



FORM 10-K

Northstar Neuroscience, Inc. - NSTR

Filed: March 17, 2008 (period: December 31, 2007)

Annual report which provides a comprehensive overview of the company for the past year

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2007

OR

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

For the transition period from _____ to _____

Commission File Number 000-51951

Northstar Neuroscience, Inc.

(Exact name of registrant as specified in its charter)

WASHINGTON

(State or other jurisdiction of incorporation or organization)

91-1976637

(IRS Employer Identification No.)

2401 FOURTH AVENUE, SUITE 300

SEATTLE, WASHINGTON

(Address of registrant's principal executive offices)

98121

(Zip Code)

(206) 728-1477

(Telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:
COMMON STOCK, \$0.001 PAR VALUE**

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

Indicate by check mark whether 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock on June 29, 2007 as reported on the NASDAQ Global Market was \$284,000,000.

As of February 29, 2008, 25,892,217 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2008 Annual Meeting of Shareholders to be held June 5, 2008 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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ITEM 1. BUSINESS**Overview**

Northstar Neuroscience, Inc. is a development stage medical device company incorporated in the State of Washington on May 18, 1999 focused on developing and commercializing innovative neuromodulation therapies to restore function and quality of life for people suffering from neurological diseases and disorders. Our proprietary *Renova*TM Cortical Stimulation System is designed to deliver targeted electrical stimulation to the cortex, the outermost layer of the brain, in a process called cortical stimulation. We are currently studying applications of our cortical stimulation therapy for several neurological conditions including major depressive disorder and stroke motor recovery. Because the cortex controls many neurological functions, we believe our cortical stimulation therapy system has the potential to treat these and other neurological diseases and disorders.

Neuromodulation Market

The field of neuromodulation, defined as the application of electrical or pharmacological stimulation to the central, peripheral, or autonomic nervous system, has grown dramatically in recent years. According to industry sources, the worldwide market for neuromodulation devices grew to greater than \$1.5 billion in 2006 and is growing at an annual rate in excess of 20%. FDA-approved and cleared neuromodulation devices are currently utilized to treat a range of indications, including chronic pain, epilepsy, essential tremor, Parkinson's disease, hearing loss, and depression. These devices are implanted in the body and are used to stimulate different parts of the central nervous system, including the spinal cord, vagus nerve, and various structures of the brain. Clinical trials are being conducted by companies utilizing these and other methods of neuromodulation for additional applications, such as treatment of obesity, hypertension, migraine headaches, and obsessive-compulsive disorder.

Our *Renova* Cortical Stimulation System Solution

Our *Renova* Cortical Stimulation System delivers targeted electrical stimulation to specific areas of the cortex. Because the cortex controls or influences many neurological functions, including neuropsychological functions, movement, hearing, and speech, cortical stimulation therapy has the potential to treat a variety of neurological diseases and disorders. We are evaluating our system for use in treating depression, stroke related upper-extremity hemiparesis, and tinnitus, which are disabling neurological disorders that afflict large numbers of patients. Because the cortex can be surgically accessed more easily than deeper brain structures, a neurosurgeon can implant our *Renova* Cortical Stimulation System in a relatively simple one- to two-hour surgical procedure. To date, we have treated over 100 patients with our system with a favorable safety profile.

The *Renova* Cortical Stimulation System is comprised of the following primary components:

- **Implantable pulse generator, or IPG**—an electrical stimulator that is implanted in the upper chest area just beneath the skin and provides the stimulation and power source for our therapy.
- **Cortical stimulation lead**—an electrode that connects to the IPG and delivers stimulation to the cortex. The electrode is placed either epidurally, on top of the dura, which is the tough membrane that covers the brain's surface, or subdurally, just under the dura.
- **Programming system**—an external device that communicates with the IPG. The programming system allows the clinician to turn the IPG on/off and to set/modify stimulation parameters.

The methods of identifying the target area of the cortex for stimulation vary by indication. After identifying the target area of the cortex to stimulate, our cortical stimulation lead is implanted and connected to the IPG. Cortical stimulation is then provided under the direction of a treating medical professional.

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Our Business Strategy

Our goal is to become a leading provider of neurostimulation solutions for patients who suffer from neurological diseases and disorders by establishing our *Renova* Cortical Stimulation System as the treatment of choice for multiple neurological indications. The key elements of the business strategy by which we intend to achieve these goals include:

- ***Evaluating our cortical stimulation therapy to treat specific neurological diseases and disorders, including depression and hand/arm impairment from stroke.*** To accomplish these goals, we plan to increase our focus on our cortical stimulation therapy for the treatment of depression, while also conducting targeted research on stroke motor recovery.
- ***Leveraging our technology platform to pursue additional neurological applications.*** We believe that cortical stimulation therapy has the potential to become an effective treatment for a variety of other neurological diseases and disorders. We are currently conducting targeted research to evaluate our cortical stimulation technology platform for other indications and may initiate additional clinical trials for these therapies.
- ***Expanding and strengthening our intellectual property position.*** We believe our cortical stimulation therapy system represents a novel, proprietary neurostimulation technology. We believe that our patents and patent applications broadly cover certain uses of cortical stimulation therapy in the treatment of neurological diseases and disorders. We intend to further pursue intellectual property protection through United States and foreign patent applications.
- ***Communicating the benefits of cortical stimulation therapy by publicizing clinical results obtained by leading clinicians.*** Although neuromodulation is a widely recognized and approved method for treating various neurological diseases and disorders, the field of cortical stimulation is an emerging treatment modality. As a result, we believe it will be important to increase awareness of our *Renova* Cortical Stimulation System, and cortical stimulation therapy in general, by continuing to generate strong clinical and scientific data through collaborations with key opinion leaders at leading academic and medical institutions.
- ***Commercializing our Renova Cortical Stimulation System.*** We intend to substantiate the benefits afforded by cortical stimulation by completing the necessary clinical studies to pursue regulatory approval. If regulatory approval is obtained, we will commercialize our *Renova* system to treat one or more neurological indications.

