavorable publicity concerning any of the Company s future product candidates, or any other product incorporating technology similar to that used by future product candidates.

The Company Does Not Have any Experience in Manufacturing Products for Commercial Sale.

The Company does not have any experience in manufacturing products for commercial sale and, if the Company is not successful in engaging a third-party to manufacture its products, no assurance can be provided that it will be able to:

develop and implement large-scale manufacturing processes and purchase needed equipment and machinery on favorable terms;

hire and retain skilled personnel to oversee manufacturing operations;

avoid design and manufacturing defects; or

develop and maintain a manufacturing facility in compliance with governmental regulations, including the FDA s GMP.

The Company s Ability to Manufacture Products Depends upon FDA Approval and Access to Third-Party Manufacturing Facilities.

The Company, or any third-party manufacturer that it contracts with to manufacture any future product candidate, must receive the FDA s approval before producing clinical material or commercial products. The Company s future product candidates may compete with other products for access to third-party manufacturing facilities and may be subject to delays in manufacture if third party manufacturers give priority to products other than the Company s future product candidates. The Company may be unable to manufacture commercial-scale quantities of gene-based therapy products or any quantities at all. Failure to successfully manufacture products in commercial-scale quantities, and on a timely basis, would prevent the Company from achieving its business objectives.

If the Company Fails to Meet Certain Milestones Related to its Intellectual Property Licenses with Third Parties, the Company Could Forfeit License Rights That Are Important to its Business.

In addition to the Company s own patents, the Company relies on license agreements with third parties relating to its intellectual property. (See Business of the Company Patents and Other Proprietary Rights). These agreements require the Company to use commercially reasonable efforts to meet certain requirements, including meeting specified milestones, to keep the agreements in effect. If the Company is not able to meet its requirements and any agreement is terminated, the Company would forfeit the licenses granted under such agreement. In such

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event, the Company would lose its rights to use the intellectual property and technology covered by such agreement in its products. Any such loss may prevent the Company from further developing such products, which circumstance could have a material and adverse impact on the Company s operations and profitability.

The Company s Intellectual Property Rights May Be Called into Question or Subject to Litigation.

Because of the complex and difficult legal and factual questions that relate to patent positions in the Company s industry, no assurance can be provided that its future product candidates or technologies will not be found to infringe upon the intellectual property or proprietary rights of others. Third parties may claim that future product candidates or the Company s technologies infringe on their patents, copyrights, trademarks or other proprietary rights and demand that it cease development or marketing of those products or technologies or pay license fees. The Company may not be able to avoid costly patent infringement litigation, which will divert the attention of management and cash resources away from the development of new products and the operation of its business. No assurance can be provided that the Company would prevail in any such litigation. If the Company is found to have infringed on a third party s intellectual property rights, it may be liable for money damages, encounter significant delays in bringing products to market or be precluded from manufacturing particular future product candidates or using a particular technology.

The Company May be Subject to Product Liability Claims in Connection with its Clinical and Pre-Clinical Trials.

Pre-clinical and clinical trials of future product candidates, and any subsequent sales of products employing the Company s technology, may involve injuries to persons using those products as a result of mislabeling, misuse or product failure. Product liability insurance is expensive. Although the Company has purchased product liability insurance to cover claims made in connection with its Phase 1 and Phase 2 clinical trials for Parkinson s disease, its previously planned Phase 1 clinical trial for epilepsy and its potential clinical trial for Huntington s disease, there can be no assurance that this insurance will be available to the Company in the future on satisfactory terms, if at all. A successful product liability claim or series of claims brought against the Company in excess of any insurance coverage that it may obtain in the future would have a material adverse effect on its business, financial condition, results of operations and future prospects.

The Company May Face Liability Due to its Use of Hazardous Materials.

The Company s research and development processes may involve the use of hazardous materials, including chemicals and radioactive and biological materials. The risk of accidental contamination or discharge or any resultant injury from these materials cannot be completely eliminated. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials, including, but not limited to, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and the Resource Conservation and Recovery Act. The Company could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, such hazardous materials. In addition, claimants may sue the Company for injury or contamination that results from its use or the use by third parties of these materials, and the Company s liability may exceed its total assets. Compliance with environmental laws and regulations may be expensive and current or future environmental regulations may impair the Company s research, development or production efforts.

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Once Approved by the FDA, the Company s Products Would Remain Subject to Continual FDA Review.

Once approved by the FDA, marketed products are subject to continual FDA review. Later discovery of previously unknown problems or failure to comply with applicable regulatory requirements may result in restrictions on marketing a product or in its withdrawal from the market, as well as potential criminal penalties or sanctions. In addition, the FDA requires that manufacturers of a product comply with current GMP requirements, both as a condition to product approval and on a continuing basis. In complying with these requirements, the Company expects to expend significant amounts of time, money and effort in production, record keeping and quality control. All manufacturing facilities are subject to periodic inspections by the FDA. If major problems are identified during these inspections that could impact patient safety, the FDA could subject the Company to possible action, such as the suspension of product manufacturing, product seizure, withdrawal of approval or other regulatory sanctions. The FDA could also require the Company to recall a product.

