

NEUROLOGIX INC/DE  
Form 10-K  
March 25, 2011

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

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2010

OR

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

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

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

Indicate by check mark 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

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates was approximately \$12,824,874, 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 11, 2011, there were outstanding 27,918,148 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 2011 Annual Meeting of Stockholders, which Proxy Statement will be filed within 120 days after the registrant's fiscal year ended December 31, 2010.

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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, predicts, 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; and

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 24. 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 Phase 1 and Phase 2 clinical trials for the treatment of Parkinson's disease. Although the Company's current operations and resources will be primarily concentrated on its investigational Parkinson's disease therapy, the Company intends to continue its efforts to develop therapies to treat other neurodegenerative and metabolic disorders, including therapies relating to epilepsy, depression and Huntington's disease. Recent highlights include:

For the 12 months ended December 31, 2010, the Company reported a net loss of approximately \$10.2 million versus a net loss of \$13.5 million for the 12 months ended December 31, 2009. Cash and cash equivalents were \$8.1 million at December 31, 2010.

On March 17, 2011, the results of the Company's Phase 2 clinical trial of its investigational gene therapy for advanced Parkinson's disease, NLX-P101, were published in an online-first edition of *The Lancet Neurology*. (See Business of the Company Parkinson's Disease ).

On February 8, 2011, the Company extended the term of its consulting agreement with Dr. Martin Kaplitt, the Company's Chairman of the Board of Directors (the Board ), effective from January 1, 2011 to December 31, 2011. (See Notes 10 and 11 to Financial Statements).

On February 8, 2011, the Company approved an extension of the term of its 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, 2011 to April 30, 2012. (See Notes 10 and 11 to Financial Statements).

On January 18, 2011, the Company entered into a fourth 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 fourth amendment, among other things, extends the term of the OSU Research Agreement to November 10, 2011. (See Notes 10 and 11 to Financial Statements).

On December 6, 2010, the Company entered into a Note and Warrant Purchase Agreement (the Purchase Agreement ), whereby it issued promissory notes (Notes ) and warrants to purchase common stock for an aggregate of \$7 million. The Notes bear interest at 10% per annum, mature on October 31, 2011, and are secured by substantially all the assets of the Company. At maturity, the Company will pay an amount equal to 1.2 times the principal amount of the Notes, plus accrued interest. Additionally, the transaction involved the issuance of warrants to purchase a total of 2,430,555 shares of Common Stock at an exercise price of \$1.44 per share, subject to certain adjustments set forth in the warrants. (See Notes 7 and 9 to Financial Statements).

On November 24, 2010, the Company entered into a letter agreement (the Panoff Letter Agreement ) with Marc L. Panoff, the Company's Chief Financial Officer,

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Treasurer and Secretary, which amended the Employment Agreement, dated August 20, 2009 (the Employment Agreement ), by and between the Company and Mr. Panoff. The Panoff Letter Agreement extended the employment period under the Employment Agreement to December 4, 2011. All other terms of the Employment Agreement are unmodified. (See Note 10 to Financial Statements).

On November 9, 2010, the Company entered into a letter agreement (the Letter Agreement ) with Dr. Matthew During, one of the Company's scientific co-founders and a member of the SAB, which amended a Consulting Agreement dated October 1, 1999, as amended (the Consulting Agreement ), by and between the Company and Dr. During. The Letter Agreement extended the term of the Consulting Agreement until September 30, 2011. (See Note 10 to Financial Statements).

On June 22, 2010, the Company announced positive results from its Phase 2 clinical trial of its investigational gene therapy for advanced Parkinson's disease, NLX-P101. Study participants who received NLX-P101 experienced statistically significant and clinically meaningful improvements in off-medication motor scores compared to control participants who received sham surgery. In the trial, this benefit was seen at one month and continued virtually unchanged throughout the six month blinded study period. The results also demonstrated a positive safety profile for NLX-P101, with no serious adverse events related to the gene transfer or surgical procedure reported. Patients enrolled in the trial had moderate to advanced Parkinson's disease and were not adequately responsive to current therapies. (See Business of the Company - Parkinson's Disease ).

In May 2010, a patent was issued to the Company by the United States Patent and Trademark Office (USPTO ) covering the treatment of seizures associated with temporal lobe epilepsy (TLE ) by direct administration of an adeno-associated virus (AAV ) vector encoding Neuropeptide Y (NPY ) into the brain's temporal lobe. (See Business of the Company - Patents and Other Proprietary Rights ).

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. (See Note 10 to Financial Statements).

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 ).

**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.



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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 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 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 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 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 Company's 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 preclinical 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 University for and on behalf of its Joan & Sanford I. Weill Medical College (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.



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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 expects to concentrate the majority of its resources and efforts to the development of its first-generation NLX product, NLX-P101, 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:

- o the therapeutic gene function is reasonably well understood and has a physiological role;
- o neurosurgical approaches are already established and standard;
- o animal studies have indicated that gene transfer technology may be effective in treating the disease;
- o specific clinical outcome is measurable;
- o partial correction of the disease is expected to be clinically proven; and
- o clinical testing can be conducted on 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.  
(See Manufacturing ).

In February 2010, the Company retained MTS Health Partners, L.P. (MTS ) 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.

*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 in order to carry out its planned business activities and plan of operations

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after October 31, 2011 and to repay the Notes as of said date. (See Item 1A 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 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.

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***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. 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 investigational gene 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 investigational gene therapy, NLX-P101, is a novel, non-dopaminergic approach that uses GAD 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. To the Company s knowledge, NLX-P101 is the only gene transfer strategy currently in development which bypasses the dopamine system. The investigational gene 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 currently 1 million Parkinson s disease patients in America, with 50,000-60,000 new cases diagnosed each year.

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 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

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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 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 Item 1A Risk Factors).

The Company initiated its Phase 2 clinical trial for the treatment of advanced Parkinson's disease in December 2008 and completed all of the planned surgeries associated with the trial in November 2009. The double-blind, multi-center, randomized, sham-procedure-controlled trial was designed to evaluate the safety and efficacy of NLX-P101 in 45 patients with moderate to advanced Parkinson's disease who were not well-controlled on available medical therapy. Half of the trial participants were randomized to receive an infusion of NLX-P101 bilaterally into each subthalamic nucleus, and the other half were randomized to receive a sham infusion of a sterile saline solution (the Control Participants). Each procedure was carried out under local



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anesthesia. Trial participants were 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 was a clinical assessment of motor function at 6 months using the Unified Parkinson's Disease Rating Scale (UPDRS). All participants in the trial were evaluated at baseline as well as one, three and six months after undergoing surgery and were monitored for safety for a 12-month period following their surgical procedure. All treated participants will continue to be monitored for safety in a long-term follow-up study.

In June 2010, the Company announced positive results from its Phase 2 clinical trial for the treatment of advanced Parkinson's disease. Trial participants who received NLX-P101 experienced statistically significant and clinically meaningful improvements in off-medication motor scores compared to control subjects who received sham surgery. In the trial, this benefit was seen at one month and continued virtually unchanged throughout the six month blinded study period. The Phase 2 results, which were published in an online-first edition of *The Lancet Neurology* on March 17, 2011, also demonstrated a positive safety profile for NLX-P101, with no serious adverse events related to the gene transfer or surgical procedure reported in the 12-month period following the surgical procedures. In accordance with the trial's protocol, treated participants will continue to be monitored for safety for a five-year period following their surgical procedures.

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. Subject to adequate funding, the Company expects to commence the open-label arm of the trial in the second or third quarter of the 2011 fiscal year. (See Item 1A 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 ).

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 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 all surgeries conducted in the pivotal trial could be completed in the first half of 2014 and the estimated total direct costs to reach that milestone are expected to be between \$30 million and \$40 million. (See Item 1A Risk Factors and Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations ).

***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 almost 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.



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**Product Development and Operations.** Over the past several years, the Company has completed multiple preclinical 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 preclinical 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 May 2010, the USPTO issued a patent to the Company for intellectual property covering the use of NPY for the treatment of TLE. The Company believes that this patent 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 preclinical trial, the availability of funding, approval by the FDA and procurement of certain intellectual property licenses. Additionally, the Company intends to concentrate its current operations and resources primarily on its investigational Parkinson's disease gene therapy. (See Item 1A—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.

## ***Depression***

**General.** Clinical depression is one of the most common mental illnesses, affecting more than 19 million Americans each year. This includes major depressive disorder, manic depression and dysthymia, a milder, longer-lasting form of depression.

Depression causes people to lose pleasure from daily life, can complicate other medical conditions, and can even be serious enough to lead to suicide. Depression can occur to anyone, at any age, and to people of any race or ethnic group. Depression is never a normal part of life, no matter what your age, gender or health situation.

Depression is treatable with treatments such as therapy, medicine, and lifestyle changes. But it may not always be easily treated. For many people, depression may continue despite treatment. They may have treatment-resistant depression or TRD. This happens when medicine



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partly relieves their symptoms or does not help at all. It is at this juncture that surgical intervention is recommended to certain of TRD patients.

Neurostimulation is becoming an option for people who have tried a variety of antidepressants that did not work, only partly worked or stopped working. Vagus Nerve Stimulation is one type of neurostimulation that has been approved as an additional treatment for long-term or recurrent depression in adults who have not had success with four or more antidepressant medicines. A device is put into the chest and sends an electrical current to the brain.

Electroconvulsive Therapy (ECT) is another type of neurostimulation. ECT can be helpful for people whose depression is severe or life-threatening and for people who cannot take antidepressant medicine. Electrodes are placed on the head to deliver electrical impulses. ECT has been controversial, but has improved in recent years. It can help when antidepressant medicines do not work well enough.

Serotonin is considered to be a key neurotransmitter in depression-like states. The serotonergic system in the brain is known to modulate mood, emotion, sleep and appetite and thus is implicated in the control of numerous behavioral and physiological functions. Decreased serotonergic neurotransmission has been proposed to play a key role in the cause of depression.

The Company believes that a gene called p11 is closely related to serotonin transmission in the brain and may be one of the causes of depression in a subset of patients. Past studies have shown that humans and animals with depression have decreased levels of p11 in an area of the brain called the nucleus accumbens. This brain structure is important for reward, drug addiction and depression. The Company's technology inserts the p11 gene into an AAV vector, and this packaged vector is introduced directly into the nucleus accumbens in order to normalize depression-like behavior.

Product Development and Operations. On January 13, 2009, the Company entered into a License Agreement with Cornell (the Cornell License Agreement) whereby Cornell granted the Company an exclusive license for the worldwide use of p11 gene therapy in the treatment of psychiatric conditions, including depression.

In October 2010, the Company announced the publication of a paper in Science Translational Medicine demonstrating the importance of the p11 gene in modulating depression in mice, utilizing the Company's investigational gene therapy approach. In the study, reduced levels of p11 in the nucleus accumbens were associated with depressive behaviors in mice. An AAV vector was used to deliver the p11 gene back into the nucleus accumbens of mice who were lacking the p11 protein, reversing the depressive behavior and returning the animals to normal function.

The study also examined samples of brain tissue from a group of deceased human patients, half of whom had severe depression. It was found that there were significantly reduced levels of p11 in the nucleus accumbens of depressed patients compared to those without depression.

The Company's development of this investigational gene therapy for depression is currently in the preclinical phase. Additional preclinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this investigational gene therapy. The timing of such trial is subject to, among other things, the completion of additional preclinical testing, the availability of funding and receipt of applicable regulatory approvals. Additionally, the Company intends to concentrate its current operations and resources primarily on its investigational Parkinson's disease gene therapy. (See Item 1A 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).

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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 preclinical 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 investigational gene therapy for Huntington s disease is currently in the preclinical phase. The Company reviewed and analyzed its initial preclinical results and determined that additional preclinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this investigational gene therapy. The timing of such trial is subject to, among other things, the completion of additional preclinical testing, the availability of funding, the availability of the AAV vector and an infusion system and the receipt of applicable regulatory approvals. Additionally, the Company intends to concentrate its current operations and resources primarily on its investigational Parkinson s disease gene therapy. (See Item 1A 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. Since the Company s primary focus remains the development of its product for the treatment of Parkinson s disease, the Company does not

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expect to allocate any further resources during the 2011 fiscal year to these other treatment candidates.

***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 over 20 issued U.S. patents and foreign patents, as well as more than 20 pending U.S. and foreign patent applications. In addition, the Company owns 3 issued U.S. patents, 10 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 a Clinical Study Agreement with Cornell (the Clinical Study Agreement) 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, depression and epilepsy (the Scientific Studies). On March 2, 2007, the parties entered into Amendment No. 2 to the Clinical Study Agreement to, among other things, 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 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.

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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 January 2011, runs through November 10, 2011. (See Note 11 to Financial Statements).

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.

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





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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 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.

In May 2010, the USPTO issued a patent to the Company for intellectual property covering the use of NPY for the treatment of TLE. The Company believes that this patent will protect the Company's intellectual property rights with respect to the use of NPY for the treatment of TLE.

The Company's intellectual property rights may be called into question, subject to litigation or forfeited in certain situations. (See Item 1A "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 Item 1A "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 product for Parkinson's disease, NLX-P101, 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 currently seeking to contract with third parties for such manufacturing.

The Company contracted with Cincinnati Children's Hospital Medical Center (CCHMC) for the production of the AAV vectors to be used in the Company's Phase 2 clinical trial for Parkinson's disease (including the open-label arm of such trial) and the Company's 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

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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 (including the open-label arm of such trial) was produced and was supplied by CCHMC as approved by the FDA. Due to facility size and other capacity constraints, the Company does not expect that CCHMC will manufacture the AAV vectors for a Phase 3 clinical trial for Parkinson's disease. The Company is currently seeking other third-party manufacturers to manufacture the AAV vectors for such Phase 3 clinical trial.

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 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 the open-label arm of such Phase 2 clinical trial and 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, 2010, 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 Item 1A 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 Item 1A 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 investigational gene therapy products. At the present time, the Company is seeking to contract with third parties for such manufacturing. (See Item 1A 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 disease, epilepsy, depression, Huntington's disease and other neurodegenerative and metabolic disorders. At this time, the Company is not aware of any new developments with respect to these

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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 neurodegenerative and metabolic disorders. Some companies, such as Genzyme Corp. (Genzyme) 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, in December 2010, three-month data from the third patient cohort of its Phase 1/2 trial of its proprietary gene therapy, ProSavin, for the treatment of Parkinson's disease. Oxford indicated that ProSavin continues to be safe and well tolerated following treatment. Previously, Oxford announced results from the first six patients in the trial, indicating 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), 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 vectors 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 October 2010, Ceregene announced it completed the open-label portion of the new trial and began enrollment for the double-blind sham surgery-controlled portion of the trial. 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.