Potential Therapeutic Applications

Depression

Overview

Major depressive disorder, also commonly referred to as clinical depression or broadly as depression, is the most common of all psychiatric disorders and has a profound impact on the quality of life and activities of daily living for individuals and families. The economic impact of depression is significant. The total economic burden of depression in the U.S. in 2000 was more than \$83 billion annually, of which \$26 billion were direct treatment costs. Published research indicates that approximately 7% of U.S. adults, or about 15 million people, suffered from major depressive disorder. Traditionally, major depressive disorder has been treated with medication and short-term psychotherapies. The National Institute of Mental Health-sponsored STAR*D study concluded that 33% of people treated for major depressive disorder suffered from treatment resistant depression, or TRD meaning that they had failed four or more therapies. The results of these studies suggest that at least 4.0 to 5.0 million people in the U.S. suffer from treatment resistant depression. For these millions of patients suffering from TRD, neuromodulation may offer the potential for an effective therapy.

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Existing Treatments

There are a number of neuromodulation therapies currently marketed or under investigation for depression, including those pursued by Cyberonics, Medtronic, Neuronetics, and St. Jude Medical. Neuromodulation therapies offered or being evaluated include electroconvulsive therapy, or ECT, vagus nerve stimulation, or VNS, deep brain stimulation, or DBS, and repetitive transcranial magnetic stimulation, or rTMS. While these therapies offer varying degrees of efficacy, some involve highly invasive surgical procedures, have a high incidence of serious side effects, provide only temporary results, or yield low efficacy rates. ECT and VNS are currently the only neuromodulation therapies cleared or approved by the FDA for the treatment of depression.

Our Therapy and Trial Results

We are currently investigating cortical stimulation therapy for TRD using our *Renova* system. We have focused our cortical stimulation therapy on the dorsolateral prefrontal cortex, which is an area of the cortex involved with reasoning and emotion, among other functions. There is clinical evidence suggesting that targeted stimulation of certain areas within the dorsolateral prefrontal cortex, using specific stimulation parameters, may help treat major depressive disorder. Previously published studies stimulating the dorsolateral prefrontal cortex using rTMS have demonstrated antidepressant effects in the treatment of depression. Although some patients with major depressive disorder benefit from rTMS, this form of therapy requires multiple sessions during the initiation phase, which typically lasts several weeks. Moreover, the effects of rTMS seem to be temporary, typically lasting only days to months, and require repeat applications.

The PROSPECT study is our ongoing feasibility trial evaluating cortical stimulation therapy in 12 patients with treatment resistant depression. In the PROSPECT study, all patients were implanted with our *Renova* Cortical Stimulation System. After a baseline observation period, half of the patients were randomized to receive active cortical stimulation during the first eight weeks of stimulation, while the other half of the patients were randomized to receive sham stimulation. After the initial eight-week period, the sham stimulation group began the same course of active stimulation provided to the other patients. The PROSPECT study evaluated improvements in patients' condition using standard outcome measures: the Hamilton Depression Rating Scale, or HDRS, and the Montgomery-Asberg Depression Rating Scale, or MADRS, both of which measure the severity of depression, and the Global Assessment of Functioning, or GAF, which evaluates social, occupational, and psychological functioning to assess quality of life and ability to function.

The patients enrolled in the PROSPECT trial suffer from severe depression, having failed an average of nine previous therapies and endured their most recent depressive episode for an average of seven years. In addition, ten of the patients in the study were previously treated with ECT. We believe the patients in our PROSPECT trial represent a severe depression population.

Initial results from the PROSPECT study patients have been encouraging. Over the initial eight-week sham controlled phase of the study, Hamilton Depression Rating Scale scores of the active cortical stimulation patients improved an average of 21% from baseline, compared to only a 3% improvement from baseline in the sham group. After 16 weeks of active stimulation for patients in both groups, HDRS scores improved by an average of 24% from baseline. MADRS scores improved by an average of 29% from baseline. Furthermore, the GAF improved by an average of 41% from baseline.

Analysis of PROSPECT results has provided direction regarding further optimization of our cortical stimulation therapy for treatment resistant depression. Based on the encouraging results from our PROSPECT trial, as well as the significant market opportunity, we have initiated planning for additional clinical work for this indication.

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Stroke Motor Recovery

Overview

Stroke is a leading cause of serious, long-term disability in the United States. According to the American Heart Association, or AHA, the annual healthcare burden of stroke-related care in the United States alone was estimated at \$62.7 billion in 2007. The AHA estimates that in the United States there currently are more than 5.7 million stroke survivors, and each year approximately 700,000 people experience a new or recurrent stroke. After an ischemic stroke, an attempt may be made to restore blood flow by using a drug to dissolve the clot that is obstructing the blocked vessel. However, the time in which clot-dissolving drugs can be safely and effectively administered is limited to approximately three hours. The AHA estimates that less than 5% of people who suffer ischemic strokes receive clot-dissolving drugs. Thus, many stroke survivors are left significantly and permanently disabled. Hemiparesis, which is weakness or partial paralysis of one side of the body, is the most common disability caused by stroke. Approximately one-half of ischemic stroke survivors in the United States suffer from hand or arm impairment, called upper-extremity hemiparesis.

Existing Treatments

Patients who are assessed to have a disability resulting from a stroke are typically referred to a rehabilitation facility to undergo rehabilitative therapy. Rehabilitative therapy for motor-impaired stroke patients involves exercises and tasks designed to increase strength, mobility, range of motion, and overall function of disabled limbs. Patients also learn to compensate with the unimpaired limb. Within several months after a stroke, improvement in motor function typically reaches a plateau. With only a partial restoration of lost motor function, patients must learn to live with and adapt to disabilities that impact their quality of life and ability to perform many of the activities of daily living.