Item 2. Properties

In August 2004, the Company subleased 1,185 square feet of space at One Bridge Plaza, Fort Lee, New Jersey 07024 (the Sublease) from Palisade Capital Securities, LLC (PCS), an affiliated company, for use as its corporate offices. The Sublease provided for a base annual rent of approximately $36,000 or $3,000 per month through the expiration of the Sublease on June 30, 2009. (See Notes 3 and 10 to Financial Statements).

Effective April 13, 2007, the Company entered into a lease (the BPRA Lease) with Bridge Plaza Realty Associates, LLC (BPRA) for an additional 703 square feet of office space at One Bridge Plaza, Fort Lee, New Jersey 07024. The BPRA Lease, which expires in April 2010, provides for a base annual rent of approximately $21,000 or $2,000 per month through its term. Pursuant to an amendment to the BPRA Lease, dated February 1, 2008, the office space leased under the Sublease was incorporated into the BPRA Lease at a base annual rent of approximately $36,000 or $3,000 per month effective July 1, 2009 through the term of the BPRA Lease. (See Note 10 to Financial Statements). The Company is currently negotiating an extension of the BPRA Lease.

The Company entered into a Facility Use Agreement (the Facility Use Agreement) in April 2006 with The Ohio State University (OSU), which allows the Company s scientists to access and use OSU s laboratory facilities and certain equipment to perform the Company s research in a laboratory directed by Dr. Matthew During. The Company is currently negotiating an extension of the term of the Facility Use Agreement beyond April 17, 2010 until November 10, 2010, which is the date of expiration of the OSU Research Agreement. As of December 31, 2009, the Company has paid OSU an amount of $93,000, representing rent for the initial term of the Facility Use Agreement. (See Note 10 to Financial Statements).

One of the Company s scientists conducts research at Cornell University in New York City in a laboratory directed by Dr. Michael Kaplitt, as provided for by the Company s research agreement with Cornell.

Management believes that the properties the Company leases are adequately covered by insurance.

Item 3. Legal Proceedings

None.

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Item 4. Reserved

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company is prohibited from declaring, paying or setting aside any distribution or dividend for the shares of Common Stock, unless all accrued and unpaid dividends have been paid in full on all outstanding shares of Series C Convertible Preferred Stock, par value $0.10 per share (the Series C Stock), and Series D Convertible Preferred Stock, par value $0.10 per share (the Series D Stock).

The Company had 316 stockholders of record as of March 11, 2010. The Company did not pay cash dividends during the two-year period ended December 31, 2009 and does not currently expect to pay any cash dividends to stockholders in the foreseeable future.

The Common Stock is traded on the OTC Bulletin Board under the symbol NRGX .

The following table shows the high and low bid quotations as furnished by Bloomberg. The quotations shown reflect inter-dealer prices, without retail mark-up, markdown or commission and may not necessarily represent actual transactions.

High and Low Bid Prices of Common Stock

	Fiscal Year 2009		Fiscal Year 2008	
	High	Low	High	Low
First quarter	$ 0.72	$ 0.20	$ 1.18	$ 0.72
Second quarter	$ 0.70	$ 0.20	$ 0.98	$ 0.53
Third quarter	$ 0.90	$ 0.42	$ 0.79	$ 0.43
Fourth quarter	$ 0.73	$ 0.40	$ 0.55	$ 0.16

Company Equity Compensation Plans

The following table sets forth information as of December 31, 2009, with respect to compensation plans (including individual compensation arrangements) under which equity securities of the Company are authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
	4,173,833	$ 1.19	898,352

2000 Stock Option Plan approved by stockholders				
Total	4,173,833	$	1.19	898,352

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the audited financial statements and accompanying notes of the Company for the fiscal year ended December 31, 2009. The Company s fiscal year ends on the last day of December in each year. References to

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2009 and 2008 shall mean the Company s fiscal year ended on December 31st of such year. All dollar amounts in this Item 7 are in thousands.

Business Overview

The Company is a development stage company that is engaged in the research and development of proprietary treatments for disorders of the brain and central nervous system using gene transfer and other innovative therapies. These treatments are designed as alternatives to conventional surgical and pharmacological treatments.

To date, the Company has not generated any operating revenues and has incurred annual net losses. From inception through December 31, 2009, the Company had an accumulated deficit of $51,528, and it expects to incur additional losses for the foreseeable future. The Company recognized net losses of $13,461 for the fiscal year ended December 31, 2009, and $6,320 for the fiscal year ended December 31, 2008.