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 preclinical 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



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Act, the FDA exercises regulatory authority over, among other things, the development, testing, formulation, manufacture, labeling, storage, record keeping, reporting, quality control, 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 Item 1A Risk Factors – The Company is Subject to Stringent Regulation; FDA Approvals ).

Preclinical trials generally require studies in the laboratory or in animals to assess the potential product's safety and effectiveness. Preclinical 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. Preclinical 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 preclinical trials as part of an IND.

If preclinical 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's 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 Item 1A Risk Factors – The Company is Subject to Stringent Regulation; FDA Approvals ).

Institutions, such as the Company, that receive funding from the National Institutes of Health (the NIH ) 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 Item 1A 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



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the target disease in order to establish preliminary effectiveness and optimal dosages and to 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 must report 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 results of the clinical trial 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 a product candidate. (See Item 1A 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 preclinical 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 Item 1A 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 Item 1A 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, 2010, 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





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Ph.D. degrees, with expertise in virology, protein chemistry and molecular biology. The 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 2010 or 2009.

*Paul Greengard, Ph.D.* Dr. Paul 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 of Molecular and Cellular Neuroscience at The Rockefeller University and Director of The Fisher Center for Alzheimer's Research. Dr. Greengard received his Ph.D. from Johns Hopkins in 1953. He spent five years in England receiving advanced training at the University of London, at Cambridge University and at the National Institute of Medical Research. Upon his return to the United States, Greengard worked as Director of the Department of Biochemistry at Geigy (now Novartis) Research Laboratories, in Ardsley, New York for eight years. In 1967, he left the pharmaceutical industry to return to academia. From 1968 to 1983 Dr. Greengard served as Professor of Pharmacology and Psychiatry at Yale University, at which time he moved to his current position at The Rockefeller University.

Over the years, Dr. Greengard's achievements have earned him many distinguished awards including the Metropolitan Life Foundation Award for Medical Research, The Charles A. Dana Award for Pioneering Achievements in Health, the Ralph W. Gerard Prize in Neuroscience from the Society for Neuroscience, The National Academy of Sciences Award in the Neurosciences and the 3M Life Sciences Award of the Federation of American Societies for Experimental Biology. In 2000, Dr. Greengard was awarded the Nobel Prize in Physiology or Medicine for his discoveries concerning signal transduction in the nervous system. He is an Honorary Member of the National Academies of Science in Sweden, Norway and Serbia and has been the recipient of many honorary degrees. He is a member of the National Academy of Sciences of the United States and of the Institute of Medicine of the National Academies.

*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 at the Environmental and Occupational Health Science Institute of the University of Medicine and Dentistry of New Jersey (UMDNJ). He is also the Chief Operating Officer at the Rutgers University's Cell and DNA Repository and Associate Professor of Medicine and Genetics at UMDNJ/Rutgers. Dr. Brooks is a molecular neuroscientist whose research focuses on deciphering the molecular mechanisms underlying memory and learning. These studies investigate gene-environment interactions in the context of aging, neurodegenerative disease and neurotoxicant exposure. Dr. Brooks was Director of the Center for Functional Genomics in the Aab Institute for Biomedical Science at the University of Rochester where 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 Neurological Surgery at The Ohio State University Medical School. He is also Professor of Molecular Medicine and Pathology at the University of Auckland in New Zealand where he directs neuroscience and gene therapy programs. From 2004 to 2006 he was the Research Lab Director of the Department of Neurological Surgery at Cornell. He served as Director of the



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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 therapy protocol. Dr. During is a graduate of the University of Auckland School of Medicine and did further postgraduate and residency training at M.I.T. from 1985 to 1987, 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, 10 and 11 to Financial Statements), but does not receive an additional fee for his participation in the SAB. Dr. Kaplitt, an expert and innovator in the development of gene therapy techniques against Parkinson's disease and other neurological disorders, performed the world's first gene therapy surgery for Parkinson's disease in 2003. He is among the first scientists to publish on the use of viruses for direct gene delivery in the living brain, and was the lead author on the first publication reporting the use of adeno-associated virus (AAV) vectors in the brain. Dr. Kaplitt is currently Associate Professor and Vice Chairman for Research, Department of Neurological Surgery, Weill Medical College of Cornell University, as well as Director Stereotactic and Functional Surgery and Director Laboratory of Molecular Neurosurgery at Cornell University. Dr. Kaplitt graduated magna cum laude with a bachelor's degree in molecular biology from Princeton University. He received his Ph.D. in molecular neurobiology from The Rockefeller University in 1993. He then received his M.D. from Cornell University School of Medicine in 1995 where he also completed his residency in Neurosurgery. Dr. Kaplitt is the son of Dr. Martin Kaplitt, the chairman of the Board.

*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 of 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 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 President of the American Epilepsy Society. His research interests have included 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, and more than 75 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 and Chairman 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 both the American and the World Society of Stereotactic and Functional Neurosurgery.

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*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 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 Friedman 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), Foundation Ipsen 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, 2010, the Company has incurred net losses of approximately \$57.9 million and negative cash flows from operating activities of approximately \$44.4 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 Item 1 Business Business of the Company Manufacturing ).

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The Company is currently seeking to raise funds sufficient to finance its ongoing operations after October 31, 2011 and to repay the Notes as of said date. If the Company is unable to obtain such additional funding, it may not be able to continue as a going concern after October 31, 2011.

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, 2010 included herein. (See Item 7 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 June 2010, the Company announced positive results from its Phase 2 clinical trial of its investigational gene therapy for Parkinson's disease. The Company is currently taking the steps necessary to receive regulatory approval to initiate a pivotal trial. At this time, the Company cannot determine whether such pivotal trial will yield successful safety results or efficacy results that would warrant regulatory approval necessary to commercialize its Parkinson's product.

If the results of a pivotal trial for Parkinson's disease do not warrant the necessary regulatory approvals, future operations and the potential for profitability will be significantly adversely affected and the business may not succeed. (See Item 1 Business 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

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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 trial for epilepsy. (See Item 1 Business 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 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 preclinical 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 for commercial use.

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





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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.

### **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 preclinical testing. It may take many years to complete preclinical 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 preclinical 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 in the field of gene transfer that may occur in the future, may result in

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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.

### **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 and Phase 2 clinical trials 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.



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**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 Item 1 Business 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 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 may 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 Preclinical Trials.**

Preclinical and clinical trials of 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 trials for depression and Huntington's disease, there can be no assurance that this insurance will continue to 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 has or may obtain in the future would have a material adverse effect on its business, financial condition, results of operations and future prospects. Further, any such claim against the Company, whether successful or not successful, may divert the attention of management and cash resources away from the development of new products and the operation of its business. (See Item 3 Legal Proceedings ).

**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

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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.

### **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 (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. 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. The BPRA Lease, which expires on April 30, 2011, provides for a base annual rent of approximately \$58,000 or \$4,833 per month through its term. (See Note 10 to Financial Statements). The Company intends to extend the term 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. On January 25, 2011, the Company amended the Facility Use Agreement, extending the term through November 10, 2013. As of December 31, 2010, the Company has paid OSU an amount of approximately \$106,500, representing rent owed under the Facility Use Agreement through November 10, 2010. Unless sooner terminated, the Company will pay an additional \$97,500 over the remaining three years of such agreement. (See Notes 10 and 11 to Financial Statements).

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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**

On February 7, 2011, plaintiffs Robert Zeman (RZ) and his wife, Julia Zeman (JZ), filed a complaint (the Complaint) in the United States District Court for the District of Massachusetts against the Company and other named defendants involved in the Company's Phase 2 clinical trial for the treatment of advanced Parkinson's disease. The Complaint is styled Robert Zeman et al v. Ziv Williams, M.D. et al.

The Complaint, among other things, alleges that RZ, a participant in the Phase 2 clinical trial, was injured during the trial's surgical procedure by receiving a double dose of the drug used in the trial on one side of his brain rather than a bilateral dose of such drug as called for by the trial's protocol, and that RZ was not adequately informed of the risks and potential consequences of his participation in the trial. The Complaint further alleges that JZ suffered loss of consortium as a result of RZ's alleged injuries.

RZ seeks from the Company approximately \$15,000,000 in damages, and JZ seeks from the Company approximately \$3,000,000 in damages.

The Company does not believe that RZ's claimed injuries are related to the drug used in the Phase 2 clinical trial or to the protocol of such trial. The Company believes that the claims against the Company set forth in the Complaint are without merit, and the Company intends to vigorously defend against such claims. (See Note 10 to Financial Statements).

**Item 4. Removed and 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 any shares of its capital stock while the Notes are outstanding. In addition, 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 268 stockholders of record as of March 11, 2011. The Company did not pay cash dividends during the two-year period ended December 31, 2010 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.



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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 2010		Fiscal Year 2009	
	High	Low	High	Low
First quarter	\$ 0.89	\$ 0.45	\$ 0.72	\$ 0.20
Second quarter	\$ 1.44	\$ 0.59	\$ 0.70	\$ 0.20
Third quarter	\$ 1.44	\$ 1.14	\$ 0.90	\$ 0.42
Fourth quarter	\$ 1.31	\$ 0.79	\$ 0.73	\$ 0.40

**Company Equity Compensation Plans**

The following table sets forth information as of December 31, 2010, 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
2000 Stock Option Plan approved by stockholders	4,606,833	\$ 0.93	2,465,352
Total	4,606,833	\$ 0.93	2,465,352

**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, 2010. The Company's fiscal year ends on the last day of December in each year. References to 2010 and 2009 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, 2010, the Company had an accumulated deficit of \$61,763, and it expects to incur additional

losses for the foreseeable future. The Company recognized net losses of \$10,163 for the fiscal year ended December 31, 2010, and \$13,461 for the fiscal year ended December 31, 2009.

Since its inception, the Company has financed its operations primarily through sales of its equity and debt securities. From inception through December 31, 2010, the Company received proceeds primarily from private sales of equity and debt securities and from the Merger

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of approximately \$51,095 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 currently 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 products for the treatment of TLE and depression but does not anticipate using its current funds for the further development of such products at this time. The Company also has undertaken efforts to develop a product for Huntington's disease and is continuing to engage in preclinical activities relating to such product. See Plan of Operation Epilepsy, Plan of Operation Depression 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 of gene transfer 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 of the planned surgeries associated with its Phase 2 clinical trial of gene transfer for the treatment of advanced Parkinson's disease. In June 2010, the Company announced positive results from such Phase 2 clinical trial. Trial participants who received NLX-P101 experienced statistically significant and clinically meaningful improvements in off-medication motor scores compared to control subjects who received sham surgery. In the trial, this benefit was seen at one month and continued virtually unchanged throughout the six month blinded study period. The results also demonstrated a positive safety profile for NLX-P101, with no serious adverse events related to the gene transfer or surgical procedure reported in the 12-month period following the surgical procedures. The results were published in an online-first edition of *The Lancet Neurology* on March 17, 2011. Subject to adequate funding, the Company expects to commence the open-label arm of the Phase 2 clinical trial in the second or third quarter of the 2011 fiscal year.

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 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 all surgeries conducted in the pivotal trial could be completed in the first half of 2014 and the estimated total direct costs to reach that milestone are expected to be between \$30 million and \$40 million. (See Item 1 Business Business of the Company Parkinson's Disease ).

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### *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.

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 Company's timetable for commencement of such 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.

The Company does not, at this time, intend to commit its current funds to continue work on its investigational gene transfer therapy for TLE. As previously stated, the Company intends to concentrate its current operations and resources primarily on its investigational Parkinson's disease therapy. (See Item 1 Business Business of the Company Epilepsy ).

### *Depression*

In October 2010, the Company announced the publication of a paper in Science Translational Medicine demonstrating the importance of the p11 gene in modulating depression in mice, utilizing the Company's investigational gene therapy approach. In the study, reduced levels of p11 in an area of the brain called the nucleus accumbens were associated with depressive behaviors in mice. An AAV vector was used to deliver the p11 gene back into the nucleus accumbens of mice who were lacking the p11 protein, reversing the depressive behavior and returning the animals to normal function.

The study also examined samples of brain tissue from a group of deceased human patients, half of whom had severe depression. It was found that there were significantly reduced levels of p11 in the nucleus accumbens of depressed patients compared to those without depression.

The Company's development of this investigational gene therapy for depression is currently in the preclinical phase. Additional preclinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this investigational gene therapy. The Company does not, at this time, intend to commit its current funds to continue work on its investigational gene transfer therapy for treating depression. As previously stated, the Company intends to concentrate its current operations and resources primarily on its investigational Parkinson's disease therapy. (See Item 1 Business Business of the Company Depression ).

### *Huntington's Disease*

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

The Company's development of this investigational gene therapy for Huntington's disease is currently in the preclinical phase. The Company reviewed and analyzed its initial preclinical results and determined that additional preclinical testing is required prior to seeking regulatory clearance to commence a Phase 1 clinical trial for this investigational gene therapy. Although currently engaged in pre-clinical activities covered under the Company's existing research agreements, the Company proposes, at this time, to defer expending additional funds for preclinical tests while the

Company focuses its current operations and resources primarily on

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its investigational Parkinson's disease gene therapy. (See Item 1 Business Business of the Company Huntington's Disease ).

*Other Therapies*

The Company has undertaken efforts to develop therapies to treat other neurodegenerative and metabolic disorders, including genetically-based obesity under its research agreements with Cornell and OSURF. Since the Company's primary focus remains the development of its product for the treatment of Parkinson's disease, the Company does not expect to allocate any further resources during the 2011 fiscal year to these other treatment candidates. (See Item 1 Business Business of the Company Other Neurodegenerative and Metabolic Disorders ).

*2011 Expenditures*

Over the next 12 months, the Company expects to spend, in addition to its normal recurring expenditures, approximately \$2,700 in Phase 2 clinical trial expenses with regard to its Parkinson's treatment; approximately \$1,800 in costs associated with preparing for a pivotal trial for its Parkinson's treatment, including the manufacturing of the product and infusion system to be used for such trial and the administrative costs associated with contracting with surgical sites for such trial; approximately \$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; approximately \$750 in expenses in order to scale up manufacturing capabilities for the supply of product for a Parkinson's pivotal trial; and approximately \$550 in research and licensing fees. The Company will require additional financing to fully fund these expenditures. (See Liquidity and Capital Resources ).