Our Therapy and Trial Results

Our EVEREST pivotal clinical trial evaluating the use of cortical stimulation in conjunction with rehabilitation therapy for the treatment of hand and arm impairment following a stroke was expected to support our application to the U.S. Food and Drug Administration, or FDA, to obtain approval to market our *Renova* Cortical Stimulation System in the United States. On January 22, 2008, we announced that, based on a preliminary analysis of data, the EVEREST trial did not meet its primary efficacy endpoint. Furthermore, we do not expect that ongoing or subsequent analysis, once completed, will demonstrate sufficient evidence of efficacy to pursue marketing approval from the FDA based on EVEREST data alone. We have continued to analyze the substantial EVEREST data set. While our analysis of the entire EVEREST data set is not complete, the ongoing analysis of the data has provided insights into opportunities we believe could improve the clinical results for cortical stimulation therapy. This data is suggestive of an opportunity to achieve meaningful improvements for stroke patients with hand/arm impairment; however, clinical trial data beyond EVEREST will be required to confirm this. We have commenced planning next steps, including additional clinical work and an analysis of the business opportunity for a potentially optimized therapy.

Other Potential Applications

We are investigating the potential application of our cortical stimulation therapy system to treat other neurological diseases and disorders. For these other investigative clinical applications, the surgery to implant the IPG and lead is substantially the same. However, the location of the electrode, the electrode configuration, and the electrical stimulation parameters may be different. The mechanism of action for other applications also may vary.

Product Development, Manufacturing and Supplier Relationships

We have designed and developed all of the elements of our *Renova* Cortical Stimulation System, other than the handheld computer hardware used in our programming system. Our development efforts have been focused

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on using proven technologies and materials for the implantable portions of our system, while developing custom, proprietary circuitry and integrated circuits that facilitate flexible application of the system, primarily through proprietary software, to various investigational applications of cortical stimulation.

Nearly all of the elements of our system are produced by outside vendors according to our proprietary specifications. We use third parties to manufacture our system to minimize our capital investment, help control costs and take advantage of the expertise these third parties have in the large-scale production of medical devices. All of our key manufacturers and suppliers have experience working with commercial implantable device systems and are regularly inspected by us. Our key manufacturers and suppliers have a demonstrated record of compliance with U.S. and international regulatory requirements.

We purchase components, materials and final assemblies from single sources due to quality considerations, costs, and constraints resulting from regulatory requirements. We have entered into multi-year agreements with our manufacturers and primary suppliers that generally require us to fulfill all of our manufacturing needs and purchase all of our worldwide requirements for components from these parties. Due to the exclusive and long-term nature of these agreements, regulatory requirements, and the custom nature of the parts we designed, we cannot quickly establish additional or replacement manufacturers or suppliers for the components of our cortical stimulation therapy system. We plan to address potential supply interruptions by maintaining a sufficient inventory stock to address potential temporary supply shortages.

Patents and Proprietary Rights

Our success depends in part on our ability to develop a competitive advantage over potential competitors for the treatment of neurological diseases and disorders with our cortical stimulation therapy. Our ability to obtain intellectual property that protects our cortical stimulation therapy and related processes will be important to our success. Our strategy is to protect our proprietary positions by, among other things, filing U.S. and foreign patent applications related to our technology, inventions, and improvements that are directed to the development of our business and our competitive advantages. Our strategy also includes developing know-how and trade secrets, and in-licensing technology related to cortical stimulation therapies. To protect our intellectual property and proprietary technology, we also rely in part on confidentiality and non-competition agreements with our employees, consultants, and other third parties.

Our ability to operate without infringing the intellectual property rights of others and to prevent others from infringing our intellectual property rights will also be important to our success. We are aware of other companies investigating neurostimulation, including cortical stimulation, and of patents and published patent applications held by these companies in those fields. To this end, we have reviewed all neurostimulation patents owned by third parties of which we are aware and believe that our current product candidates do not infringe any valid claims of the third party patents that we have analyzed. There are a large number of patents directed to stimulation therapies, however, and there may be other patents or pending patent applications of which we are currently unaware that may impair our ability to operate. We are currently not aware of any third parties infringing our issued claims.

Government Regulation

United States

The *Renova* Cortical Stimulation System is currently labeled for investigational use only. Commercial distribution of the *Renova* system in the United States will require prior approval or clearance from the FDA. In so doing, the FDA can also impose restrictions on the sale, distribution, or use of devices at the time of their approval or clearance, or subsequent to marketing.

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Clinical Trials

Clinical trials for a new device that may pose a “significant risk,” such as our *Renova* Cortical Stimulation System, require submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for an investigational device may begin once the IDE application is approved by the FDA and the institutional review boards, or IRBs, overseeing the clinical trial at the various investigational sites. We have obtained all such required approvals for all of our ongoing clinical trials prior to enrolling patients at our investigational sites. Clinical trials require extensive record keeping and reporting. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, good clinical practice, or GCP, requirements. We, the FDA, or the institutional review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study patients outweigh the anticipated benefits.

Premarket Approval

Our *Renova* system is anticipated to be categorized as a class III medical device. FDA approval of a premarket approval application, or PMA, is required before marketing of most new class III medical devices in the United States. The process of obtaining premarket approval is costly, lengthy and uncertain. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, and clinical trials to demonstrate to the FDA’s satisfaction the safety and effectiveness of the device. Among other information, the PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed device labeling.

If the FDA determines that a PMA is complete, the FDA files the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an application and provide a response, although the review and response activities generally occur over a significantly longer period of time, typically one year, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. During the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Because there is no FDA-approved cortical stimulation device on the market, a review panel may be convened as part of any FDA review of our *Renova* Cortical Stimulation System. In addition, the FDA will conduct a preapproval inspection of our and our suppliers’ facilities to evaluate compliance with quality system regulations. The FDA will also conduct inspection of our records and our trial sites’ clinical records under the Bioresearch Monitoring inspection program. Under the Medical Device User Fee and Modernization Act of 2002, a fee to submit a PMA is generally applied, but certain companies, like Northstar Neuroscience, may qualify for a reduced fee for small businesses. New PMAs or PMA supplements are required for modifications to the manufacturing process, labeling, use, and design of a device.