Since its inception, the Company has financed its operations primarily through sales of its equity and debt securities. From inception through December 31, 2009, the Company received proceeds primarily from private sales of equity and debt securities and from the Merger of approximately $44,531 in the aggregate. While the Company will continue to seek additional funds through the sale of its securities to fund its operations, the Company will also seek to obtain strategic collaborations to finance the further development of its Parkinson s product, including the ultimate marketing and sale of such product. (See Liquidity and Capital Resources).

The Company has devoted a significant portion of its capital resources to the research and development of its products. The Company s primary efforts are directed to the development of a therapeutic product to meet the needs of patients suffering from Parkinson s disease.

In addition to its product for Parkinson s disease, the Company has undertaken efforts to develop a product for the treatment of TLE but does not anticipate using its current funds for the further development of its TLE product at this time. The Company also has undertaken efforts to develop a product for Huntington s disease and is engaged in pre-clinical activities relating to such product. See Plan of Operation Epilepsy and Plan of Operation Huntington s Disease below.

Plan of Operation

Parkinson s Disease

In October 2006, the Company announced that it had completed its Phase 1 clinical trial for Parkinson s disease. The results of this trial indicated that the treatment, which was confined to only one side of the brain, appeared to be safe and well-tolerated in trial participants with advanced Parkinson s disease, with no evidence of adverse effects or immunologic reaction related to the study treatment. The trial also yielded statistically significant clinical efficacy and neuro-imaging results. The results were published in two leading peer-reviewed medical and scientific journals: the June 23, 2007 issue of the journal *The Lancet* and the online edition of the *Proceedings of the National Academy of Sciences* in November 2007.

In November 2009, the Company completed all 44 of the planned surgeries associated with its Phase 2 clinical trial for the treatment of advanced Parkinson s disease. Half of the trial participants were randomly selected to receive an infusion of the gene-based treatment bilaterally and the other half, the Control Participants, were randomly selected to receive a sterile saline solution. Trial participants are being assessed for safety and for treatment effects by standardized Parkinson s disease ratings at multiple time points both pre and post-procedure. The primary endpoint for the trial will be a clinical assessment of motor function at 6 months using the Unified Parkinson s Disease Rating Scale

(UPDRS). The Company expects to receive

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initial results, based on these assessments, of its Phase 2 clinical trial at the end of the 6-month period following the completion of the last participant s surgical procedure. All participants in the trial will continue to be monitored for safety for 12 months following their respective surgical procedures. If such initial efficacy results are significantly positive and if the 12-month safety data is acceptable, then those Control Participants who continue to meet all entry, medical and surgical criteria for the trial will be offered the opportunity to participate in the open label arm of the trial to receive a bilateral infusion of the gene-based treatment.

The Company is currently taking steps to move toward a pivotal trial for treatment of Parkinson s disease and hopes to be in a position to file its protocol with the U.S. Food and Drug Administration (the FDA) in 2010 or 2011. The ability of the Company to conduct such a trial will require, among other things, the approval of the FDA and the availability of adequate funds, which, in turn, will be largely dependent upon the safety and efficacy results obtained from its Phase 2 clinical trial. Currently, the Company estimates that the pivotal trial could be completed in 2013 and the estimated total direct costs to reach that milestone are expected to be between $20 million and $40 million.

Epilepsy

In December 2006, the Company submitted an investigational new drug application to the FDA for permission to begin a Phase 1 clinical trial of gene transfer therapy for TLE. The proposed clinical protocol for this study was presented to the National Institute of Health s Office of Biotechnology Activities Recombinant DNA Advisory Committee on September 23, 2004 and was reviewed favorably.

The Company does not, at this time, intend to commit its current funds to continue work on its gene transfer therapy for TLE. As previously stated, the Company intends to focus its efforts and resources on its Parkinson s product. (See Business of the Company Epilepsy).

Huntington s Disease

In November 2005, the Company announced findings from pre-clinical studies that showed that a form of the gene dXIAP may prevent the progression of Huntington s disease.

The Company s development of this therapy for Huntington s disease is currently in the pre-clinical phase. The Company reviewed and analyzed its initial pre-clinical results and determined that additional pre-clinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this therapy. The Company proposes, at this time, to defer additional pre-clinical tests while the Company focuses its efforts and resources on its Parkinson s product.

Other Therapies

The Company will also continue its efforts in developing therapies to treat other neurodegenerative and metabolic disorders, including depression and genetically-based obesity under its research agreements with Cornell and OSURF.

2010 Expenditures

Over the next 12 months, in addition to its normal recurring expenditures, the Company expects to spend approximately $3,900 in Phase 2 clinical trial expenses with regard to its Parkinson s treatment; $1,000 in costs associated with operating as a publicly traded company, such as legal fees, accounting fees, insurance premiums, investor and public relations fees; $700 in expenses in order to scale up its manufacturing capabilities for the supply of product for a Parkinson s pivotal trial; and $550 in research and licensing fees.