**Results of Operations****Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009**

*Revenues.* The Company did not generate any operating revenues in 2010 and 2009.

*Research and Development Expenses.* The following table summarizes the Company's research and development expenses for fiscal years ended December 31, 2010 and 2009:

	<b>2010</b>	<b>2009</b>	<b>\$ Change</b>
Clinical Trial Expenses	\$ 3,027	\$ 4,413	\$ (1,386)
Compensation Expenses	1,304	1,121	183
Research, Development and Licensing Fees	553	747	(194)
Manufacturing Process Development	292	617	(325)
Medical and Scientific Consultants	626	555	71
Laboratory Expenses	152	216	(64)
Other R&D Expenses	81	175	(94)
Totals	\$ 6,035	\$ 7,844	\$ (1,809)

Research and development expenses decreased by \$1,809 in 2010 from the comparable expenses in 2009. The decrease was mainly due to a \$1,386 decrease in expenses related to the Company's Phase 2 clinical trial for Parkinson's disease, including a (i) \$653 decrease in fees due to the investigator, surgical sites and brain imaging sites

participating in the clinical trial, (ii) \$288 decrease in Manufacturing and Development Agreement expenses relating to the catheter infusion device used in the Phase 2 clinical trial, (iii) \$240 decrease 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, and (iv) \$205

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decrease in costs associated with the manufacturing of product for a potential open-label arm to the Phase 2 clinical trial. The decrease was also due to a \$325 decrease in Manufacturing Process Development expenses for large scale manufacturing of the Company's products and infusion devices, a \$194 decrease in fees related to license agreements and sponsored research agreements and a \$158 decrease in laboratory and other miscellaneous research and development expenses. These decreases were offset, in part, by a \$254 increase in cash and non-cash compensation paid to the Company's researchers and scientific consultants.

*General and Administrative Expenses.* General and administrative expenses increased by \$320 to \$3,217 in 2010 as compared to \$2,897 in 2009. This increase was due mainly to a \$423 increase in professional fees, including legal fees, strategic advisory fees, accounting fees and investor and public relations fees. The increase was also due to \$208 increase in cash and non-cash compensation expense to Company employees. These increases were offset by \$244 in grant monies received in 2010 as part of the Therapeutic Discovery Tax Credit Program administered by the U.S. Internal Revenue Service and by decreases in miscellaneous general and administrative expenses.

*Other (Expense) Income, Net.* The Company had net other expense of \$911 in 2010 as compared to net other expense of \$2,720 in 2009. The change is mainly due to a \$2,319 decrease in charges recognized for the change in fair value of its derivative liabilities in 2010. This decrease is offset by a \$455 increase in interest expense for the year ended December 31, 2010 related to the issuance of the Notes in December 2010, as well as a \$55 decrease in interest income for the year ended December 31, 2010.

## **Liquidity and Capital Resources**

Cash and cash equivalents were \$8,055 at December 31, 2010.

The Company is still in the development stage and has not generated any operating revenues as of December 31, 2010. 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 plan of operations after October 31, 2011 and to repay the Notes as of said date. If the Company is unable to obtain such additional funding, it may not be able to continue as a going concern after October 31, 2011.

The Company 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. (See Item 1 Business Business of the Company Business Strategy ). 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 Item 1A 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, 2010 included herein.

Net cash used in operating activities was \$7,870 in fiscal year 2010 as compared to \$8,971 in fiscal year 2009. The \$1,101 decrease in net cash used in operations was primarily due to a \$3,298 decrease in net loss, offset by \$2,091 in adjustments to net loss for decreased non-cash expenses, as well as a \$106 increase in cash used as a result of changes to working capital in 2010.





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The Company had net cash used in investing activities of \$276 during the year ended December 31, 2010 as compared to \$298 during the year ended December 31, 2009. Cash used in investing activities relates to purchases of equipment and additions to intangible assets made by the Company during 2010 and 2009.

Net cash provided by financing activities during the year ended December 31, 2010 was \$6,564, solely as a result of the proceeds received from the issuance of the Notes and warrants by the Company in December 2010. (See Note 9 to Financial Statements). The Company had no net cash used in or provided by financing activities during the year ended December 31, 2009.

## **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 United States 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, 2010, as outlined in the accompanying notes to the financial statements, have been applied consistently for the year ended December 31, 2010. 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



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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 Accounting Standards Codification (the Codification or 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.

**Recent Accounting Pronouncements**

In January 2010, the Financial Accounting Standards Board 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 interim and annual reporting 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 impact of this update on the Company's financial statements will depend on the size and nature of future business combinations.

Effective January 1, 2010, the Company adopted the provisions relating to Level 1 and Level 2 disclosures and such provisions did not have a material impact on its financial statements. The Company does not expect the provisions relating to Level 3 disclosures to 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, 2010 and 2009, 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, 2010. 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 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 provide a reasonable basis for our opinion.

In our opinion, based on our audits, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2010 and 2009 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, 2010, in conformity with accounting principles generally accepted in the United States of America.

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 deficiencies in working capital and capital 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 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP  
New York, New York  
March 25, 2011

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

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$8,055	\$9,637
Prepaid expenses and other current assets	481	395
Total current assets	8,536	10,032
Equipment, less accumulated depreciation of \$682 and \$624 at December 31, 2010 and 2009, respectively	71	129
Intangible assets, less accumulated amortization of \$364 and \$262 at December 31, 2010 and 2009, respectively	1,065	891
Other assets	5	5
Total Assets	\$9,677	\$11,057
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$2,302	\$1,834
Notes payable, net of discount	4,695	
Derivative financial instruments, at estimated fair value    warrants	6,840	3,847
Total liabilities	13,837	5,681
Commitments and contingencies		
Stockholders' equity (deficit):		
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, 2010 and 2009, with an aggregate liquidation preference of \$1	-	-
Series C    Convertible, \$0.10 par value; 700,000 shares designated, 278,849 and 281,263 shares issued and outstanding at December 31, 2010 and 2009, respectively, with an aggregate liquidation preference of \$8,369 and \$7,008 at December 31, 2010 and 2009, respectively	28	28
Series D    Convertible, \$0.10 par value; 792,100 shares designated, 734,898 shares issued and outstanding at December 31, 2010 and 2009,	73	73

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with an aggregate liquidation preference of \$32,547 and \$29,420, at December 31, 2010 and 2009, respectively

Common Stock:

\$0.001 par value; 100,000,000 shares authorized, 27,918,148 and 27,865,010 shares issued and outstanding at December 31, 2010 and 2009, respectively

	28	28
Additional paid-in capital	57,474	56,775
Deficit accumulated during the development stage	(61,763)	(51,528)
Total stockholders' equity (deficit)	(4,160)	5,376
Total Liabilities and Stockholders' Equity (Deficit)	\$9,677	\$11,057

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, 2010
	2010	2009	
Revenues	\$ -	\$ -	\$ -
Operating expenses:			
Research and development	6,035	7,844	33,496
General and administrative expenses	3,217	2,897	22,214
Loss from operations	(9,252)	(10,741)	(55,710)
Other (expense) income:			
Dividend, interest and other (expense) income, net	2	57	1,885
Interest expense-related parties	(455)	-	(866)
Change in estimated fair value of derivative financial instruments - warrants	(458)	(2,777)	(3,235)
Other (expense) income, net	(911)	(2,720)	(2,216)
Net loss	(10,163)	(13,461)	\$(57,926)
Preferred stock dividends	(3,202)	(2,974)	
Charge for contingent beneficial conversion feature	(72)	-	
Net loss applicable to common stock	\$(13,437)	\$(16,435)	
Net loss applicable to common stock per share, basic and diluted	\$(0.48)	\$(0.59)	
Weighted average common shares outstanding, basic and diluted	27,867,485	27,830,714	



See accompanying notes to financial statements.

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**NEUROLOGIX, INC.**  
**(A Development Stage Company)**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE PERIOD FROM FEBRUARY 12, 1999 (INCEPTION) THROUGH DECEMBER 31, 2010**  
**(Amounts in thousands, except for share and per share amounts)**

	Series D		Series C		Common Stock		Additional		Deficit		Total
	Preferred	Preferred	Preferred	Preferred	Shares	Amount	Paid-in	Unearned	Development	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Compensation	Stage	During	
										the	
Sale of common stock to founders	-	\$ 0	-	\$ 0	6,004,146	\$ 0	\$ 4	\$ 0	\$ 0	\$ 0	\$ 4
Net loss	-	-	-	-	-	-	-	-	-	(328)	(328)
<b>Balance, December 31, 1999</b>	-	0	-	0	6,004,146	0	4	0		(328)	(324)
Net loss	-	-	-	-	-	-	-	-	-	(1,055)	(1,055)
<b>Balance, December 31, 2000</b>	-	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)
<b>Balance, December 31, 2001</b>	-	0	-	0	6,263,637	0	37	0		(2,253)	(2,216)
Retirement of founder shares	-	-	-	-	(33,126)	-	-	-	-	-	-
	-	-	-	-	368,761	-	577	(577)	-	-	-

Common Stock issued pursuant 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)
<b>Balance, December 31, 2002</b>	-	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)
<b>Balance, December 31, 2003</b>	-	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
	-	-	-	-	-	-	-	202	-	202

Amortization of unearned compensation										
Stock options granted for services	-	-	-	-	-	-	42	(42)	-	-
Exercise of stock options	-	-	-	-	10,000	-	15	-	-	15
Net loss	-	-	-	-	-	-	-	-	(2,937)	(2,937)
<b>Balance, December 31, 2004</b>	-	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)

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<b>Balance, December 31, 2005</b>	-	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
Dividend and accretion of fair value of beneficial conversion charge	-	-	25,298	3	-	-	(3)	-	(2,621)	(2,621)
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)
<b>Balance, December 31, 2006</b>	-	0	368,155	37	26,542,924	27	34,573	0	(23,786)	10,851
	428,571	43	-	-	-	-	14,727	-	-	14,770

Sale of Series D Preferred Stock through private placement at an average price of \$35.00 per share										
Fair value of beneficial conversion rights issued in connection with the issuance of Series D Preferred Stock	-	-	-	-	-	-	2,130	-	-	2,130
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 to Series C Preferred Stock	-	-	-	-	-	-	627	-	(627)	-
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	-	-	-	-	-	-	702	-	-	702

expense										
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)
<b>Balance, December 31, 2007</b>	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
	-	-	-	-	-	-	3	-	-	3

Non-employee share-based compensation										
Conversion of Series C Preferred Stock to Common Stock	-	-	(6,000)	-	131,250	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	(6,320)	(6,320)



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<b>Balance, December 31, 2008</b>	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)
<b>Balance, December 31, 2009</b>	734,898	\$ 73	281,263	\$ 28	27,865,010	\$ 28	\$ 56,775	\$ 0	\$ (51,528)	\$ 5,376
Contingent beneficial conversion feature related to Series C Preferred Stock	-	-	-	-	-	-	72	-	(72)	-
Employee share-based compensation expense	-	-	-	-	-	-	501	-	-	501
Non-employee share-based compensation	-	-	-	-	-	-	126	-	-	126
Conversion of Series C Preferred Stock to Common Stock	-	-	(2,414)	-	53,138	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	(10,163)	(10,163)

**Balance,  
December 31,  
2010**

734,898	\$	73	278,849	\$	28	27,918,148	\$	28	\$	57,474	\$	0	\$	(61,763)	\$	(4,160)
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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, 2010
	2010	2009	
Operating activities:			
Net loss	\$(10,163)	\$(13,461)	\$(57,926)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	58	82	688
Amortization	102	80	504
Gain on redemption of investment	-	-	(62)
Stock options granted for services	-	-	9
Impairment of intangible assets	-	5	199
Amortization of deferred financing cost and discount on notes payable	270	-	270
Amortization of non-employee share-based compensation	140	228	1,847
Change in estimated fair value of derivative financial instrument warrants	458	2,777	3,235
Share-based employee compensation expense	501	448	3,333
Non-cash interest expense	-	-	378
Changes in operating assets and liabilities			
Decrease (increase) in prepaid expenses and other current assets	296	(115)	834
Increase in accounts payable and accrued expenses	468	985	2,242
 Net cash used in operating activities	 (7,870)	 (8,971)	 (44,449)
Investing activities:			
Security deposits paid	-	-	(7)
Purchases of equipment	-	(70)	(645)
Additions to intangible assets	(276)	(228)	(1,738)
Proceeds from redemption of investment	-	-	65
Purchases of marketable securities	-	-	(12,673)
Proceeds from maturities of marketable securities	-	-	12,673
 Net cash used in investing activities	 (276)	 (298)	 (2,325)

Financing activities:			
Proceeds from notes payable and warrants issued	6,564	-	7,664
Borrowings from related party	-	-	2,000
Cash acquired in Merger	-	-	5,413
Merger-related costs	-	-	(375)
Payments of capital lease obligations	-	-	(99)
Proceeds from exercise of stock options	-	-	733
Proceeds from issuance of common stock and warrants	-	-	5,066
Proceeds from issuance of preferred stock	-	-	34,427
Net cash provided by financing activities	6,564	-	54,829
Net (decrease) increase in cash and cash equivalents	(1,582)	(9,269)	8,055
Cash and cash equivalents, beginning of period	9,637	18,906	-
Cash and cash equivalents, end of period	\$8,055	\$9,637	\$8,055
Supplemental disclosure of non-cash investing and financing activities:			
Dividends on Series C Preferred Stock paid in preferred shares	\$-	\$-	\$1,811
Accrued dividends on Preferred Stock	\$3,202	\$2,974	\$9,120
Accretion of fair value of beneficial conversion on preferred stock	\$-	\$-	\$5,313
Accretion of contingent beneficial conversion related on Series C Preferred Stock	\$72	\$-	\$911
Induced conversion of preferred stock in connection with issuance of Series D Preferred Stock	\$-	\$-	\$2,796
Issuance of Common Stock to pay debt	\$-	\$-	\$2,372
Reverse acquisition net liabilities assumed, excluding cash	\$-	\$-	\$(214)
Mandatory redeemable convertible preferred stock converted to Common Stock	\$-	\$-	\$500
Common Stock issued to acquire intangible assets	\$-	\$-	\$24
Stock options granted for services	\$-	\$-	\$1,424
Deferred research and development cost resulting from Medtronic Stock Purchase	\$-	\$-	\$795
Acquisition of equipment through capital leases	\$-	\$-	\$106

See accompanying notes to financial statements.