Pervasive and Continuing FDA Regulation

Both before and after FDA approval, numerous regulatory requirements apply. These include:

- quality system regulation, which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures during the design and manufacturing processes and into commercialization;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

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- notices of correction or removal and recall regulations.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Some promotional activities for FDA-regulated products have in the past resulted in enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The primary regulatory environment in Europe is that of the European Community, or EC, which consists of 27 countries encompassing nearly all the major countries in Europe. The EC has adopted directives for active implantable medical devices and numerous standards that govern and harmonize the national laws and standards regulating a company's quality system and the device design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which they are first marketed will be entitled to affix the CE mark, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within EC states and other countries that recognize this mark for regulatory purposes.

The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our *Renova* Cortical Stimulation System (which falls into a class III category), the method involves a combination of a design dossier review of the safety and performance of the device, and an assessment of the manufacturer's quality system by a third party Notified Body. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements.

Research and Development

Our research and development expenses were approximately \$19.4 million in 2007, \$18.3 million in 2006, and \$11.8 million in 2005. We expect our research and development expenditures to decrease in 2008, relative to 2007, as we are not planning to conduct a large-scale pivotal trial in 2008.

Employees

As of December 31, 2007, we had 84 employees. Approximately 62 employees were engaged in research and development and 22 in marketing, finance and other administrative functions. None of our employees is represented by a labor union or is covered by a collective bargaining agreement. We believe that we maintain good relations with our employees.

On January 22, 2008 we announced that our EVEREST pivotal clinical trial evaluating cortical stimulation for the treatment of hand and arm impairment following a stroke failed to meet its primary endpoint. Subsequently, on February 15, 2008, we implemented a reduction in our workforce including 19 employees, leaving 58 employees. We took this action to reduce operating costs and align operations with our strategic and clinical research plan.

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Available Information

Our Internet website address is www.northstarneuro.com. We provide free access to various reports that we file with, or furnish to, the United States Securities and Exchange Commission, or SEC, through our website, as soon as reasonably practicable after they have been filed or furnished. These reports include, but are not limited to, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports. Our SEC reports can be accessed through the investor relations section of our website, or through www.sec.gov. Also available on our website are printable versions of Northstar's Code of Conduct and charters of the Audit, Compensation, and Nominating and Corporate Governance Committees of our Board of Directors. Information on our website does not constitute part of this annual report on Form 10-K or any other report we file or furnish with the SEC.

ITEM 1A. RISK FACTORS

The following important factors, among others, could cause our stock price to fall and our financial condition and operating results to differ materially from those indicated or suggested by forward-looking statements made in this Annual Report on Form 10-K or presented elsewhere by management from time to time.

Risks Related to Our Business and Industry

We have incurred losses since inception and anticipate that we will continue to incur increasing losses for the foreseeable future.

We are a development stage company with a limited operating history and no revenue. We have incurred losses in each year since our formation in 1999. We currently do not have, and do not expect to have for several years, any products approved for commercialization or any source of revenue. We have been engaged in research and development since our inception and have invested substantially all of our time and resources in developing our *Renova*TM Cortical Stimulation System. Development of a new medical device, including conducting clinical trials, seeking regulatory approvals and developing markets, is a long, expensive and uncertain process. We expect to continue incurring significant operating losses for at least the next several years. These losses, among other things, have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We expect to incur significant clinical and regulatory expenses in connection with our ongoing clinical trials and trials that we may initiate in the future. We also expect our product development expenses to continue in connection with our ongoing and future product development initiatives. In addition, if the FDA approves our *Renova* Cortical Stimulation System for any indication, we expect to incur significant corporate infrastructure and sales and marketing expenses, prior to recording sufficient revenue to offset these expenses. If we are unable to successfully develop, receive regulatory approval for, and commercialize, our *Renova* Cortical Stimulation System for any indication, we may never generate revenue or be profitable and we may have to cease operations. Because of the numerous risks and uncertainties associated with developing new medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

Our success as a company depends heavily on the success of our Renova Cortical Stimulation System. If we are unable to commercialize our Renova system for any reason, including but not limited to the following factors, our ability to generate revenue will be significantly harmed and our stock price will likely decline.

Since June 2003 we have invested substantially all of our financial resources and our research and product development efforts in our *Renova* Cortical Stimulation System. We do not anticipate generating any revenue for several years and may not become profitable until we are well established, if at all. The commercial success of our *Renova* system depends upon:

- completing our ongoing trials and successfully demonstrating the safety and efficacy of our system for the treatment of neurological diseases or disorders;
- completing a future pivotal trial that successfully demonstrates the safety and efficacy of our system for an identified indication;
- obtaining FDA approval to market our *Renova* Cortical Stimulation System in the U.S.;
- manufacturing our system in commercial quantities;
- the commercial launch of our system; and
- obtaining levels of reimbursement by governmental and other third party payors, such as the Medicare and Medicaid programs and private healthcare insurers.

If we do not achieve each of these objectives, we may be unable to commercialize our *Renova* system or generate any revenue, which would materially and adversely affect our financial position, operating results, and stock price and could force us to cease operations.

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Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The use of our *Renova* system to treat neurological diseases and disorders is a novel application of neurostimulation therapy that has not previously been investigated to any meaningful extent. The novel nature of the application results in significant technical, scientific, and regulatory challenges related to product development and system optimization, government regulation, third-party reimbursement, and market acceptance. No cortical stimulation device for the treatment of neurological diseases and disorders has ever achieved FDA approval or been commercialized. Accordingly, while we believe there would be a commercial market for an FDA-approved cortical stimulation device, there can be no assurance that our *Renova* system will become a viable commercial alternative to other treatment delivery methods, including other methods based on electrical stimulation of other parts of the brain or nervous system. These challenges may prevent us from developing and commercializing products on a timely and profitable basis, or at all.

We may not be successful in our efforts to utilize our cortical stimulation therapy in various applications.