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Results of Operations

Year Ended December 31, 2009 Compared to the Year Ended December 31, 2008

Revenues. The Company did not generate any operating revenues in 2009 and 2008.

Research and Development Expenses. The following table summarizes the Company s research and development expenses for fiscal years ended December 31, 2009 and 2008 (certain prior period amounts have been reclassified to conform to current period presentation):

	2009	2008	$ Change
Clinical Trial Expenses	$ 4,413	$ 1,155	$ 3,258
Compensation Expenses	1,121	1,054	67
Research, Development and Licensing Fees	747	726	21
Manufacturing Process Development	617	79	538
Medical and Scientific Consultants	555	503	52
Laboratory Expenses	216	191	25
Other R&D Expenses	175	221	(46)
Totals	$ 7,844	$ 3,929	$ 3,915

Research and development expenses increased by $3,915 in 2009 over the comparable expenses in 2008. The increase was mainly due to a $3,258 increase in expenses related to the Company s Phase 2 clinical trial for Parkinson s disease, including a (i) $1,975 increase in fees due to the investigator, surgical sites and brain imaging sites participating in the clinical trial, (ii) $609 increase in other expenses related to the administration of the clinical trial, including fees to the clinical research organization assisting the Company in overseeing the conduct of the trial, (iii) $355 increase in costs associated with the manufacturing of product for a potential open-label arm to the Phase 2 clinical trial, and (iv) $319 increase in Manufacturing and Development Agreement expenses relating to the catheter infusion device used in the Phase 2 clinical trial. The increase was also due to a $538 increase in Manufacturing Process Development expenses for large scale manufacturing of the Company s products and infusion devices and a $119 increase in cash and non-cash compensation to the Company s researchers and scientific consultants.

General and Administrative Expenses. General and administrative expenses decreased by $76 to $2,897 in 2009 as compared to $2,973 in 2008. This decrease was due, in part, to a $28 decrease in information technology and web site design fees, as well as a $24 decrease in patent impairment expense and a $14 decrease in cash and non-cash compensation to the Company s employees in 2009.

Other Income (Expense), Net. The Company had net other expenses of $2,720 in 2009 as compared to net other income of $582 in 2008. The change is mainly due to charges of $2,777 recognized for the increase in fair value of its derivative liabilities in 2009. Additionally, the Company earned $525 less in interest income during 2009 as compared to 2008.

Liquidity and Capital Resources

Cash and cash equivalents were $9,637 at December 31, 2009.

The Company is still in the development stage and has not generated any operating revenues as of December 31, 2009. In addition, the Company will continue to incur net losses and cash flow deficiencies from operating activities for the foreseeable future.

Based on its cash flow projections, the Company will need additional financing to carry out its planned business activities and complete its plan of operations through December 31,

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2010. At the Company s present level of activities, the Company s cash and cash equivalents are believed, at this time, to be sufficient to fund its operations only into the fourth quarter of this current fiscal year. Accordingly, there is substantial doubt as to the Company s ability to continue as a going concern by the end of its current fiscal year.

Much of the Company s ability to raise additional capital or secure a strategic collaboration for the financing of its continued operations and product development will depend substantially on the successful outcome of its Phase 2 clinical trial for its Parkinson s product. The initial 6-month safety and efficacy results from that trial will not be available until June or July of 2010. Since the Company is unable to fund its operations through December 31, 2010, it is making every effort to secure capital commitments for funds at this time. The Company is also currently seeking to raise funds through corporate collaboration and licensing arrangements in connection with its ongoing and long-term operations.

The Company does not know whether additional financing will be available when needed or, if available, will be on acceptable or favorable terms to it or its stockholders. (See Risk Factors The Company Does Not Have Sufficient Funds to Continue its Operations in the Long Run or to Commercialize its Product Candidates).

The Company s independent registered public accounting firm has expressed substantial doubt about the Company s ability to continue as a going concern in the audit report on the Company s audited financial statements for the fiscal year ended December 31, 2009 included herein.

Net cash used in operating activities was $8,971 in fiscal year 2009 as compared to $5,959 in fiscal year 2008. The $3,012 increase in net cash used in operations was primarily due to a $7,141 increase in net loss, offset by $2,895 in adjustments to net loss for increased non-cash expenses, as well as a $1,234 decrease in cash used as a result of changes to working capital in 2009.

The Company had net cash used in investing activities of $298 during the year ended December 31, 2009 as compared to $224 during the year ended December 31, 2008. Cash used in investing activities relates to purchases of equipment and additions to intangible assets made by the Company during 2009 and 2008.

The Company had no net cash used in or provided by financing activities during the year ended December 31, 2009. Net cash provided by financing activities during the year ended December 31, 2008 was $4,932, which represented net proceeds received by the Company in a private placement of its Series D Stock in April 2008.