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**NEUROLOGIX, INC.**  
**(A Development Stage Company)**

**NOTES TO FINANCIAL STATEMENTS**  
**(Amounts in thousands, except for share and per share amounts)**

**(1) Description of Business**

Neurologix, Inc. (Neurologix or the Company ), is engaged in the research and development of proprietary treatments for disorders of the brain and central nervous system, primarily utilizing gene therapies. These treatments are designed as alternatives to conventional surgical and pharmacological treatments. The Company has not generated any operating revenues and, accordingly, it is a development stage company as defined by ASC Topic 915.

The Company incurred net losses of \$10,163, \$13,461 and \$57,926 and negative cash flows from operating activities of \$7,870, \$8,971 and \$44,449 for the years ended December 31, 2010 and 2009 and for the period from February 12, 1999 (inception) to December 31, 2010, respectively. The Company expects that it will continue to incur net losses and cash flow deficiencies from operating activities for the foreseeable future.

**(2) Summary of significant accounting policies and basis of presentation**

**(a) Basis of Presentation:**

As of December 31, 2010, the Company had cash and cash equivalents of \$8,055. Based on its cash flow projections, the Company will need additional financing to carry out its planned business activities and plan of operations after October 31, 2011 and to repay the promissory notes (Notes ) for an aggregate of \$7,000 issued pursuant to the Note and Warrant Purchase Agreement (the Purchase Agreement ), dated December 6, 2010. The Company is currently seeking to raise funds, through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, sufficient to finance its ongoing 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. If the Company is unable to obtain such additional funding, it may not be able to continue as a going concern after October 31, 2011. The accompanying financial statements have been prepared assuming the Company's ability to continue as a going concern. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

On February 10, 2004, the Company completed the merger (the Merger ) of a wholly-owned subsidiary with Neurologix Research, Inc. (NRI ). Following the Merger, NRI became a wholly-owned subsidiary of the Company and stockholders of NRI received an aggregate number of shares of the Company's common stock, par value \$0.001 per share (the Common Stock ), representing approximately 68% of the total number shares of Common Stock outstanding after the Merger. The shares of NRI common stock, convertible preferred stock and Series B convertible preferred stock outstanding at the effective time of the Merger were converted into an aggregate of 15,408,413 shares of Common Stock and outstanding options to purchase an aggregate of 257,000 shares of the NRI common stock were converted into options to purchase an aggregate of 709,459 shares of Common Stock. In addition, the Board and management of the Company were controlled by members of the board of directors and management of NRI prior to the Merger.

Accordingly, the Merger was accounted for as a reverse acquisition, with NRI being the accounting parent and Neurologix being the accounting subsidiary. The financial statements include the operations of Neurologix, the accounting subsidiary, from the date of acquisition. Since the Merger was accounted for as a reverse acquisition, the accompanying financial statements reflect the historical financial statements of NRI, the accounting acquirer, as

adjusted

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**NEUROLOGIX, INC.  
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for the effects of the exchange of shares on its equity accounts, the inclusion of net liabilities of the accounting subsidiary as of February 10, 2004 on their historical basis and the inclusion of the accounting subsidiary's results of operations from that date.

On September 10, 2004, the Company amended and restated its Certificate of Incorporation, as a result of which it effected a reverse stock split of the shares of Common Stock at a ratio of 1 for 25 and reduced the Company's number of authorized shares of Common Stock from 750,000,000 to 60,000,000. All information related to Common Stock, preferred stock, options and warrants to purchase Common Stock and loss per share included in the accompanying financial statements has been retroactively adjusted to give effect to the Company's 1 for 25 reverse stock split, which became effective on September 10, 2004.

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 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. As a result of such short form merger, the Company no longer classified its financial statements and notes thereto as consolidated.

On May 9, 2007, at the Company's Annual Meeting of Stockholders, the Company's Certificate of Incorporation was restated to: (i) increase the number of authorized shares of Common Stock from 60,000,000 to 100,000,000, (ii) increase the total number of authorized shares of capital stock from 65,000,000 to 105,000,000, (iii) delete the designation of Series B Preferred Stock and (iv) decrease the number of authorized shares of Series A Preferred Stock from 300,000 to 650.

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

**(b) *Development Stage:***

The Company has not generated any revenues and, accordingly, is in the development stage as defined in the provisions of Accounting Standards Codification (the Codification or ASC) Topic 915, Development Stage Entities.

**(c) *Use of Estimates:***

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





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***(d) Cash and Cash Equivalents:***

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company is subject to credit risk related to its cash equivalents and marketable securities. From time to time, the Company places its cash and cash equivalents in money market funds and United States Treasury bills with a maturity of three months or less.

***(e) Equipment:***

Equipment is stated at cost less accumulated depreciation. The Company records depreciation of property and equipment using accelerated methods over an estimated useful life of between three and seven years.

***(f) Intangible Assets:***

Intangible assets consist of patents and patent rights developed internally and obtained under licensing agreements and are amortized on a straight-line basis over their estimated useful lives, which range from 15 to 20 years. The Company estimates amortization expenses related to intangible assets owned as of December 31, 2010 to be approximately \$110 per year for the next five years.

***(g) Impairment of Long-Lived Assets:***

The Company follows the provisions of ASC Topic 360-10, Impairment or Disposal of Long-Lived Assets, which requires impairment losses to be recorded on long-lived assets with definitive lives when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the asset's carrying amount. In the evaluation of the fair value and future benefits of long-lived assets, the Company performs an analysis of the anticipated undiscounted future net cash flows of the related long-lived assets. If the carrying value of the related asset exceeds the undiscounted cash flows, the carrying value is reduced to its fair value. Various factors including future sales growth and profit margins are included in this analysis. The Company recognized losses of \$0 and \$5 associated with abandoned patent applications that were written-off in the years ended December 31, 2010 and 2009, respectively.

***(h) Income Taxes:***

The Company follows the provisions of ASC Topic 740, Income Taxes (ASC Topic 740), which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed for temporary differences between the financial statement and tax bases of assets and liabilities that will result in future taxable or deductible amounts, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

***(i) 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

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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. Up front license fees are expensed when paid, and milestone fees are expensed upon the attainment of such milestone. Certain other 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.

***(j) Stock-Based Compensation:***

At December 31, 2010, the Company had one active share-based employee compensation plan. Stock option awards granted from this plan are granted at the fair market value on the date of grant, and vest over a period determined at the time the options are granted, ranging from one to five years, and generally have a maximum term of ten years. Certain options provide for accelerated vesting if there is a change in control (as defined in the plan) or if there is a termination of employment event for specified reasons set forth in certain employment agreements. When options are exercised, new shares of Common Stock are issued.

At the Company's Annual Meeting of Stockholders held on May 9, 2006, the Company's 2000 Stock Option Plan was amended to increase the number of shares that may be issued pursuant thereto from 1,300,000 to 3,800,000 shares. At the Company's Annual Meeting of Stockholders held on May 8, 2008, the Company's 2000 Stock Option Plan was further amended to increase the number of shares that may be issued pursuant thereto from 3,800,000 to 6,000,000 shares. At the Company's Annual Meeting of Stockholders held on May 11, 2010, the Company's 2000 Stock Option Plan was further amended to increase the number of shares that may be issued pursuant thereto from 6,000,000 to 8,000,000 shares.

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.

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.

***(k) Basic and Diluted Net Loss Per Common Share:***

Basic net loss per common share excludes the effects of potentially dilutive securities and is computed by dividing net loss applicable to holders of Common Stock by the weighted average number of common shares outstanding for the period. Diluted net income or loss per common share is adjusted for the effects of convertible securities, options, warrants and other potentially dilutive financial instruments only in the periods in which such effects would have been dilutive.



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The following securities were not included in the computation of diluted net loss per share because to do so would have had an anti-dilutive effect for the periods presented:

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Stock options	4,606,833	4,173,833
Warrants	8,965,617	7,441,920
Common Stock issuable upon conversion of Series A Convertible Preferred Stock	645	645
Common Stock issuable upon conversion of Series C Convertible Preferred Stock	6,138,186	6,152,628
Common Stock issuable upon conversion of Series D Convertible Preferred Stock	22,173,647	22,173,647

***(l) Derivative Instruments:***

The Company's derivative liabilities are related to warrants issued in connection with financing transactions and are therefore not designated as hedging instruments. All derivatives are recorded on the Company's balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. (See Note 4 and Note 5).

***(m) Financial Instruments and Fair Value:***

ASC Topic 820, Fair Value Measurements and Disclosures, (ASC Topic 820) establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC Topic 820 are described below:

*Level 1* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

*Level 2* Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

*Level 3* Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

In estimating the fair value of the Company's derivative liabilities, the Company used a probability-weighted Black-Scholes option pricing model. (See Note 4 and Note 5).

Financial assets with carrying values approximating fair value include cash and cash equivalents. Financial liabilities with carrying values approximating fair value include accounts payable and other accrued liabilities. The financial statement carrying value of the Company's debt approximates its fair value based on interest rates currently available to the Company for borrowings with similar characteristics and maturities.

**(n) Subsequent Events:**

The Company follows the provisions of ASC Topic 855-10, Subsequent Events, relating to subsequent events. This guidance establishes principles and requirements for

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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. The Company has evaluated subsequent events up to the date of issuance of this report.

**(o) *Recent Accounting Pronouncements:***

In January 2010, the Financial Accounting Standards Board 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 interim and annual reporting 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 impact of this update on the Company's financial statements will depend on the size and nature of future business combinations.

Effective January 1, 2010, the Company adopted the provisions relating to Level 1 and Level 2 disclosures and such provisions did not have a material impact on its financial statements. The Company does not expect the provisions relating to Level 3 disclosures to have a material impact on its financial statements.

**(3) *Related Party Transactions***

The Company is party to an Amended and Restated Consulting Agreement, dated April 25, 2005, with Dr. Michael Kaplitt (Michael Kaplitt), one of the Company's scientific co-founders and the son of Dr. Martin J. Kaplitt (Martin Kaplitt), the Company's Chairman of the Board. Pursuant to the terms of this agreement, Michael Kaplitt provides advice and consulting services on an exclusive basis in scientific research on human gene transfer in the nervous system and serves as a member of the Company's Scientific Advisory Board (the SAB). Michael Kaplitt is also the neurosurgeon that performed the surgical procedures on the twelve patients required by the protocol for the Company's Phase 1 clinical trial for the treatment of Parkinson's disease, and assisted the Company in its Phase 2 clinical trial for the treatment of Parkinson's disease. The Company paid Michael Kaplitt approximately \$175 in consulting fees in each of 2010 and 2009, respectively. Under this agreement, the Company granted Michael Kaplitt non-qualified stock options to purchase 160,000 shares of Common Stock at an exercise price of \$2.05 per share on April 25, 2005, all of which expired unexercised in 2010. On May 11, 2010, the Company granted Michael Kaplitt non-qualified options to purchase 160,000 shares of Common Stock at an exercise price of \$0.65 per share. (See Notes 10 and 11).

In accordance with The Rockefeller University's (Rockefeller) Intellectual Property Policy, an aggregate of one-third of all income that it receives from licensing transactions is paid to the inventors. Michael Kaplitt received less than \$2 in each of 2010 and 2009 from Rockefeller as a result of payments made by the Company to Rockefeller under a non-exclusive license agreement. (See Note 10).

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In accordance with Cornell University's (Cornell) Inventions and Related Property Rights Policy, an aggregate of one-third of all income that it receives from licensing transactions is paid to the inventors. Michael Kaplitt received approximately \$6 and \$21 in 2010 and 2009, respectively as a result of payments made by the Company to Cornell under the Cornell License Agreement. (See Note 10).

Dr. Matthew During, one of the Company's scientific co-founders and a member of the SAB, received approximately \$17 in each of 2010 and 2009 from Thomas Jefferson University (TJU) as a result of payments made by the Company to TJU under two exclusive license agreements. The amounts received by Dr. During represent approximately 18% of the total payments made by the Company to TJU in each of 2010 and 2009.

Dr. During received less than \$2 in each of 2010 and 2009 from Yale University (Yale) as a result of payments made by the Company to Yale under a non-exclusive license agreement. The amounts received by Dr. During represent approximately 25% of the total payments made by the Company to Yale in each of 2010 and 2009.

Dr. During and the Company entered into a consulting agreement in October 1999 which was subsequently amended. The consulting agreement, as amended, provides for payments to Dr. During of \$175 per year through September 2011. On May 11, 2010, the Company granted Dr. During non-qualified options to purchase 60,000 shares of Common Stock at an exercise price of \$0.65 per share. (See Note 10).

In August 2004, the Company subleased office space at One Bridge Plaza, Fort Lee, New Jersey from Palisade Capital Securities, LLC (PCS), an affiliated company, for use as its corporate offices for a base annual rent of approximately \$36 or \$3 per month, and such lease (the Sublease) expired on June 30, 2009. (See Note 10).

Effective February 23, 2007, the Company entered into a consulting agreement with Martin Kaplitt. Under the terms of this agreement, Martin Kaplitt provides medical and scientific consulting and advisory services to the Company. The Company paid Dr. Kaplitt \$125 in each of 2010 and 2009 under this agreement. (See Notes 10 and 11).

On December 6, 2010, the Company issued an aggregate of \$7,000 of the Notes and warrants to purchase an aggregate of 2,430,555 shares of Common Stock to General Electric Pension Trust (GE), Corriente Master Fund, L.P. (Corriente) and Palisade Concentrated Equity Partnership II, L.P. (Palisade). At the time of the issuance of the Notes and the related warrants each of GE, Corriente and Palisade, or affiliated entities thereof, were each existing stockholders of the Company.

The Notes bear interest at 10% per annum, mature on October 31, 2011, and are secured by substantially all of the assets of the Company. At maturity, the Company will pay an amount equal to 1.2 times the principal amount of the Notes, plus accrued interest included in accrued expenses. No principal or interest had been paid on the Notes as of December 31, 2010. (See Note 9).

**(4) Derivative Financial Instruments**

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40. ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an





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embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception.

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, all warrants (the Warrants) issued in connection with the issuance of the Notes, the Series C Stock and the Series D Stock must be treated as derivative liabilities on the Company's balance sheet.