A key element of our business strategy is to develop a cortical stimulation technology platform for use in treating multiple neurological diseases and disorders. We are conducting research on different potential applications of our cortical stimulation therapy, each of which may have a unique and discrete mechanism of action. Research to identify new target applications requires substantial technical, financial, and human resources, whether or not any new applications for our cortical stimulation therapy are ultimately identified. We may be unable to identify or pursue other applications of our technology for many reasons, including the following:

- the research methodology used may not be successful in identifying other potential applications;
- we may not be able to optimize the delivery of our cortical stimulation therapy in a manner that would effectively treat a particular neurological disease or disorder, if such optimization is even possible;
- our cortical stimulation therapy may not be suitable for certain other potential applications;
- cortical stimulation therapy for certain neurological diseases or disorders may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective;
- cortical stimulation therapy may be ineffective in treating a sufficiently large patient population with a particular disorder to make further study cost-effective; and
- competitors may develop alternatives, including nonsurgical alternatives, that render our cortical stimulation therapy obsolete for treating a particular neurological disease or disorder.

Even if we identify a potential new application for our cortical stimulation therapy, investigating the safety and efficacy of our therapy requires extensive clinical testing, which is expensive and time-consuming, and the results of that clinical testing may not be successful. If we terminate a clinical trial in which we have invested significant resources, our prospects will also suffer, as we will have expended resources on a program that will not provide a return on our investment and missed the opportunity to allocate those resources to potentially more productive uses. We will also need to obtain regulatory approval for these new applications, as well as achieve market acceptance and an acceptable level of reimbursement.

If we are unable to complete, or experience delays in completing, our clinical trials, or if our clinical trial results are insufficient in meeting clinical or regulatory objectives, our ability to commercialize our Renova Cortical Stimulation System and our financial position will be impaired.

Conducting clinical trials is a long, expensive, complex, and uncertain process. The length of time required to conduct a clinical trial varies based on a number of factors, including the treatment plan for the particular neurological disease or disorder, the type of device being tested, the complexity of clinical trial design, regulatory compliance requirements, and the rate of patient enrollment for the clinical trials. Conducting clinical

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trials involves screening, assessing, testing, treating, and monitoring patients at clinical sites, and coordinating with patients and clinical institutions as well as with neurologists, neurosurgeons, radiologists, and other medical specialists. As a result, we may experience obstacles in completing any of our clinical trials or they could be delayed or cancelled for several reasons, including:

- patients may not enroll, randomize, or complete the clinical trials at the rate we expect;
- patient attrition rates may significantly exceed our expected attrition rates;
- patients may experience serious device or procedure-related adverse events, causing us, a clinical site Institutional Review Board, or IRB, the FDA, or other regulatory authorities to place the clinical trial on hold;
- clinical investigators may not perform the trial on schedule or consistent with the trial protocol, regulations, and good clinical practices; and
- regulatory inspections of the trial or manufacturing facilities may result in our being required to undertake corrective action or suspend or terminate our clinical trial if inspectors find us to be out of compliance with regulatory requirements.

In addition, unanticipated adverse device events, or UADEs, during our clinical trials could cause us to repeat or terminate a trial, or cancel an entire development program. Since the core elements of our cortical stimulation system are relatively the same for different applications, UADEs in one clinical trial or indication may have implications or impact other indications or programs. If our clinical trials are delayed, it will take longer to commercialize related products and achieve revenue. In addition, our research and development costs will likely increase if we experience material delays in our clinical trials or if we need to perform more or larger clinical trials than planned.

Our research and development programs are at an early stage. If the results of our feasibility studies or clinical trials are initially positive, it is possible that we will obtain different results during pivotal trials or that initial results seen in clinical trials will not continue with longer term treatment. Devices in late stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. For example, the results of our early clinical trials for stroke motor recovery were not repeated in our EVEREST pivotal trial.

Future clinical trials of any or all of our cortical stimulation devices could be unsuccessful, which would prevent us from commercializing the *Renova* Cortical Stimulation System. The FDA conducts its own independent analysis of some or all of the preclinical and clinical trial data submitted in a regulatory filing and often comes to different and potentially more negative conclusions than the analysis we performed. Our failure to develop safe, commercially viable devices approved by the FDA would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our stock price.

We may not secure regulatory approval for our Renova Cortical Stimulation System or any other products that we may develop in the future, even if we believe our clinical trial results demonstrate the efficacy of our cortical stimulation therapy.

We cannot market our products unless the FDA has approved, or cleared them. Even if we submit an application to the FDA with clinical data that we believe justifies marketing approval for the *Renova* Cortical Stimulation System or any other product we may develop in the future, the FDA may not approve our submission, or may request additional information, including data from additional clinical trials. The FDA may also approve our system or any other product for very limited purposes with many restrictions on its use, may delay approval, or ultimately may not grant marketing approval for our system. Because our system represents a novel way to treat neurological diseases and disorders such as depression and stroke and there are large populations of patients who might be eligible for treatment, and due to the recent lack of success with our

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EVEREST pivotal trial for stroke motor recovery, it is possible that the FDA and other regulatory bodies will review an application for approval of our *Renova* system with greater scrutiny, thereby causing the regulatory review process to be lengthier and more involved than that for products without such characteristics. There can be no assurance that the FDA will approve our *Renova* Cortical Stimulation System for the treatment of any indication, even if the clinical trial data meets or exceeds our anticipated levels of safety and efficacy.

Even if our Renova Cortical Stimulation System is approved by regulatory authorities, if we fail to comply with ongoing regulation, or if we experience unanticipated problems with our products, our products could be subject to restrictions or withdrawal from the market, and we and/or our suppliers could be subject to legal action.

Any product for which we obtain approval to market will be subject to ongoing regulation, including inspections by the FDA and other regulatory agencies of our products' manufacturing processes, compliance with Quality System Regulations, and review of post-market approval data, as well as review of our promotional activities. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses or populations for which the product may be marketed. For example, we might be limited to marketing our *Renova* system for only a subpopulation of patients, which could significantly reduce the size of the potential market. As a condition of approval, the FDA may mandate a post-market approval trial, which will entail greater clinical costs. In addition, if the data from an FDA-mandated post-market approval trial are not obtained, we may incur additional costs and continued FDA oversight. Furthermore, later discovery of previously unknown problems with our products, including UADEs, manufacturer or manufacturing problems, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions, or the imposition of civil or criminal penalties.

The manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If these manufacturing facilities do not maintain or receive regulatory approval, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our *Renova* system require access to manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. We rely primarily on third parties to manufacture, assemble, and sterilize our system. The FDA must determine that compliance is satisfactory at facilities that manufacture our products. Suppliers of some components of our products must also comply with FDA regulation, which often requires significant time, money, and record-keeping and quality assurance efforts, and subjects us and our suppliers to potential regulatory inspections and stoppages. Our suppliers may not satisfy these requirements. If the FDA finds their compliance status to be unsatisfactory, completion of our clinical trials could be delayed, which would harm our business and our results of operations.

Our Renova Cortical Stimulation System may never achieve market acceptance or adequate levels of reimbursement even if we obtain regulatory approvals.

Market acceptance of our *Renova* Cortical Stimulation System will depend on successfully communicating the benefits of our cortical stimulation therapy to each of the different constituencies involved in deciding whether to treat a particular patient using cortical stimulation therapy:

- the patients and their families;
- the various healthcare providers, and other specialists who treat patients with neurological diseases and disorders;
- institutions such as hospitals and, as applicable, rehabilitation centers, as well as opinion leaders in these institutions; and
- third party payors, such as private healthcare insurers and Medicare, which would ultimately bear most of the costs for the various providers and medical devices involved in the procedures.

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Marketing to each of these constituencies requires a different approach, and we must convince each of these groups of the efficacy and utility of using our *Renova* Cortical Stimulation System to be successful. Our ability to market our system successfully to each of these constituencies will depend on a number of factors, including:

- the perceived effectiveness and long term results of our therapy;
- the level of education and awareness among physicians, and potential patients and their families, concerning our therapy;
- acceptance of the measures used to assess the efficacy of our therapy;
- the price of our system and the associated costs of the surgical procedure and treatment;
- the availability of sufficient third party coverage or reimbursement;
- the frequency and severity of any side effects;
- the willingness of patients to undergo surgery; and
- the availability and perceived advantages and disadvantages of alternative treatments.

If our cortical stimulation therapy does not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable.

If we fail to obtain adequate levels of reimbursement for our products by the government and other third party payors, there may be no commercially viable markets for our Renova Cortical Stimulation System or other products we may develop or our target markets may be much smaller than expected.

The availability and levels of reimbursement by government and other third party payors, such as Medicare, Medicaid, and private healthcare insurers, will substantially affect the markets for cortical stimulation therapy and our ability to commercialize our *Renova* Cortical Stimulation System for any future indications. The efficacy, safety, ease of use, and cost-effectiveness of our system, and of any competing products, will in part determine the availability and level of reimbursement. In particular, we expect that securing reimbursement for our system will be more difficult if our future clinical trials do not demonstrate levels of improvement that healthcare providers and patients consider clinically meaningful, whether or not regulatory agencies consider the improvement of patients treated in clinical trials to have been clinically meaningful. Reimbursement also may be more difficult to obtain if payors view our system as adding to their costs because our therapy may be delivered to patients who are not otherwise receiving a significant amount of reimbursed therapy. Moreover, the novelty of cortical stimulation to treat patients will likely complicate the establishment of a uniform and favorable reimbursement policy.

We expect that both government and third party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our *Renova* Cortical Stimulation System, the related surgery, and hospital stay, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our system may be impaired and our future revenue, if any, may be materially and adversely affected.

We depend on a limited number of manufacturers and single source suppliers of various key components for our Renova Cortical Stimulation System. The loss of any of these manufacturer or supplier relationships could delay our clinical trials or prevent or delay commercialization of our Renova Cortical Stimulation System.

We rely primarily on third parties to manufacture our *Renova* Cortical Stimulation System and to supply us with all of the key components of our system, including our IPGs, cortical stimulation leads and handheld programmers. We have entered into multi-year agreements with our manufacturers and primary suppliers that generally require us to fulfill all of our manufacturing needs and purchase all of our worldwide requirements for

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components from these parties. These agreements expire during 2010. There is no overlap among these suppliers, insofar as we obtain each of our components from a single supplier. There are a limited number of alternative suppliers that are capable of manufacturing the components of system, and the terms of our agreements significantly limit our ability to work with other suppliers to ensure backup sources of our components. If any of our existing suppliers was unable or unwilling to meet our demand for product components, or if the components or finished products that they supply do not meet quality and other specifications, our clinical trials could be delayed and the development of our *Renova* system could be delayed or prevented.

If we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our system could be interrupted for an extended period of time, which could delay completion of our clinical trials. In addition, we may be required to obtain regulatory approval from the FDA to use different suppliers or components. To date, our component requirements have consisted only of the limited quantities that we need to conduct our clinical trials. However, if we obtain market approval for our *Renova* Cortical Stimulation System, we anticipate that we will require substantially larger quantities of various components. Our suppliers may not provide us with sufficient quantities of necessary components in a timely manner that meet quality and other specifications, and we may not be able to locate an alternative supplier in a timely manner or on commercially reasonable terms, if at all. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA.

Even if we obtain regulatory approval to commercialize our Renova Cortical Stimulation System, we will need to develop an infrastructure, or contract with a third party, capable of successfully marketing and selling our products.

To generate sales, we will need to develop a sales and marketing infrastructure or contract with a third party to perform that function. We currently have limited marketing capabilities and have no sales capabilities. Establishing these capabilities will be expensive and time-consuming. We may be unable to develop an effective sales and marketing organization. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

Some of the potential applications of our cortical stimulation therapy system will likely involve implanting an electrode below the dura, the outermost membrane covering the brain, which involves additional risks.

To achieve the maximum benefit from our cortical stimulation therapy system, we believe that for some applications, the electrode through which cortical stimulation is provided may be implanted below the dura. In all of our completed and ongoing clinical trials, the electrode is or has been implanted on the dura. Implanting the electrode grid below the dura may involve additional risks, including the risk that any infections that might occur could be more serious than if the electrode were implanted on the dura, and a risk of a subdural hemorrhage. These additional risks may adversely affect the willingness of potential patients to participate in our clinical trials, and the safety profile of our products in these potential applications, which could make regulatory approval and market acceptance less likely.