Critical Accounting Estimates and Policies

The Company s discussion and analysis and plan of operation is based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for financial statements filed with the Securities and Exchange Commission (the SEC). The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates, including those related to fixed assets, intangible assets, stock-based compensation, income taxes and contingencies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The accounting policies and estimates used as of December 31, 2009, as outlined in the accompanying notes to the financial statements, have been applied consistently for the year

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ended December 31, 2009. The Company believes the following critical accounting policies affect the significant estimates and judgments used in the preparation of its financial statements.

Carrying Value of Fixed and Intangible Assets

The Company s fixed assets and certain of its patents have been recorded at cost. The Company s fixed assets are being amortized using accelerated methods and its patents are being amortized on a straight-line basis over the estimated useful lives of those assets. If the Company becomes aware of facts that indicate one or more of those assets may be impaired, the Company assesses whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the Company determines that an asset is impaired, the Company measures the amount of such impairment by comparing the carrying value of the asset to the fair value determined by the present value of the expected future cash flows associated with the use of the asset. Adverse changes to the Company s estimates of the future cash flows to be received from a particular long-lived asset could indicate that the asset is impaired, and would require the Company to write down the asset s carrying value at that time.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees of the Company s scientific and research consultants and related costs, contracted research fees and expenses, clinical studies and license agreement milestone and maintenance fees. Research and development costs are expensed as incurred. Certain of these expenses, such as fees to consultants, fees to collaborators for research activities and costs related to clinical trials are incurred over multiple reporting periods. Management assesses how much of these multi-period costs should be charged to research and development expense in each reporting period.

Stock Based Compensation

The Company follows the provisions of ASC Topic 718, Compensation Stock Compensation (ASC Topic 718) for employee stock options and other share-based employee compensation using the modified prospective method. The Company continues to reflect share-based employee compensation cost in net loss. The total value of the stock option awards is expensed ratably over the service period of the employees receiving the awards.

The Black-Scholes option pricing model used to compute share-based compensation expense requires extensive use of accounting judgment and financial estimates. Items requiring estimation include the expected term option holders will retain their vested stock options before exercising them, the estimated volatility of the Company s common stock price over the expected term of a stock option, and the number of stock options that will be forfeited prior to the completion of their vesting requirements. Application of alternative assumptions could result in significantly different share-based compensation amounts being recorded in the Company s financial statements.

For equity awards to non-employees, the Company also applies the Black-Scholes method to determine the fair value of such awards in accordance with ASC Topic 718 and the provisions of ASC Topic 505-50, Equity-Based Payments to Non-Employees. The options granted to non-employees are re-measured as they vest and the resulting value is recognized as an adjustment against the Company s net loss over the period during which the services are received.

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Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2009-01, Generally Accepted Accounting Principles (ASC Topic 105), which establishes the FASB Accounting Standards Codification (the Codification or ASC) as the single source of authoritative Generally Accepted Accounting Principles (GAAP). All existing accounting standards in effect prior to the Codification were superseded by the Codification. All other accounting guidance not included in the Codification will be considered non-authoritative. The Codification also includes all relevant SEC guidance organized using the same topical structure in separate sections within the Codification. The Codification does not change GAAP and does not impact the Company s financial statements. All references to authoritative accounting literature (including references related to periods prior to the establishment of the Codification) will be referenced in accordance with the Codification.

In January 2008, the FASB issued guidance within ASC Topic 260, Earnings Per Share. (ASC Topic 260). ASC Topic 260 requires that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and should be included in the two-class method of computing earnings per share. ASC Topic 260 is effective for fiscal years beginning after December 15, 2008. The adoption of ASC Topic 260 did not have a material impact on the Company s financial statements.

In February 2008, the FASB issued guidance within ASC Topic 820, Fair Value Measurements and Disclosures. (ASC Topic 820). This guidance within ASC Topic 820 delayed the effective date of certain provisions of ASC Topic 820 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years beginning after November 15, 2008. In October 2008, the FASB issued further guidance under ASC Topic 820 specifically related to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with ASC Topic 820. This guidance clarifies the application of ASC Topic 820 in determining the fair values of assets or liabilities in a market that is not active. ASC Topic 820 was effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of this guidance did not have a material impact on the Company s financial statements.

In March 2008, the FASB issued guidance within ASC Topic 815, Derivatives and Hedging. (ASC Topic 815). ASC Topic 815 requires disclosures of the fair values of derivative instruments and their gains and losses in a tabular format. ASC Topic 815 also requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. This guidance is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of this guidance did not have a material impact on the Company s financial statements.

In June 2008, the FASB issued guidance within ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity. (ASC Topic 815-40). This guidance provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument s contingent exercise and the instrument s settlement provisions. ASC Topic 815-40 clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. This guidance is effective for fiscal years beginning after December 15, 2008. Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, all warrants issued in connection with the issuance of the Series C Stock and the Series D Stock must now be treated as derivative liabilities in the

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Company s balance sheet. See Note 4 to the financial statements for further discussion on the accounting treatment of these warrants.