Consistent with ASC Topic 815-40 requirements, the Company recognized the cumulative effect of the change in accounting principle to reduce the opening balance of the deficit accumulated during the development stage for fiscal year 2009. The cumulative effect adjustment of \$5,183 represents the difference between the amounts recognized on the balance sheet before initial application of ASC Topic 815-40 on January 1, 2009. Additionally, the initial fair value of the Warrants, aggregating \$6,252, which were initially recorded as additional paid-in capital upon issuance, was reclassified to long-term liabilities upon the adoption of ASC Topic 815-40. The amounts recognized at initial issuance were determined based on the estimated fair value of the Warrants using a probability-weighted Black-Scholes option pricing model. Prospectively, the Warrants are re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value are recorded as non-cash valuation adjustments within other income (expense) in the Company's statement of operations. The Company recorded other expense relating to the change in fair value of the Warrants of \$458 and \$2,777 for the years ended December 31, 2010 and 2009, respectively.

The Company estimates the fair value of the Warrants using the probability-weighted Black-Scholes option pricing model. The assumptions used for the years ended December 31, 2010 and 2009 are noted in the following table:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Expected term	3 to 7 years	5 to 7 years
Risk-free interest rate	1.02% - 2.71%	2.31% - 2.93%
Expected volatility	129%	123%
Dividend yield	0%	0%

Expected volatility is based on historical volatility of the Common Stock. The Warrants have a transferability provision and based on guidance provided in SAB 107 for options issued with such a provision, the Company used the full contractual term as the expected term of the Warrants. The risk free interest rate is based on the three-year, five-year and seven-year U.S. Treasury security rates. (See Note 7).

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**(5) Fair Value Measurements**

The following tables present the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2010 and December 31, 2009:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010
Derivative liabilities related to Warrants	\$ -	\$ -	\$ 6,840	\$ 6,840

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2009
Derivative liabilities related to Warrants	\$ -	\$ -	\$ 3,847	\$ 3,847

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the years ended December 31, 2010, 2009 and 2008:

Balance at December 31, 2008	\$ -
Cumulative effect of change in accounting	1,070
Unrealized losses	2,777
Balance at December 31, 2009	3,847

Fair value of warrants issued	2,535
Unrealized losses	458
Balance at December 31, 2010	\$ 6,840

The unrealized losses on the derivative liabilities are classified in other expenses as a change in derivative liabilities in the Company's statement of operations. Fair value is determined based on a probability-weighted Black-Scholes option pricing model calculation. (See Note 4).

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC Topic 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

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**(6) Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Net deferred income tax assets:		
Net operating losses	\$24,017	\$19,740
Research & development credit	2,506	2,056
Equity based compensation	1,712	1,512
Unrealized loss on derivatives	-	1,109
Depreciable assets	56	38
Total net deferred income tax assets	28,291	24,455
Valuation allowance	(28,291)	(24,455)
Total net deferred income tax assets	\$-	\$-

At December 31, 2010, the Company has net operating loss carryforwards (NOLs) for federal income tax purposes of approximately \$50,189 which, if not used, expire through 2030. At December 31, 2010, the Company has NOLs for state income tax purposes of approximately \$44,133 which, if not used, expire through 2017. The Company has a deferred tax asset from research and development credits of approximately \$2,506 and \$2,056 at December 31, 2010 and 2009, respectively, which, if not used, will also expire through 2030. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of the Company pursuant to Internal Revenue Code Section 382. The Company has determined that an ownership change had occurred as of November 19, 2007. The Company does not believe that the changes in ownership will restrict its ability to use its losses and credits within the carryforward period. The Company records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the significant doubt related to the Company's ability to utilize its deferred tax assets, a valuation allowance for the full amounts of the deferred tax assets of \$28,291 and \$24,455 have been established at December 31, 2010 and 2009, respectively.

As a result of the increases in the valuation allowance of \$3,836, \$9,085 and \$28,145 during the years ended December 31, 2010 and 2009 and for the period from February 12, 1999 (inception) to December 31, 2010, respectively, there are no income tax benefits reflected in the accompanying statements of operations to offset pre tax

losses.

In order for the Company to recognize the accounting for uncertainty in the amount of income taxes recognized in the financial statements by prescribing a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by the taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company evaluated its tax positions as of December 31, 2010 and 2009 and does not have any unrecognized tax positions. The Company does not currently expect any significant changes to unrecognized tax positions during the fiscal

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year ended December 31, 2010. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2010 and 2009, the Company had no accrued interest or penalties.

In certain cases, the Company's uncertain tax positions are related to tax years that remain subject to examination by the relevant tax authorities. The Company files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 1999 through 2010 tax years generally remain subject to examination by federal and most state tax authorities.

**(7) Stock Options and Warrants****(a) 2000 Stock Option Plan:**

During 2000, the Company approved a stock option plan (the Plan) which provides for the granting of stock options and restricted stock to employees, independent contractors, consultants, directors and other individuals. A maximum of 800,000 shares of Common Stock were originally approved for issuance under the Plan by the Board. The Plan was amended in 2010 by the Board and the Company's stockholders to increase the number of shares available for issuance to 8,000,000 shares. As of December 31, 2010, the Company had 2,465,352 shares available for issuance under the Plan.

On November 9, 2005, the Board decided that all non-vested options held by any of the Company's consultants would be accelerated to vest as of December 31, 2005. There were 220,500 of non-vested options which vested as of December 31, 2005. No other terms or conditions of the options held by the consultants were modified. The acceleration of these options was approved to eliminate unnecessary variation in the statement of operations and the expense associated with the accounting for such options to the extent that they remained unvested. The fair value of these options is being amortized to expense over the term of the respective consulting agreements. The amount charged to operations for the years ended December 31, 2010 and 2009 were \$14 and \$43, respectively.

**(b) Option Activity:**

The amount of employee compensation expense recognized during the years ended December 31, 2010 and 2009 was comprised of the following:

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development	\$ 153	\$ 135
General and administrative	348	313
Share-based compensation expense	\$ 501	\$ 448

Net share-based compensation expense per basic and diluted common share	\$ (0.02)	\$ (0.02)
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A summary of option activity for the two years ended December 31, 2010 and December 31, 2009 is presented below:

Options	Shares Subject to Option (000)	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	3,623	\$ 1.38		
Granted	1,088	0.65		
Exercised	-	-		
Forfeited or expired	(537)	1.36		
Outstanding at December 31, 2009	4,174	1.19		
Granted	1,015	0.65		
Exercised	-	-		
Forfeited or expired	(582)	2.29		
Outstanding at December 31, 2010	4,607	\$ 0.93	4.77	\$ 817
Exercisable at December 31, 2010	3,711	\$ 1.00	4.42	\$ 652

The following are the assumptions used with the Black-Scholes option pricing model in determining stock-based compensation under ASC Topic 718 in 2010 and 2009:

	Year Ended December 31, 2010	2009
Expected option term	5 to 6 years	5 to 6 years
Risk-free interest rate	2.26%	2.06%
Expected volatility	129%	116%
Dividend yield	0%	0%

The fair value of each stock option award is estimated on the date of the grant using the Black-Scholes option pricing model. Expected volatility is based on historical volatility of the Common Stock. The risk-free interest rate is based on

the U.S. Treasury security rate.

The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin No. 107 (SAB 107) which averages an award's weighted-average vesting period and expected term for plain vanilla share options. Under SAB 107, options are considered to be plain vanilla if they have the following basic characteristics: granted at-the-money; exercisability is conditioned upon service through the vesting date; termination of service prior to vesting results in forfeiture; limited exercise period following termination of service; and options are non-transferable and non-hedgeable.

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In December 2007, the United States Securities and Exchange Commission (the SEC) issued Staff Accounting Bulletin No. 110 (SAB 110). SAB 110 was effective January 1, 2008 and expresses the views of the staff of the SEC with respect to extending the use of the simplified method, as provided in SAB 107, in developing an estimate of the expected term of plain vanilla share options in accordance with ASC Topic 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB 107, as amended by SAB 110. For the expected option term, the Company has plain-vanilla stock options and, therefore, used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB 107.

The weighted average grant-date fair value of options granted during 2010 and 2009 was \$0.57 and \$0.52, respectively and were estimated using the Black Scholes option valuation model. There were no options exercised in 2010 or 2009. The total intrinsic value of options outstanding at December 31, 2010 and 2009 was \$817 and \$0, respectively. The total intrinsic value of options exercisable at December 31, 2010 and 2009 was \$652 and \$0 respectively.

As of December 31, 2010, there was approximately \$170 of total unrecognized employee compensation expense related to non-vested share-based compensation arrangements, which is expected to be recognized over a weighted average period of one year.

As of December 31, 2010, there were 3,710,823 outstanding stock options that had vested with a weighted average exercise price of \$1.00, a weighted average remaining contractual term of approximately 4.4 years and an intrinsic value of \$652.

**(c) Warrants:**

On December 6, 2010, in connection with the issuance of the Notes, the Company issued warrants to purchase a total of 2,430,555 shares of Common Stock at an exercise price of \$1.44 per share, subject to certain adjustments set forth in the warrants. Such warrants expire on December 6, 2017 (See Notes 2 and 9). If such warrants are not exercised by December 6, 2017, they will terminate. The initial fair value of such warrants of approximately \$2,535 was recorded as a discount on the Notes and is being amortized as interest expense over the term of the Notes. The Company used the Black-Scholes option pricing model to compute the fair value of such warrants. Such warrants are exercisable at any time within their terms. No such warrants were exercised in the year ended December 31, 2010.

On April 28, 2008, in connection with the sale of the Series D Stock, the Company issued warrants to purchase a total of 1,077,586 shares of Common Stock at an exercise price of \$1.39 per share that expire on April 28, 2015 (See Note 9). If such warrants are not exercised by April 28, 2015, they will terminate. The Company initially computed the fair value of the warrants, or \$633, using the Black-Scholes option pricing model and then used the relative fair value method to allocate the proceeds from the offering to the warrants and the Series D Stock. As a result of that allocation, the value of the common shares issuable upon the conversion of the Series D Stock as of the date of issuance (the amount for which the shares could have been sold) exceeded the proceeds from the offering allocable to the Series D Stock by \$562. This amount represented the value of beneficial conversion rights which was immediately accreted. The warrants are exercisable at any time within their terms. No such warrants were exercised in the years ended December 31, 2010 and 2009.



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On November 19, 2007, in connection with the sale of the Series D Stock, the Company issued warrants to purchase a total of 3,232,758 shares of Common Stock at an exercise price of \$1.39 per share that expire on November 19, 2014. (See Note 9). If such warrants are not exercised by November 19, 2014, they will terminate. The warrants are exercisable at any time within their terms. No such warrants were exercised in the years ended December 31, 2010 and 2009.

On May 10, 2006, in connection with the sale of the Series C Stock, the Company issued warrants (the Series C Warrants) to purchase a total of 2,224,718 shares of Common Stock at an exercise price of \$2.05 per share that expire on May 10, 2013 (See Note 9). The Series C Warrants are exercisable anytime within their terms. No such warrants were exercised in the years ended December 31, 2010 and 2009. As a result of the issuance of the Notes and the sales of the Series D Stock, the exercise price of the Series C Warrants has been adjusted to \$1.75 per share.

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, all warrants issued in connection with the Notes, the Series D Stock and the Series C Stock are accounted for as derivative liabilities in the Company's balance sheet. (See Note 4).

In connection with the sale of shares of Common Stock to investors led by Merlin Biomed Group, the Company, during the period from February 4, 2005 to April 4, 2005, issued five-year warrants to purchase a total of 618,470 shares of Common Stock at an exercise price of \$1.625 per share. No such warrants were exercised throughout their respective terms and therefore expired in the year ended December 31, 2010.

In connection with the sale of shares of Common Stock to Medtronic International, Ltd. the Company, on April 27, 2005, issued five-year warrants to purchase a total of 285,388 shares of Common Stock at an exercise price of \$2.19 per share. No such warrants were exercised throughout their respective terms and therefore expired in the year ended December 31, 2010.

The following summarizes warrant activity for the years ended December 31, 2010 and 2009:

	Warrants		Weighted Average Exercise Price
January 1, 2009	7,441,920	\$	1.56
Granted	-		-
January 1, 2010	7,441,920		1.56
Granted	2,430,555		1.44
Forfeited/Cancelled	(906,858)		1.88
December 31, 2010	8,965,617		1.49

The weighted-average remaining contractual life of warrants outstanding was 4.4 and 3.9 years at December 31, 2010 and 2009, respectively. The exercise prices for the warrants outstanding at December 31, 2010 ranged from \$1.39 to \$1.75 per share.

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**(8) Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following:

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Accounts payable	\$ 988	\$ 880
Clinical trial fees	475	550
Professional fees	366	301
Compensation expense	195	-
Interest payable	186	-
Research fees	66	66
Other	26	37
	<b>\$ 2,302</b>	<b>\$ 1,834</b>

**(9) Private Placements****(a) Notes Payable**

On December 6, 2010, the Company entered into the Purchase Agreement with GE, Corriente and Palisade. (Palisade, together with GE and Corriente, are hereafter referred to as the Debt Investors ). The Debt Investors, or affiliated entities thereof, are each existing stockholders of the Company.

Pursuant to the Purchase Agreement, the Company issued the Notes for an aggregate of \$7,000. The Notes bear interest at 10% per annum, mature on October 31, 2011, and are secured by substantially all the assets of the Company. At maturity, the Company will pay an amount equal to 1.2 times the principal amount of the Notes, plus accrued interest. The Debt Investors also received 7-year warrants exercisable for an aggregate of 2,430,555 shares of Common Stock at an exercise price of \$1.44 per share, subject to certain adjustments set forth in such warrants.

The Notes will automatically be converted into a new series of the Company's preferred stock if such stock is senior to all other equity securities of the Company with respect to liquidation and dividend rights and is sold by the Company in a transaction or series of transactions in which the Company receives proceeds of \$30,000 or more (excluding proceeds attributable to conversion of the Notes). Should such transaction(s) occur prior to July 1, 2011, the Company will issue conversion shares in an amount equal to 1.1 times the principal amount of the Notes, plus accrued interest, divided by the price paid for the conversion shares. Should such transaction(s) occur between July 1, 2011 and October 30, 2011, the Company will issue conversion shares in an amount equal to 1.2 times the principal amount

of the Notes, plus accrued interest, divided by the price paid for the conversion shares.