The medical device and pharmaceutical industries are highly competitive and subject to rapid technological change. If our competitors are able to develop and market products that are safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The medical device and pharmaceutical industries are highly competitive and subject to rapid technological change. In particular, the neuromodulation industry in which we operate has grown significantly in recent years, and is expected to continue to expand as technology continues to evolve and awareness of neuromodulation as an effective or potential therapy for many applications expands. We face potential competition from other neuromodulation technologies, off-label use of current technologies, and currently available, non-invasive,

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therapies that are medically accepted for treating large populations of patients affected by neurological diseases and disorders for which reimbursement levels are already or may be established. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies. Our competitors may:

- develop and patent processes or products earlier than us;
- obtain regulatory approvals for competing products more rapidly than us; or
- develop more effective, safer, less-invasive, or less-expensive products or technologies.

The field of human therapeutics is characterized by large public and private investment in existing and new technologies, constant evolution, and occasional breakthrough products that revolutionize treatment of a particular disease or disorder. It is possible that, even if we successfully commercialize a product, subsequent pharmaceutical or medical device breakthroughs would render our product non-competitive or obsolete.

Some of the potential applications of our Renova Cortical Stimulation System will likely require sustained delivery of electrical stimulation, which involves additional risks.

Some of the applications for our cortical stimulation therapy system that we are studying, such as the treatment of depression, will likely require a long-term implant and sustained delivery of electrical stimulation to the cortex. Long-term implants and sustained delivery of stimulation may involve additional challenges and risks, including the following:

- the battery in our current IPG is not rechargeable, and IPG replacements in patients may be necessary to support sustained electrical stimulation;
- the therapeutic effect on the patient may not be sustained;
- the clinical trials necessary to support FDA approval of a long-term implantable device that delivers sustained electrical stimulation will likely take longer, and may require longer term follow-up data for such trials; and
- the FDA may require additional data.

We will need substantial additional funding and may not be able to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We believe that our cash, cash equivalents and investments will be sufficient to fund our continuing operations and other demands and commitments into 2011. Prior to that we may elect to raise substantial additional capital to:

- continue our research and development programs;
- commercialize our *Renova* Cortical Stimulation System, if approved by the FDA, for commercial sale; and
- fund our ongoing operations.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress, and cost of our clinical trials and other research and development activities;
- clinical trial results;
- the costs and timing of regulatory approvals;
- the working capital required for general and administrative expenses;

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- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and potential commercial supplies of our *Renova* Cortical Stimulation System and any other products that we may develop;
- the rate of market acceptance of our device;
- the effect of competing products and market developments;
- any revenue generated by sales of our future products;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third party patent or other intellectual property rights;
- the cost of defending other litigation or disputes with third parties; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Until the time, if ever, when we can generate a sufficient amount of product revenue, we expect to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration, or licensing arrangements, as well as through income earned on cash and investment balances.

Additional capital may not be available on terms favorable to us, if at all. If we raise additional funds by issuing equity securities, our shareholders will experience dilution. Debt financing, if available, would likely involve restrictive covenants or additional security interests in our assets. Examples of such restrictive covenants may include limitations on our ability to incur additional debt or liens on any of our assets, dispose of our property, make dividend payments or distributions to our shareholders, or enter into certain transactions that would result in a change in control. Any additional debt or equity financing may contain terms that are not favorable to our shareholders or us. If we raise additional funds through collaboration or licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs, or liquidate some or all of our assets.

We may be unable to attract and retain management and other personnel we need to succeed.

Our success depends substantially on the services of our senior management and other key employees. The loss of the services of one or more of these employees could have a material adverse effect on our business. Each of our officers may terminate his or her employment without notice and without cause or good reason. We do not carry key person life insurance on any of our officers. We have historically used stock options as key components of our total employee compensation program. Many of our outstanding stock options have exercise prices in excess of our stock price, which reduces their value to employees and could affect our ability to retain present and attract prospective employees. Our future success will depend in large part on our ability to attract, retain and motivate highly skilled employees. We cannot be certain that we will be able to do so.

The financial reporting obligations of being a public company and other laws and regulations relating to corporate governance matters place significant demands on our management and cause increased costs.

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and new rules adopted or proposed by the Securities and Exchange Commission, will result in ongoing costs to us as we comply with new and existing rules and regulations and respond to requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. As an early development stage company with limited capital and human resources, management's time and attention will be diverted from our business in

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order to ensure compliance with these regulatory requirements. This diversion of management's time and attention as well as ongoing legal and compliance costs may have a material adverse effect on our business, financial condition and results of operations.

Failure of the our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining effective internal control over financial reporting. Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Internal control over financial reporting includes: (i) maintaining reasonably detailed records that accurately and fairly reflect our transactions; and (ii) providing reasonable assurance that we (a) record transactions as necessary to prepare the financial statements, (b) make receipts and expenditures in accordance with management authorizations, and (c) would timely prevent or detect any unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that we would prevent or detect a misstatement of our financial statements or fraud. Changes in our business will place additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report financial results accurately and timely or to detect and prevent fraud. A significant financial reporting failure could cause an immediate loss of investor confidence and our management and a sharp decline in the market price of our common stock.

If we do not achieve our projected business goals in the time frames we announce and expect, our stock price may decline.

From time to time, we estimate and publicly announce expectations for future financial results and the anticipated timing of the accomplishment of various clinical, regulatory and product development goals. These statements, which are forward-looking statements, include but are not limited to our estimates regarding cash use, operating losses, cortical stimulation applications that we expect to pursue, patient enrollment in our clinical trials, when we expect to complete our clinical trials, when trial data will be publicly disclosed, and when we expect to obtain FDA approval for or begin to receive revenue from any of our products. These estimates are, and must necessarily be, based on a variety of assumptions. The timing of the actual achievement of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control. Our failure to meet any publicly-announced goals may be perceived negatively by the public markets, and, as a result, our stock price may decline.

We face the risk of product liability claims and may not be able to obtain adequate insurance.