In May 2009, the FASB issued guidance within ASC Topic 855-10, Subsequent Events, relating to subsequent events. This guidance establishes principles and requirements for subsequent events. This guidance defines the period after the balance sheet date during which events or transactions that may occur would be required to be disclosed in a company s financial statements. Public entities are required to evaluate subsequent events through the date that financial statements are issued. This guidance also provides guidelines for evaluating whether or not events or transactions occurring after the balance sheet date should be recognized in the financial statements. This guidance requires disclosure of the date through which subsequent events have been evaluated. The Company has evaluated subsequent events up to the date of issuance of this report.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, Measuring Liabilities at Fair Value (ASU 2009-05). ASU 2009-05 amends ASC Topic 820 and clarifies that, where a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of ASC Topic 820. ASU 2009-05 also clarifies that, when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of ASU 2009-05 did not have a material impact on the Company s financial statements.

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales, issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The provisions of ASU 2010-06 are effective for periods beginning after December 15, 2009. The disclosures relating to Level 3 activity are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The Company is currently evaluating the potential impact of the provisions of ASU 2010-06, but does not expect that the adoption of ASU 2010-06 will have a material impact on its financial statements.

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Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Neurologix, Inc.
Fort Lee, NJ

We have audited the accompanying balance sheets of Neurologix, Inc. (the Company) (a development stage company) as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders equity (deficit) and cash flows for the years then ended, and for the period from February 12, 1999 (inception) to December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We did not audit the statements of operations, shareholders deficit and cash flows for the period from February 12, 1999 (inception) to December 31, 2005, which reflect expenses of approximately $14.0 million, other expense, net of $0.1 million, cash used in operating activities of $11.4 million, cash used in investing activities of approximately $3.8 million and cash provided by financing activities of $16.4 million. Those financial statements were audited by another auditor whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such period, is based solely on the report of the other auditor.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditor provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditor, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2009 and 2008 and the results of its operations and its cash flows for the years then ended, and for the period from February 12, 1999 (inception) to December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 4 to the financial statements, the Company adopted ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity as it related to the Company s warrants.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, expects to incur future losses for the foreseeable future and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO Seidman, LLP
New York, New York
March 26, 2010

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Neurologix, Inc.

We have audited the consolidated statements of operations, changes in stockholders equity (deficiency) and cash flows of Neurologix, Inc. and subsidiary (the Company) (a development stage company) for the period from February 12, 1999 (date of inception) through December 31, 2005 (not presented herein) which are a component of the period from February 12, 1999 (date of inception) through December 31, 2009. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of the Company (a development stage company) for the period from February 12, 1999 (date of inception) through December 31, 2005 (not presented herein) which are a component of the period from February 12, 1999 (date of inception) through December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The consolidated financial statements referred to above had been prepared assuming that the Company would continue as a going concern. Through December 31, 2005, the Company had incurred recurring losses from operations and had negative cash flows from its operating activities. These matters raised substantial doubt about the Company s ability to continue as a going concern. Management s plans concerning these matters were described in the notes to the financial statements referred to above. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. Cohn LLP
Jericho, New York
March 24, 2006

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NEUROLOGIX, INC.
(A Development Stage Company)
BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$9,637	$18,906
Prepaid expenses and other current assets	395	323
Total current assets	10,032	19,229
Equipment, less accumulated depreciation of $624 and $542 at December 31, 2009 and 2008, respectively	129	141
Intangible assets, less accumulated amortization of $262 and $182 at December 31, 2009 and 2008, respectively	891	748
Other assets	5	5
Total Assets	$11,057	$20,123
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$1,834	$850
Derivative financial instruments, at estimated fair value Warrants	$3,847	-
Total liabilities	$5,681	$850
Commitments and contingencies		
Stockholders equity:		
Preferred stock; 5,000,000 shares authorized		
Series A Convertible, $0.10 par value; 650 shares designated, 645 shares issued and outstanding at December 31, 2009 and 2008, with an aggregate liquidation preference of $1	-	-
Series C Convertible, $0.10 par value; 700,000 shares designated, 281,263 and 285,878 shares issued and outstanding at December 31, 2009 and 2008, respectively, with an aggregate liquidation preference of $7,008 and $5,863 at December 31, 2009 and 2008, respectively	28	29
Series D Convertible, $0.10 par value; 792,100 shares designated, 734,898 shares issued and outstanding at December 31, 2009 and 2008, with an aggregate liquidation preference of $29,420 and $27,031, at	73	73

December 31, 2009 and 2008, respectively		
Common Stock:		
$0.001 par value; 100,000,000 shares authorized, 27,865,010 and 27,764,058 shares issued and outstanding at December 31, 2009 and 2008, respectively	28	28
Additional paid-in capital	56,775	62,393
Deficit accumulated during the development stage	(51,528)	(43,250)
Total stockholders equity	5,376	19,273
Total Liabilities and Stockholders Equity	$11,057	$20,123

See accompanying notes to financial statements.