In connection with the Notes, the Company recorded debt issuance costs, including placement agent fees and legal fees of approximately \$436, which were recorded as deferred charges on the balance sheet and are being amortized as interest expense over the term of the Notes. In addition, the Company recorded a discount on notes payable of approximately \$2,535 which represents the fair value of the warrants issued in connection with the notes payable, as determined utilizing the Black-Scholes pricing model with assumptions of expected life of seven years, volatility rate of 128%, risk-free interest rate of 2.26% and dividend rate of 0%. The



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discount on notes payable is reported net of related notes payable and is being amortized as interest expense over the term of the Notes. The estimated fair value of the warrants issued in connection with the Notes was recorded as a contingent liability, which is revalued each balance sheet date. Notes payable and related discount at December 31, 2010 and activity during the year then ended are as follows:

	<b>Notes Payable</b>	<b>Discount</b>	<b>Notes Payable, net of Discount</b>
Issuance of notes payable and warrants	\$ 7,000	\$ (2,535)	\$ 4,465
Amortization of discount to interest expense	-	230	230
Balance at December 31, 2010	\$ 7,000	\$ (2,305)	\$ 4,695

The Company will be required to pay an amount equal to 1.2 times the principal amount of the Notes, plus accrued interest at maturity. The Company is recording the additional 20% of principal as interest expense over the term of the Notes. Total interest accrued, including (i) the 10% interest the Notes bear, (ii) the amortization of debt discount, (iii) the amortization of debt issuance costs and (iv) the 20% additional principal due at maturity, for the year ended December 31, 2010 was \$455.

The Notes will become accelerated upon, among other things: (i) a sale of the Company or its assets or a merger or consolidation of the Company with or into another entity or entities and (ii) the receipt by the Company of at least \$30,000 in connection with the licensing of its rights to its Parkinson's product.

The Debt Investors were granted certain preemptive rights with respect to future financings of the Company and were granted certain registration rights with respect to the shares of Common Stock issuable on exercise of the warrants issued in connection with the Notes. Such registration rights were granted pursuant to a second amendment to the Registration Rights Agreement (the Registration Rights Agreement), dated as of November 19, 2007, by and among the Company, Corriente, GE and the holders of the Series C Stock.

In connection with the issuance of the Notes and the warrants issued in connection therewith, the holders of the Company's Series C Stock and Series D Stock (collectively, the Equity Investors), consented to a modification of the preemptive rights granted to them pursuant to (i) the Stock and Warrant Subscription Agreement, dated as of May 10, 2006, by and among the Company, GE, DaimlerChrysler Corporation Master Retirement Trust, n/k/a Chrysler Group LLC Master Retirement Trust (Chrysler), certain funds managed by ProMed Asset Management LLC (collectively, ProMed), Paul Scharfer, and David Musket, as amended by a letter agreement dated November 8, 2007, (ii) the Stock and Warrant Subscription Agreement, dated as of November 19, 2007, by and among the Company, GE and Corriente, and (iii) the Stock and Warrant Subscription Agreement, dated as of April 28, 2008, by and among the

Company, GE and Corriente. The modification resulted in a cutback in the amount of the Company's securities which could be acquired pursuant to such holders' preemptive rights in order to allow the Debt Investors to acquire up to 19% of the aggregate amount of securities offered by the Company in a future financing. Such modification was made pursuant to a Letter Agreement re Proposed Financing, dated November 23, 2010, among the Company, GE, Chrysler, ProMed, Corriente and David Musket.

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As a result of this financing, in accordance with the contingent anti-dilution terms of the Series C Stock, the Series C Stock's conversion rate was adjusted from 21.875 to 22.012579. This anti-dilution adjustment resulted in a contingent beneficial conversion charge of approximately \$72, which was used to calculate the net loss applicable to common stock for the year ended December 31, 2010.

**(b) *Series D Convertible Preferred Stock:***

On April 28, 2008, the Company issued and sold 142,857 shares of Series D Stock, at a price of \$35.00 per share, or a total of \$5,000, to Corriente in a private placement transaction, resulting in net proceeds after expenses of approximately \$4,932. Each share of Series D Stock is currently convertible into 30.172414 shares of Common Stock. The Series D Stock is not redeemable by the Company. In connection with the sale of the Series D Stock on April 28, 2008, the Company issued warrants to purchase approximately 1,077,586 shares of the Common Stock at an exercise price of \$1.39 per share that expire on April 28, 2015. (See Note 7).

On April 28, 2008, the Company also entered into an amendment to the Registration Rights Agreement, which provides an additional right to demand a registration (the Series D Demand), which may be requested by holders of the Series D Stock. All of the Debt Investors and the Equity Investors (collectively, the Investors) have a right to participate in the Series D Demand. The Company is required to pay a cash amount, as liquidated damages, to those Investors participating in the Series D Demand if a registration statement filed pursuant to such Series D Demand is not declared effective within 150 days of the notice containing the Series D Demand. With respect to the participating Equity Investors, the cash amount shall equal 1% of the total amount that such participating Equity Investors invested in the Company and, with respect to the participating Debt Investors, the cash amount shall equal 1% of the total principal amount then outstanding on Notes issued to such participating Debt Investors. Such cash amount is payable until such registration statement is declared effective up to an aggregate amount of \$1,000. This liquidated damages provision does not result in the Company recording a charge at this time.

Additionally, as a result of this financing, in accordance with the contingent anti-dilution terms of the Series C Stock, the Series C Stock's conversion rate was adjusted from 21.4724 to 21.875.

Upon a liquidation event (such as a liquidation, merger or sale of substantially all of the Company's assets), the holders of the Series D Stock, on a pari passu basis with the holders of the Company's Series A Preferred Stock, will have a liquidation preference prior and in preference to the holders of the Series C Stock and Common Stock or any other class or series of capital stock ranking junior to the Series D Stock, and will be entitled to receive a per share amount equal to the greater of: (i) \$35 plus all accrued and unpaid dividends thereon or (ii) the amount payable upon conversion of the Series D Stock into shares of Common Stock.

The Series D Stock accrues dividends at a rate of 7% per annum, payable in semi-annual installments, which accrue, cumulatively, until paid. The Company is prohibited from declaring, paying or setting aside any distribution or dividend for any shares of its capital stock (including the Series D Stock) while the Notes are outstanding. The Company accrued dividends on Series D Stock with a fair value of \$2,107 and \$1,967 as of December 31, 2010 and 2009, respectively. The Company disclosed this aggregate amount of arrearages in cumulative



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dividends on the face of the statement of operations below the net loss line, and such amount was used to calculate net loss applicable to common stock and common stock per share.

The holders of Series D Stock shall vote together with all other classes and series of capital stock of the Company as a single class on all actions to be taken by the Company's stockholders, except that, as long as the Series D Stock comprises at least 5% of the Company's outstanding capital stock, the approval of the holders in interest of 70% of the Series D Stock is required to (i) create any new class of capital stock that is senior to, or on parity with, the Series D Stock, (ii) amend the Company's Certificate of Incorporation, including the Series D Certificate, in any manner that adversely affects the Series D Stock and (iii) purchase or redeem any of the Company's capital stock or pay dividends thereon. Each share of Series D Stock will be entitled to a number of votes per share equal to the number of shares of Common Stock underlying such share of Series D Stock.

The Series D Stock's conversion rate will be adjusted if the Company issues Common Stock (or convertible securities) at a price per share below \$1.16. There is no termination date for this anti-dilution protection. The Series D Stock is also subject to customary adjustment for stock splits and reverse splits, and corporate transactions such as mergers and reorganizations.

In connection with the sale of the Series D Stock on November 19, 2007, the Company also issued warrants to purchase approximately 3,232,758 shares of Common Stock at an exercise price of \$1.39 per share that expire on November 19, 2014. (See Note 7).

***(c) Series C Convertible Preferred Stock:***

On May 10, 2006, the Company issued and sold 342,857 shares of Series C Stock, at a price of \$35.00 per share, or a total of approximately \$12,000, to GE, DaimlerChrysler Corporation Master Retirement Trust and certain funds managed by ProMed Management, LLC in a private placement transaction, resulting in net proceeds after expenses of approximately \$11,612. The shares of Series C Stock, including all in-kind dividends paid to date, are currently convertible into 22.012579 shares of Common Stock per share. The Series C Stock is not redeemable by the Company.

Upon a liquidation event (such as a liquidation, a merger or a sale of substantially all of the Company's assets), the holders of Series C Stock will have a liquidation preference prior and in preference to the holders of Common Stock or any other class or series of capital stock ranking junior to the Series C Stock, and will be entitled to receive a per share amount equal to the greater of: (i) \$35 plus unpaid dividends or (ii) the amount payable upon conversion to Common Stock.

Through November 19, 2007, the Series C Stock accrued paid-in-kind cumulative dividends at a rate of 9% per annum, payable in quarterly installments in shares of Series C Stock (PIK Dividends). Effective November 19, 2007, certain terms of the Series C Stock were amended as part of the issuance of Series D Stock, including the payment of a 9% semi-annual cash dividend in lieu of the PIK Dividends, and the inclusion of a provision that allows the Company to pay accrued and unpaid dividends in either cash or shares of Common Stock upon conversion of the Series C Stock. As of December 31, 2009, the Company paid PIK Dividends that had accrued through November 19, 2007 by issuing approximately 90,858 shares of Series C Stock with a fair value of \$1,811. The Company accrued cash dividends on

Series C Stock with a fair value of \$1,095 and \$1,007 as of December 31, 2010 and 2009, respectively.

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The Company disclosed this aggregate amount of arrearages in cumulative dividends on the face of the statement of operations below the net loss line, and such amount was used to calculate net loss applicable to common stock and common stock per share. The Company is prohibited from declaring, paying or setting aside any distribution or dividend for any shares of its capital stock (including the Series C Stock) while the Notes are outstanding.

Each share of Series C Stock will be entitled to a number of votes per share equal to the number of shares of underlying Common Stock. As long as the Series C Stock comprises at least 5% of the Company's outstanding securities, the Company may not create any new class of stock that is pari passu with or senior to the Series C Stock and junior to the Series D Stock without the consent of the holders of at least 70% of the Series C Stock.

As a result of the issuances of the Notes in December 2010 and the Series D Stock in November 2007 and April 2008, in accordance with the contingent anti-dilution terms of the Series C Stock's Certificate of Designation in effect at the time of each such issuance, the Series C Stock's conversion rate has been adjusted to 22.012579 shares of Common Stock per share. The Series C Stock's conversion rate will be further adjusted if the Company issues Common Stock (or convertible securities) at a price per share that is less than \$1.59. There is no termination date for this anti-dilution protection. The Series C Stock is also subject to customary adjustment for stock splits and reverse splits, and corporate transactions such as mergers and reorganizations.

In connection with the sale of the Series C Stock, the Company also issued Series C Warrants to purchase a total of 2,224,718 shares of Common Stock at an exercise price of \$2.05 per share that expire on May 10, 2013 (See Note 7).

In accordance with the contingent anti-dilution terms of the Series C Warrants, the exercise price of the warrants originally issued to the Series C Investors was adjusted from \$2.05 to \$1.81 per share in 2007, from \$1.81 to \$1.76 per share in 2008 and from \$1.76 to \$1.75 per share in 2010.

The holders of both the Series C Stock and the Series D Stock, among other things, have certain demand and piggyback registration rights with respect to the Common Stock underlying the Series C Stock, the Series D Stock and warrants issued to such holders.

**(10) Commitments and Contingencies**

**(a) License Agreements:**

On January 13, 2009, the Company entered into a License Agreement with Cornell (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 Cornell an annual license maintenance fee and certain milestone and royalty payments as provided for in the Cornell License Agreement. In addition, the Company agreed to continue to provide research support to Cornell under the Clinical Study Agreement (as defined below) during the term of the Cornell License Agreement.

On August 28, 2008, the Company entered into a License Agreement (the Aegera License Agreement) with Aegera Therapeutics Inc. (Aegera), whereby Aegera granted the





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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. Pursuant to the Aegera License Agreement, the Company paid Aegera an initial fee that was expensed as a research and development expense on the effective date of the Aegera License Agreement. Additionally, the Company will pay annual license maintenance fees beginning on January 1, 2009 through the term of the Aegera License Agreement and will make certain milestone and royalty payments to Aegera as provided for in the Aegera License Agreement.

The Company entered into a Sublicense Agreement (the Sublicense Agreement ), effective as of August 4, 2006, with Diamyd Therapeutics AB (Diamyd ), a company organized under the laws of Sweden. 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 glutamic acid decarboxylase (GAD ) 65 in connection with the gene transfer treatment of Parkinson's disease as conducted by the Company. Diamyd is the exclusive licensee of such patent rights owned by the Regents of the University of California, Los Angeles, which has approved the Sublicense Agreement. Pursuant to the Sublicense Agreement, the Company paid Diamyd an initial fee of \$500, an amount that was expensed as research and development expense on the effective date of the Sublicense Agreement. The Company is committed to pay an annual maintenance fee of \$75 through the term of the Sublicense Agreement and will make certain milestone and royalty payments to Diamyd as provided for in the Sublicense Agreement. The Sublicense Agreement is terminable at any time by the Company upon 90 days' notice. The Company expenses maintenance fees when the services are rendered. The amounts charged to operations in connection with the Sublicense Agreement was \$75 for each of the years ended December 31, 2010 and 2009, respectively.

In 2002, the Company entered into two license agreements with TJU whereby TJU granted to the Company the sole and exclusive right and license to certain patent rights and technical information. In conjunction with the agreements, the Company paid TJU an initial fee of \$100 and \$50, respectively, for each agreement. In addition, the Company is committed to pay annual maintenance fees of \$75 and \$20, respectively, through the term of the agreements, as well as benchmark payments and royalties. The maintenance fees can be applied to royalty and benchmark fees incurred in the calendar year of payment only. The licenses will continue for the lives of the patents covered in the agreements, which are currently set to expire in October 2021. The Company has the right to terminate the agreements at any time upon 90 days' written notice to TJU. The Company expenses maintenance fees when the services are rendered. The amount charged to operations in connection with the TJU agreements for each of the years ended December 31, 2010 and 2009 was \$95. (See Note 3).

In August 2002, the Company entered into a license agreement with Rockefeller and Yale (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 was paid to each of the two universities pursuant to the agreement. In addition, the Company is committed to pay an annual maintenance fee of \$5 per year to each university through the term of the agreement. Pursuant to the agreement, the Company must make payments upon reaching certain milestones. The Company has the right to terminate the agreement at any time upon 90 days' written notice. The Company expenses maintenance fees when the services are

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rendered. The amount charged to operations in connection with the Rockefeller-Yale Agreement for each of the years ended December 31, 2010 and 2009 was \$10.