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NEUROLOGIX, INC.
(A Development Stage Company)
STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,		For the period February 12, 1999 (inception) through December 31, 2009
	2009	2008	
Revenues	$ -	$ -	$ -
Operating expenses:			
Research and development	7,844	3,929	27,461
General and administrative expenses	2,897	2,973	18,997
Loss from operations	(10,741)	(6,902)	(46,458)
Other income (expense):			
Dividend, interest and other income	57	582	1,883
Interest expense-related parties	-	-	(411)
Change in estimated fair value of derivative financial instruments - Warrants	(2,777)	-	(2,777)
Other (expense) income, net	(2,720)	582	(1,305)
Net loss	(13,461)	(6,320)	$(47,763)
Preferred stock dividends	(2,974)	(2,652)	
Charge for accretion of beneficial conversion feature	-	(562)	
Charge for contingent beneficial conversion feature	-	(212)	
Net loss applicable to common stock	$(16,435)	$(9,746)	
	$(0.59)	$(0.35)	

Net loss applicable to common stock per share, basic and diluted		
Weighted average common shares outstanding, basic and diluted	27,830,714	27,692,337

See accompanying notes to financial statements.

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NEUROLOGIX, INC.
(A Development Stage Company)
STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)
FOR THE PERIOD FROM FEBRUARY 12, 1999 (INCEPTION) THROUGH DECEMBER 31, 2009
(Amounts in thousands, except for share and per share amounts)

	Series D Preferred Stock		Series C Preferred Stock		Common Stock		Additional		Deficit Accumulated During the	
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Unearned Compensation	Development Stage	Total
Sale of common stock to founders	-	$ 0	-	$ 0	6,004,146	$ 0	$ 4	$ 0	$ 0	$ 4
Net loss	-	-	-	-	-	-	-	-	(328)	(328)
Balance, December 31, 1999	-	0	-	0	6,004,146	0	4	0	(328)	(324)
Net loss	-	-	-	-	-	-	-	-	(1,055)	(1,055)
Balance, December 31, 2000	-	0	-	0	6,004,146	0	4	0	(1,383)	(1,379)
Stock options granted for services	-	-	-	-	-	-	9	-	-	9
Common stock issued for intangible assets at $0.09 per share	-	-	-	-	259,491	-	24	-	-	24
Net loss	-	-	-	-	-	-	-	-	(870)	(870)
Balance, December 31, 2001	-	0	-	0	6,263,637	0	37	0	(2,253)	(2,216)
Retirement of founder shares	-	-	-	-	(33,126)	-	-	-	-	-
Common Stock issued pursuant	-	-	-	-	368,761	-	577	(577)	-	-

to license agreement at $1.56 per share										
Private placement of Series B convertible preferred stock	-	-	-	-	-	-	2,613	-	-	2,613
Amortization of unearned compensation	-	-	-	-	-	-	-	24	-	24
Net loss	-	-	-	-	-	-	-	-	(1,310)	(1,310)
Balance, December 31, 2002	-	0	-	0	6,599,272	0	3,227	(553)	(3,563)	(889)
Sale of Common Stock	-	-	-	-	276,054	-	90	(89)	-	1
Amortization of unearned compensation	-	-	-	-	-	-	-	164	-	164
Net loss	-	-	-	-	-	-	-	-	(2,274)	(2,274)
Balance, December 31, 2003	-	0	-	0	6,875,326	0	3,317	(478)	(5,837)	(2,998)
Conversion of note payable to Common Stock at $2.17 per share	-	-	-	-	1,091,321	1	2,371	-	-	2,372
Conversion of mandatory redeemable preferred stock to Common Stock	-	-	-	-	6,086,991	6	494	-	-	500
Conversion of Series B convertible preferred stock to Common Stock	-	-	-	-	1,354,746	1	(1)	-	-	-
Effects of reverse acquisition	-	-	-	-	7,103,020	14	5,886	-	-	5,900
Amortization of unearned compensation	-	-	-	-	-	-	-	202	-	202
Stock options granted for services	-	-	-	-	-	-	42	(42)	-	-

Exercise of stock options	-	-	-	-	10,000	-	15	-	-	15
Net loss	-	-	-	-	-	-	-	-	(2,937)	(2,937)

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Balance, December 31, 2004	-	0	-	0	22,521,404	22	12,124	(318)	(8,774)	3,054
Sale of Common Stock through private placement at an average price of $1.30 per share	-	-	-	-	2,473,914	4	3,062	-	-	3,066
Sale of Common Stock at an average price of $1.752 per share and warrants to Medtronic	-	-	-	-	1,141,552	1	2,794	-	-	2,795
Amortization of unearned compensation	-	-	-	-	-	-	-	825	-	825
Stock options granted for services	-	-	-	-	-	-	1,305	(1,305)	-	-
Exercise of stock options	-	-	-	-	406,054	-	127	-	-	127
Net loss	-	-	-	-	-	-	-	-	(5,345)	(5,345)
Balance, December 31, 2005	-	0	-	0	26,542,924	27	19,412	(798)	(14,119)	4,522
Sale of Preferred Stock through private placement at an average price of $35.00 per share	-	-	342,857	34	-	-	11,578	-	-	11,612
Fair value of beneficial conversion rights issued in connection with issuance of Series C Preferred Stock	-	-	-	-	-	-	2,621	-	-	2,621
Preferred Dividend and accretion of fair	-	-	25,298	3	-	-	(3)	-	(2,621)	(2,621)

value of beneficial conversion charge										
Employee share-based compensation expense	-	-	-	-	-	-	1,193	-	-	1,193
Non-employee share-based compensation	-	-	-	-	-	-	83	-	-	83
Reclassification of prior year non-employee compensation to prepaid expenses	-	-	-	-	-	-	-	487	-	487
Effects of adoption of ASC Topic 718	-	-	-	-	-	-	(311)	311	-	-
Net loss	-	-	-	-	-	-	-	-	(7,046)	(7,046)
Balance, December 31, 2006	-	0	368,155	37	26,542,924	27	34,573	0	(23,786)	10,851
Sale of Series D Preferred Stock through private placement at an average price of $35.00 per share	428,571	43	-	-	-	-	14,727	-	-	14,770
Fair value of beneficial conversion rights issued in connection with the issuance of Series D Preferred Stock	-	-	-	-	-	-	2,130	-	-	2,130
Preferred Dividend and accretion of fair value of beneficial conversion charge	5,108	1	68,801	7	-	-	(8)	-	(2,130)	(2,130)
Contingent beneficial conversion feature related	-	-	-	-	-	-	627	-	(627)	-

to Series C Preferred Stock										
Induced conversion of preferred stock in connection with the issuance of Series D Preferred Stock	163,470	16	(230,184)	(23)	-	-	(347)	-	354	-
Issuance of Series C Preferred Stock in connection with induced conversion of preferred stock	-	-	93,940	9	-	-	2,949	-	(2,958)	-
Issuance of Common Stock in connection with issuance of Series D Preferred Stock	-	-	-	-	192,017	-	192	-	(192)	-
Employee share-based compensation expense	-	-	-	-	-	-	702	-	-	702
Non-employee share-based compensation	-	-	-	-	-	-	72	-	-	72
Conversion of Series C Preferred Stock to Common Stock	-	-	(5,597)	-	110,052	-	-	-	-	-
Exercise of stock options	-	-	-	-	787,815	1	590	-	-	591
Net loss	-	-	-	-	-	-	-	-	(6,817)	(6,817)

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Balance, December 31, 2007	597,149	60	295,115	30	27,632,808	28	56,207	0	(36,156)	20,169
Sale of Series D Preferred Stock through private placement at an average price of $35.00 per share	142,857	14	-	-	-	-	4,918	-	-	4,932
Fair value of beneficial conversion rights issued in connection with the issuance of Series D Preferred Stock	-	-	-	-	-	-	562	-	-	562
Accretion of fair value of beneficial conversion charge	-	-	-	-	-	-	-	-	(562)	(562)
Contingent beneficial conversion feature related to Series C Preferred Stock	-	-	-	-	-	-	212	-	(212)	-
Adjustment to preferred dividends accrued	(5,108)	(1)	(3,237)	(1)	-	-	2	-	-	-
Employee share-based compensation expense	-	-	-	-	-	-	489	-	-	489
Non-employee share-based compensation	-	-	-	-	-	-	3	-	-	3
Conversion of Series C Preferred Stock to Common Stock	-	-	(6,000)	-	131,250	-	-	-	-	-

Net loss	-	-	-	-	-	-	-	-	(6,320)	(6,320)
Balance, December 31, 2008	734,898	73	285,878	29	27,764,058	28	62,393	0	(43,250)	19,273
Employee share-based compensation expense	-	-	-	-	-	-	448	-	-	448
Non-employee share-based compensation	-	-	-	-	-	-	185	-	-	185
Cumulative effect of adoption of ASC Topic 815-40	-	-	-	-	-	-	(6,252)	-	5,183	(1,069)
Conversion of Series C Preferred Stock to Common Stock	-	-	(4,615)	(1)	100,952	-	1	-	-	-
Net loss	-	-	-	-	-	-	-	-	(13,461)	(13,461)
Balance, December 31, 2009	734,898	$ 73	281,263	$ 28	27,865,010	$ 28	$ 56,775	$ 0	$ (51,528)	$ 5,376

See accompanying notes to financial statements.

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NEUROLOGIX, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year Ended December 31,		For the period February 12, 1999 (inception) through December 31, 2009
	2009	2008	
Operating activities:			
Net loss	$(13,461)	$(6,320)	