**(b) *Research Agreements:***

Effective May, 2006, the Company entered into a Master Sponsored Research Agreement ( Research Agreement ) with The Ohio State University Research Foundation ( OSURF ) which provides for research covering the development of gene transfer approaches to neurodegenerative disorders, including Parkinson's disease, epilepsy, Huntington's disease, Alzheimer's disease, as well as gene transfer approaches to pain, stroke, neurovascular diseases and other research. The Research Agreement required the Company to pay \$250 over the initial 18 month term, which originally expired in November 2007. The Company and OSURF have subsequently amended the Research Agreement to extend the term through November 10, 2011 at an annual rate of \$167. (See Note 11). The amount charged to operations in connection with the sponsored research for each of the years ended December 31, 2010 and 2009 was \$167.

On July 2, 2003, the Company entered into a Clinical Study Agreement (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 when each patient commenced treatment and \$23 annually for the services of a nurse to assist in the clinical study. 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, depression 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 performance period of the sponsored research program and to further revise and expand the scope of the work to be performed. On July 23, 2009, the Company entered into Amendment No. 3 to the Clinical Study Agreement to eliminate from the scope of work certain research and activities and to extend the performance period of the sponsored research program until the Clinical Study Agreement is terminated by either the Company upon 30 days' prior written notice or Cornell if circumstances beyond its 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, one of the Company's scientific co-founders. The Company is required to pay Cornell \$135 per year for the duration of the Scientific Studies. Cornell has agreed that the Company has a sixty (60) day exclusive right and option to negotiate with it an exclusive, worldwide right and license to make, have made, use and sell commercial products embodying any inventions conceived or first reduced to practice by it in the course of this work. Pursuant to the terms of the Cornell License Agreement (as defined above), the Company agreed to continue to provide research support to Cornell under the Clinical Study Agreement during the term of the Cornell License Agreement. The amounts charged to operations in connection with the

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sponsored research for the years ended December 31, 2010 and 2009 were \$135 and \$166, respectively.

***(c) Consulting and Employment Agreements:***

Effective March 10, 2010, John E. Mordock resigned as a director and as President and Chief Executive Officer of the Company, and, in connection therewith, entered into a separation agreement, dated March 1, 2010, with the Company, pursuant to which his employment agreement, dated August 20, 2009 was terminated, except for the provisions thereunder relating to non-competition, non-solicitation, indemnification and confidentiality. Under the separation agreement, the Company agreed to pay or provide to Mr. Mordock the severance benefits contained in his employment agreement. Accordingly, in 2010, Mr. Mordock was paid one year of base salary of \$275 and one year of health, disability and life insurance premiums of approximately \$16. The Company recognized and paid these amounts as compensation expense on the effective date of Mr. Mordock's resignation. Also, all 800,000 stock options held by him vested on March 10, 2010, the effective date of his resignation, and expired unexercised on March 10, 2011. The Company recognized a net non-cash compensation charge of \$98 on the effective date of Mr. Mordock's resignation as a result of the accelerated vesting of and the extension of the exercise period for Mr. Mordock's stock options.

The Company paid Mr. Mordock an annual base salary of \$275 through the effective date of his resignation for the years ended December 31, 2010 and 2009. During the period of his employment, Mr. Mordock was reimbursed for temporary housing and automobile expenses related to his employment. Since all of Mr. Mordock's stock options vested, there is no unrecognized compensation cost related to such options as of December 31, 2010.

Effective July 10, 2006, Dr. Christine V. Sapan was appointed as Executive Vice President, Chief Development Officer of the Company under a letter agreement dated June 23, 2006. Dr. Sapan is eligible to receive an annual base salary and a discretionary annual bonus each year, with a target bonus of 40% of her annual base salary. Effective January 1, 2008, Dr. Sapan's annual base salary was set at \$264. (See Note 11). Dr. Sapan earned bonuses of \$70 and \$0 in 2010 and 2009, respectively. If Dr. Sapan's employment is terminated by the Company without Cause (as defined in her letter agreement), or by Dr. Sapan as a result of a demotion of her position, a diminution in her duties or a Change of Control (as defined in the Company's 2000 Stock Option Plan), she will be entitled to receive a lump sum payment of twelve months' base salary. All of her options shall immediately vest and be exercisable for up to one year following the date of any such termination. As of December 31, 2010, total unrecognized compensation cost related to Dr. Sapan's stock option awards was approximately \$26.

On January 23, 2006, the Company hired Marc L. Panoff as its Chief Financial Officer and Treasurer. Mr. Panoff was also appointed as the Company's Secretary on May 9, 2006.

On August 20, 2009, the Company entered into an employment agreement with Mr. Panoff, which superseded his prior agreement. The employment agreement, as amended on November 24, 2010, provides that Mr. Panoff shall be employed by the Company until December 4, 2011, shall be entitled to receive an annual base salary set by the Board and shall be eligible to receive an annual bonus in the discretion of the Board. Effective January 1, 2008, Mr. Panoff's annual base salary was set at \$203. (See Note 11). Mr. Panoff earned bonuses of \$50 and \$0 in 2010 and 2009, respectively. If Mr. Panoff's employment is terminated by the



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Company without Cause or by Mr. Panoff for Good Reason (including a Change in Control), as those terms are defined in his employment agreement, he shall be entitled to a lump sum payment equal to one year of base salary. In addition, all of his options shall immediately vest and be exercisable for up to one year following the date of any such termination. As of December 31, 2010, total unrecognized compensation cost related to Mr. Panoff's stock option awards was approximately \$26.

Effective September 30, 2010, the Company extended, for a period of one year, the term of its consulting agreement with Dr. Matthew During, one of the Company's scientific co-founders and a member of the SAB. Pursuant to the consulting agreement, dated as of October 1, 1999, as amended, Dr. During provides advice and consulting services to the Company on an exclusive basis in scientific research on human gene transfer in the central nervous system. The consulting agreement also provides for Dr. During to assist the Company in its fund raising efforts and to serve as a member of the SAB. Dr. During's consulting agreement, as amended, provides for payments of \$175 per annum. The Company paid Dr. During \$175 in consulting fees in both 2010 and 2009. Under this agreement, the Company granted Dr. During non-qualified stock options to purchase 60,000 shares of Common Stock at an exercise price of \$0.65 per share on May 11, 2010. The Company recognized a non-cash charge of \$56 in 2010 related to Dr. During's stock option awards.

The Company is party to an Amended and Restated Consulting Agreement, dated April 25, 2005, with Dr. Michael Kaplitt, one of the Company's scientific co-founders and the son of Dr. Martin Kaplitt, the Company's Chairman of the Board. Pursuant to the terms of this agreement, Michael Kaplitt provides advice and consulting services on an exclusive basis in scientific research on human gene transfer in the nervous system and serves as a member of the SAB. Michael Kaplitt is also the neurosurgeon that performed the surgical procedures on the twelve patients required by the protocol for the Company's Phase 1 clinical trial for the treatment of Parkinson's disease, and assisted the Company in its Phase 2 clinical trial for the treatment of Parkinson's disease. On April 26, 2010, the Company amended the consulting agreement, extending the term of the consulting agreement to April 30, 2011. (See Note 11). The Company paid Michael Kaplitt \$175 in consulting fees in each of 2010 and 2009, respectively.

Under this agreement, the Company granted Michael Kaplitt non-qualified stock options to purchase 160,000 shares of Common Stock at an exercise price of \$2.05 per share on April 25, 2005, all of which expired unexercised in 2010. On May 11, 2010, the Company granted Michael Kaplitt non-qualified stock options to purchase 160,000 shares of Common Stock at an exercise price of \$0.65 per share. The Company recognized non-cash charges of \$57 and \$43 in 2010 and 2009, respectively, related to Michael Kaplitt's stock option awards.

Effective February 23, 2007, the Company entered into a consulting agreement with Martin Kaplitt. Under the terms of this agreement, Martin Kaplitt provides medical and scientific consulting and advisory services to the Company. On March 23, 2010, the Company extended the term of its consulting agreement with Martin Kaplitt effective from January 1, 2010 to December 31, 2010. (See Note 11). The Company paid Martin Kaplitt \$125 in each of 2010 and 2009 under the agreement.

The Company has consulting agreements with five scientists who, in addition to Michael Kaplitt and Dr. During, comprise the SAB. These agreements provide that the scientists are engaged by the Company to provide advice and consulting services in scientific research on



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human gene transfer in the brain and central nervous system and to assist the Company in seeking financing and meeting with prospective investors.

In May 2003, the Company entered into a stock purchase agreement to sell shares of its Common Stock at a purchase price of \$0.01 per share to Dr. Paul Greengard, the Chairman of the SAB. At the time of such agreement, the fair value per share of Common Stock based on an estimate of the fair market value of common equity in Neurologix on a minority interest basis, as of April 28, 2003, was deemed to be \$0.90 per share. The reduced purchase price was provided to Dr. Greengard as an inducement for him to serve as the Chairman of the SAB. Accordingly, the fair value of the shares of approximately \$89, based on the difference between the purchase price of \$0.01 per share and the fair value per share of \$0.90, was recognized as an advisory board fee over the service period of three years. In connection therewith, on July 1, 2003, the Company entered into a consulting agreement with Dr. Greengard to serve as the Chairman of the SAB for a three year term, with automatic one year renewals, until terminated by either party pursuant to the terms of the agreement. Pursuant to the terms of the agreement, Dr. Greengard receives compensation of \$25 annually. The shares issued to the Chairman of the SAB were converted into 276,054 shares of Common Stock in connection with the Merger.

The agreements with the remaining four SAB members provide for payments aggregating \$12 per annum for three of the members and \$25 per annum for one of the members for a duration of three years from the date of each respective agreement, and are automatically renewed from year to year unless terminated for cause or upon 30 days written notice to the other party prior to an annual anniversary date. All of the consulting agreements with the SAB members are subject to confidentiality, proprietary information and invention agreements. Any discoveries and intellectual property obtained through these agreements related to the research covered under the agreements are the property of the Company.

**(d) *Legal Proceedings:***

On February 7, 2011, plaintiffs Robert Zeman ( RZ ) and his wife, Julia Zeman( JZ ), filed a complaint (the Complaint ) in the United States District Court for the District of Massachusetts against the Company and other named defendants involved in the Company's Phase 2 clinical trial for the treatment of advanced Parkinson's disease. The Complaint is styled Robert Zeman et al v. Ziv Williams, M.D. et al.

The Complaint, among other things, alleges that RZ, a participant in the Phase 2 clinical trial, was injured during the trial's surgical procedure by receiving a double dose of the drug used in the trial on one side of his brain rather than a bilateral dose of such drug as called for by the trial's protocol, and that RZ was not adequately informed of the risks and potential consequences of his participation in the trial. The Complaint further alleges that JZ suffered loss of consortium as a result of RZ's alleged injuries.

RZ seeks from the Company approximately \$15,000 in damages, and JZ seeks from the Company approximately \$3,000 in damages.

The Company does not believe that RZ's claimed injuries are related to the drug used in the Phase 2 clinical trial or to the protocol of such trial. The Company believes that the claims against the Company set forth in the Complaint are without merit, and the Company intends to vigorously defend against such claims.





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**(e) *Operating Lease Agreements:***

In August 2004, the Company entered into the Sublease (See Note 3). The Sublease provided for a base annual rent of approximately \$36 through the expiration of the Sublease on June 30, 2009.

Effective April 13, 2007, the Company entered into a lease (the BPRA Lease) with Bridge Plaza Realty Associates, LLC (BPRA) for additional office space at One Bridge Plaza, Fort Lee, New Jersey. 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. The BPRA Lease, which expires in April 30, 2011, provides for a base annual rent of approximately \$58 or approximately \$4.8 per month through its term. The Company intends to extend the term 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. (See Note 11). As of December 31, 2010, the Company has paid OSU an amount of approximately \$106.5, representing rent owed under the Facility Use Agreement through November 10, 2010.

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 Clinical Study Agreement.

The Company incurred total rent expense associated with operating leases and subleases of \$82 and \$81 for the years ended December 31, 2010 and 2009, respectively.

At December 31, 2010, approximate future lease payments under the Company's operating leases and subleases are as follows:

**Year Ending December 31,**

2011	\$79
2012	38
Thereafter	-
	\$117

**(11) Subsequent Events**

**(a) *Research Agreements:***

On January 18, 2011, the Company entered into a fourth amendment to the OSURF Research Agreement. The fourth amendment, among other things, extended the term of the OSURF Research Agreement to November 10, 2011 at an annual rate of \$167.

**(b) Consulting and Employment Agreements:**

On March 22, 2011, the Board increased Dr. Sapan's annual base salary from \$264 to \$285, effective January 1, 2011. In addition, the Board awarded Dr. Sapan an annual bonus for the 2010 fiscal year of \$70.

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On March 22, 2011, the Board increased Mr. Panoff's annual base salary from \$203 to \$220, effective January 1, 2011. In addition, the Board awarded Mr. Panoff an annual bonus for the 2010 fiscal year of \$50.

On February 8, 2011, the Company extended the term of its consulting agreement with Dr. Martin Kaplitt, effective from January 1, 2011, until December 31, 2011, at the current annual rate of \$125.

On February 8, 2011, the Company approved an extension of its consulting agreement with Dr. Michael Kaplitt from April 30, 2011 until April 30, 2012 at the current annual rate of \$175.

***(c) Operating Lease Agreements:***

On January 25, 2011, the Company amended the Facility Use Agreement, extending the term through November 10, 2013. Unless sooner terminated, the Company will pay an additional \$97.5 over the remaining three years of such agreement.

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

N/A.

**Item 9A. Controls and Procedures**

*Disclosure Controls and Procedures.*

The Company maintains disclosure controls and procedures as required under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act, that are designed to ensure that information required to be disclosed in the Company's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2010, the Company's management carried out an evaluation, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of its disclosure controls and procedures. Based on the foregoing, its Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of December 31, 2010.

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

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act.

As of December 31, 2010, the Company's management assessed the effectiveness of the Company's internal control over financial reporting based on criteria for effective internal control over financial reporting established in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that the Company's internal control over financial reporting, as of December 31, 2010, is effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements under all potential conditions. Therefore, effective internal control over financial reporting provides only reasonable, and not absolute, assurance that a misstatement of our financial statements would be prevented or detected.

*Changes in Internal Control Over Financial Reporting.*

There were no changes in the Company's internal control over financial reporting that occurred during the fourth fiscal quarter of 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.



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**PART III**

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

The information required by this item will be included in the Company's definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders and is hereby incorporated herein by reference.

**Item 11. Executive Compensation**

The information required by this item will be included in the Company's definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders and is hereby incorporated herein by reference.

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

The information required by this item will be included in the Company's definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders and is hereby incorporated herein by reference.

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

The information required by this item will be included in the Company's definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders and is hereby incorporated herein by reference.

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

The information required by this item will be included in the Company's definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders and is hereby incorporated herein by reference.

**PART IV**

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

- (a) The following financial statements are included in Item 8 herein and are filed as a part of this report:
1. Balance sheets of Neurologix, Inc. as of December 31, 2010 and 2009; and
  2. Statements of operations, changes in stockholders' equity (deficit) and cash flows for the years ended December 31, 2010 and 2009, and for the period from February 12, 1999 (inception) to December 31, 2010.
- (b) See the Exhibit Index attached hereto for a list of the exhibits filed or incorporated by reference as a part of this report.

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**Signatures**

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

Dated: March 25, 2011

**NEUROLOGIX, INC.**

/s/ Clark A. Johnson

Clark A. Johnson  
President and Chief Executive Officer  
(Principal Executive Officer)

/s/ Marc L. Panoff

Marc L. Panoff,  
Chief Financial Officer, Secretary and Treasurer  
(Principal Financial Officer and Principal Accounting  
Officer)

In accordance with the Exchange Act, this Report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Dated: March 25, 2011

/s/ Cornelius E. Golding  
Cornelius E. Golding, Director

Dated: March 25, 2011

/s/ Reginald L. Hardy  
Reginald L. Hardy, Director

Dated: March 25, 2011

/s/ Martin J. Kaplitt  
Martin J. Kaplitt, Director

Dated: March 25, 2011

/s/ Clark A. Johnson  
Clark A. Johnson, Director

Dated: March 25, 2011

/s/ Jeffrey B. Reich  
Jeffrey B. Reich, Director

Dated: March 25, 2011

/s/ Elliott Singer  
Elliott Singer, Director





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**EXHIBIT INDEX**

Exhibit No.	Exhibit
3.1	Restated Certificate of Incorporation of Neurologix, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 10-QSB, dated May 14, 2007, and incorporated herein by reference).
3.2	Amended and Restated by-laws of Neurologix, Inc. (filed as Exhibit 3.4 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of Neurologix, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, dated May 11, 2006, and incorporated herein by reference).
4.2	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of Neurologix, Inc. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
4.3	Certificate of Designations, Preferences and Rights of Series D Convertible Preferred Stock of Neurologix, Inc. (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
4.4	Registration Rights Agreement, dated as of November 19, 2007, by and among Neurologix, Inc., General Electric Pension Trust, the DaimlerChrysler Corporation Master Retirement Trust, certain funds managed by ProMed Asset Management LLC and Corriente Master Fund, L.P. (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
4.5	Amendment to Registration Rights Agreement, dated as of April 28, 2008, by and among the Company, General Electric Pension Trust, Chrysler LLC Master Retirement Trust, certain funds managed by ProMed Asset Management LLC and Corriente Master Fund, L.P. (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, dated April 29, 2008, and incorporated herein by reference).
4.6	Second Amendment to Registration Rights Agreement, dated December 6, 2010, by and among Neurologix, Inc., General Electric Pension Trust, Corriente Master Fund, L.P., Palisade Concentrated Equity Partnership II, L.P., Chrysler Group LLC Master Retirement Trust and Promed Partners, LP (filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).
4.7	Letter Agreement re Proposed Financing, dated November 23, 2010, from Neurologix, Inc. and consented and accepted by General Electric Pension Trust, Chrysler Group LLC Master Retirement Trust, Promed Partners, LP, Promed Offshore Fund Ltd., Corriente Master Fund, L.P. and David Musket (filed as Exhibit 10.6 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).

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- 10.1 Consulting Agreement, dated as of October 1, 1999, by and between Dr. Matthew During and Neurologix, Inc. (filed as Exhibit 10.29 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.2 Arinco Computer Systems Inc. 2000 Stock Option Plan, effective as of March 28, 2000 (filed as Annex E to the Registrant's Proxy Statement on Schedule 14A, dated August 11, 2000, and incorporated herein by reference).
- 10.3 Amendment One to Arinco Computer Systems Inc. 2000 Stock Option Plan, effective as of June 27, 2000 (filed as Annex E to the Registrant's Proxy Statement on Schedule 14A, dated August 11, 2000, and incorporated herein by reference).
- 10.4 Exclusive License Agreement, effective as of June 1, 2002, by and between Thomas Jefferson University and Neurologix Inc. (filed as Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.5 Exclusive License Agreement, effective as of August 1, 2002, by and between Thomas Jefferson University and Neurologix, Inc. (filed as Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.6 Non-Exclusive License Agreement, dated as of August 28, 2002, by and between Yale University, The Rockefeller University and Neurologix, Inc. (filed as Exhibit 10.33 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.7 License Agreement, dated as of November 1, 2002, by and between The Rockefeller University and Neurologix, Inc. (filed as Exhibit 10.34 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.8 Clinical Study Agreement, dated as of July 2, 2003, by and between Cornell University and Neurologix, Inc. (filed as Exhibit 10.35 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.9 Amendment, dated as of October 8, 2003, to that certain Consulting Agreement, dated October 1, 1999, by and between Dr. Matthew During and Neurologix, Inc. (filed as Exhibit 10.37 to the Registrant's Annual Report on Form 10-K, dated April 9, 2004, and incorporated herein by reference).
- 10.10 Amendment No. 1 to Clinical Study Agreement, dated September 24, 2004, by and between Cornell University for its Medical College and Neurologix, Inc. (filed as Exhibit 99.1 to the Registrant's Report on Form 8-K, dated September 30, 2004, and incorporated herein by reference).
- 10.11 Amended and Restated Consulting Agreement, dated April 25, 2005, by and between Michael G. Kaplitt and Neurologix Research, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated April 29, 2005, and incorporated herein by reference).

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- 10.12 Stock Purchase Agreement, dated as of April 27, 2005, by and among Neurologix, Inc. and Medtronic International, Ltd. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated May 2, 2005, and incorporated herein by reference).
- 10.13 Development and Manufacturing Agreement, dated as of April 27, 2005, by and among Neurologix, Inc. and Medtronic, Inc. (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-QSB, dated May 13, 2005, and incorporated herein by reference).
- 10.14 Neurologix, Inc. 2000 Stock Option Plan Amendment No. 2, effective as of May 9, 2006 (filed as Exhibit A to the Registrant's Proxy Statement on Schedule 14A, dated April 5, 2006, and incorporated herein by reference).
- 10.15 Master Sponsored Research Agreement, dated as of May 10, 2006, by and between The Ohio State University Research Foundation and Neurologix, Inc. (filed as Exhibit 10.19 to the Registrant's Annual Report on Form 10-KSB, dated March 24, 2008, and incorporated herein by reference).
- 10.16 Stock and Warrant Subscription Agreement, dated as of May 10, 2006, by and between Neurologix, Inc., General Electric Pension Trust, the DaimlerChrysler Corporation Master Retirement Trust, ProMed Partners, LP, ProMed Partners II, LP, ProMed Offshore Fund Ltd., ProMed Offshore Fund II, Ltd., Paul Scharfer and David B. Musket (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated May 11, 2006, and incorporated herein by reference).
- 10.17 Form of Warrant Certificate to purchase shares of common stock of Neurologix, Inc. (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, dated May 11, 2006, and incorporated herein by reference).
- 10.18 Letter Agreement, dated June 23, 2006, by and between Christine V. Sapan and Neurologix, Inc. (filed as Exhibit 10.22 to the Registrant's Annual Report on Form 10-KSB, dated March 24, 2008, and incorporated herein by reference).
- 10.19 Sublicense Agreement, dated July 27, 2006, by and between Neurologix, Inc. and Diamyd Therapeutics AB (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated August 7, 2006, and incorporated herein by reference).
- 10.20 Consulting Agreement, dated February 23, 2007, by and between Neurologix, Inc. and Dr. Martin J. Kaplitt (filed as Exhibit 99.1 to the Registrant's Current Report on Form 8-K, dated February 26, 2007, and incorporated herein by reference).
- 10.21 Amendment No. 2 to Clinical Study Agreement, dated March 2, 2007, by and between Cornell University and Neurologix, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated March 7, 2007, and incorporated herein by reference).
- 10.22 Neurologix, Inc. 2000 Stock Option Plan Amendment No. 3, effective as of May 8, 2007 (filed as Exhibit A to the Registrant's Proxy Statement on Schedule 14A, dated April 10, 2008, and incorporated herein by reference).



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- 10.23 Amendment to Consulting Agreement, dated October 1, 2007, by and between Matthew During and Neurologix, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated October 5, 2007, and incorporated herein by reference).
- 10.24 Stock Purchase Letter Agreement, dated November 8, 2007, by and between Neurologix, Inc. and General Electric Pension Trust (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
- 10.25 Stock Purchase Letter Agreement, dated November 8, 2007, by and between Neurologix, Inc. and DaimlerChrysler Corporation Master Retirement Trust (filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
- 10.26 Stock Purchase Letter Agreement, dated November 8, 2007, by and between Neurologix, Inc. and ProMed Partners LP (filed as Exhibit 10.6 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
- 10.27 Form of Warrant Certificate to purchase shares of common stock of Neurologix, Inc. (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, dated November 21, 2007, and incorporated herein by reference).
- 10.28 Stock and Warrant Subscription Agreement, dated as of April 28, 2008, by and between Neurologix, Inc., Corriente Master Fund, L.P. and, solely with respect to Article V thereof, General Electric Pension Trust (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated April 29, 2008, and incorporated herein by reference).
- 10.29 Form of Warrant Certificate (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, dated April 29, 2008, and incorporated herein by reference).
- 10.30 Amendment to the Master Sponsored Research Agreement, dated as of May 29, 2008, between Neurologix, Inc. and The Ohio State University Research Foundation, on behalf of Ohio State University (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated June 11, 2008, and incorporated herein by reference).
- 10.31 Addendum to the Development and Manufacturing Agreement, effective as of August 1, 2008, between Neurologix, Inc. and Medtronic, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated August 15, 2008, and incorporated herein by reference).
- 10.32 License Agreement, dated as of August 28, 2008, between Neurologix, Inc. and Aegera Therapeutics, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated September 4, 2008, and incorporated herein by reference).
- 10.33 Letter Agreement, dated October 3, 2008, between Neurologix, Inc. and Dr. Matthew During (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated October 7, 2008, and incorporated herein by reference).



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- 10.34 Second Amendment to Master Sponsored Research Agreement, dated as of October 29, 2008, between Neurologix, Inc. and The Ohio State University Research Foundation, on behalf of Ohio State University (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated December 16, 2008, and incorporated herein by reference).
- 10.35 License Agreement, dated as of January 13, 2009, by and between Neurologix, Inc. and Cornell University (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated January 14, 2009, and incorporated herein by reference).
- 10.36 Amendment No. 3 to the Clinical Study Agreement between Neurologix, Inc. and Cornell University for and on behalf of its Joan & Sanford I. Weill Medical College, dated as of July 23, 2009 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated July 23, 2009, and incorporated herein by reference).
- 10.37 Employment Agreement between John E. Mordock and Neurologix, Inc., dated as of August 20, 2009 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated August 20, 2009, and incorporated herein by reference).
- 10.38 Employment Agreement between Marc L. Panoff and Neurologix, Inc., dated as of August 20, 2009 (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, dated August 20, 2009, and incorporated herein by reference).
- 10.39 Letter Agreement dated August 31, 2009 between Neurologix, Inc. and Dr. Matthew During (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated August 31, 2009, and incorporated herein by reference).
- 10.40 Third Amendment to Master Sponsored Research Agreement between Neurologix, Inc. and The Ohio State University Research Foundation, on behalf of Ohio State University, dated as of September 24, 2009 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated September 24, 2009, and incorporated herein by reference).
- 10.41 Letter Agreement dated March 1, 2010 between Neurologix, Inc. and John E. Mordock (filed as Exhibit 10.49 to the Registrant's Annual Report on Form 10-K, dated March 26, 2010, and incorporated herein by reference).
- 10.42 Amendment No. 4 to 2000 Stock Option Plan, effective as of March 23, 2010 (filed as Exhibit 10.50 to the Registrant's Annual Report on Form 10-K, dated March 26, 2010, and incorporated herein by reference).
- 10.43 Letter Agreement dated April 26, 2010 between Neurologix, Inc. and Dr. Michael G. Kaplitt (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated April 27, 2010, and incorporated herein by reference).
- 10.44 Letter Agreement dated November 9, 2010 between Neurologix, Inc. and Dr. Matthew During (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, dated November 12, 2010, and incorporated herein by reference).
- 10.45

Letter Agreement between Marc L. Panoff and Neurologix, Inc., dated as of November 24, 2010 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated November 30, 2010, and incorporated herein by reference).



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- 10.46 Note and Warrant Purchase Agreement, dated December 6, 2010, by and among Neurologix, Inc., General Electric Pension Trust, Corriente Master Fund, L.P. and Palisade Concentrated Equity Partnership II, L.P. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).
- 10.47 Form of Secured Senior Convertible Promissory Note (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).
- 10.48 Form of Warrant to Purchase Common Stock of Neurologix, Inc. (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).
- 10.49 Security Agreement, dated December 6, 2010, by and among Neurologix, Inc., General Electric Pension Trust, Corriente Master Fund, L.P. and Palisade Concentrated Equity Partnership II, L.P. (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K, dated December 6, 2010, and incorporated herein by reference).
- 10.50 Fourth Amendment to Master Sponsored Research Agreement between Neurologix, Inc. and The Ohio State University Research Foundation, on behalf of Ohio State University, dated as of January 18, 2011 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, dated January 20, 2011, and incorporated herein by reference).
- 23.1 Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.\*\*
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer.\*\*
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer/Treasurer.\*\*
- 32.1 Section 1350 Certification, Chief Executive Officer and Chief Financial Officer/Treasurer.\*\*

\*\* Filed herewith