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing, and marketing of medical devices. We may be subject to product liability claims if our *Renova* Cortical Stimulation System, or any other products we sell, causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third party strategic collaborators or others selling our products. We have a product liability insurance policy, which covers the use of our products in our clinical trials, of which the amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall, or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our ongoing clinical programs or future commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers.

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We may be subject to product liability claims even if it appears that the claimed injury is due to the actions of others. For example, we rely on the expertise of surgeons, other physicians, therapists, and other medical personnel to perform the medical procedures to implant and remove our *Renova* system and participate in other facets of our therapies. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our system may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the negligence of one of our suppliers could be the basis for a claim against us.

We may be unable to manage our company's growth effectively.

If we engage in a pivotal clinical trial or commercialization efforts in the future, our business will undergo significant growth. For example, we will have to expand existing operations in order to conduct a pivotal trial and additional clinical trials, increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our products, assist in obtaining reimbursement for the use of our products, and create and develop new applications for our technology. Such growth may place significant strain on our management, financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems, and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

Risks Related to Intellectual Property

If we are unable to obtain or maintain intellectual property rights relating to our technology and cortical stimulation therapy system, the commercial value of our technology and any future products will be adversely affected and our competitive position will be harmed.

Our success depends in part on our ability to obtain protection in the United States and other countries for our cortical stimulation therapy system and processes by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. While we hold a number of patents in the neurostimulation field, several other companies also hold patents in the field. In particular, there are several patents and patent applications that address neurostimulation for the treatment of depression, which is one of the applications that we are evaluating. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in patent laws, patent rules, or their interpretations in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the availability of patents in foreign markets, and the nature of any protection against competition that may be afforded by those patents, is often difficult to predict and vary significantly from country to country. We, our licensors, or our licensees may choose not to seek, or may be unable to obtain, patent protection in a country that could potentially be an important market for our *Renova* system. The confidentiality agreements that are designed to protect our trade secrets could be breached, and we might not have adequate remedies for the breach. Additionally, our trade secrets and proprietary know-how might otherwise become known or be independently discovered by others. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products.

If we infringe or are alleged to infringe the intellectual property rights of third parties, our business could be adversely affected.

Our cortical stimulation therapy may infringe or be claimed to infringe patents that we do not own or license, including patents that may issue in the future based on patent applications of which we are currently

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aware, as well as applications of which we are unaware. We are aware of other companies that are investigating neurostimulation, including deep brain stimulation, vagus nerve stimulation, and rTMS, as well as cortical stimulation, and of certain patents and published patent applications held by companies in those fields that may limit our ability to secure patent protection for certain of our technologies. While the applicability of such patents and patent applications to our products and technologies under development and validity of these patents and patent applications are uncertain, third parties who own or control these patents and patent applications in the United States and abroad, could bring claims against us that could cause us to incur substantial expenses and, if successfully asserted against us, could cause us to pay substantial damages and would divert management's attention. As the number of competitors in the market for the treatment of neurological diseases and disorders, specifically with neurostimulation treatment grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases. Further, if a patent infringement suit were brought against us, we could be forced to delay or abandon commercialization of the product that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes, and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Risks Related to Our Common Stock

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price has recently been highly volatile and is likely to continue to be volatile. The stock market in general and the market for small healthcare companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The price for our common stock may be influenced by many factors, including:

- results of our clinical trials;
- delays in enrolling or conducting our ongoing clinical trials, or other developments concerning ongoing clinical trials;
- delays or failures in submitting applications for, or obtaining, regulatory approvals for clinical trials or commercial marketing efforts;
- failure of any of our future products, if approved for commercial sale, to achieve commercial success;
- regulatory developments in the United States and foreign countries;
- regulatory issues related to our quality systems;
- developments or disputes concerning patents or other proprietary rights;

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- ability to develop or manufacture our products;
- public concern over our products;
- introduction of competing products;
- litigation or other disputes with third parties;
- departure of key personnel;
- sales or anticipated sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors' perceptions of us; and
- general economic, industry and market conditions.

A decline in the market price of our common stock could cause investors to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, because of the past significant declines in our stock price, shareholders may initiate securities class action lawsuits against us, which may cause us to incur substantial costs and could divert the time and attention of our management.

We are at risk of securities class action litigation due to our stock price volatility.

We are at risk of being subject to securities class action lawsuits if our stock price declines substantially. Securities class action litigation has often been brought against other companies following a decline in the market price of its securities, such as the stock price decline that we experienced in late January 2008 following our announcement that our EVEREST pivotal trial did not meet its primary endpoint. While no securities class action claims have been brought against us, it is possible that lawsuits will be filed based on such stock price decline naming our company, directors, and officers. Securities litigation could result in substantial costs, divert management's attention and resources, and seriously harm our business, financial condition and results of operations.

If there are substantial sales of common stock, our stock price could decline.

If our existing shareholders sell a large number of shares of common stock or the public market perceives that existing shareholders might sell shares of common stock, the market price of our common stock could decline significantly. Additionally, the potential sale of additional shares of our common stock may cause our stock price to decline. We have an effective Registration Statement on Form S-3 that enables us to offer and sell up to an aggregate of \$100 million shares of our common stock. The potential sale of additional shares of our common stock may be dilutive to our shares outstanding and may cause our stock price to decrease.

Anti-takeover defenses that we have in place could prevent or frustrate attempts to change our direction or management.

Provisions of our articles of incorporation and bylaws and applicable provisions of Washington law may make it more difficult or impossible for a third party to acquire control of us without the approval of our board of directors. These provisions:

- limit who may call a special meeting of shareholders;
- provide for a classified board of directors;
- provide that our board of directors may only be removed for cause by the affirmative vote of our shareholders;

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- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on at shareholder meetings;
- prohibit cumulative voting in the election of our directors; and
- provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without shareholder approval.

In addition, the Washington Business Corporation Act generally prohibits us from engaging in any business combination with certain persons who acquire 10% or more of our voting securities without the prior approval of our board of directors for a period of five years following the date such person acquires the shares. We cannot “opt out” of this statute. These provisions may have the effect of entrenching our management team and may deprive investors of the opportunity to sell their shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Failure to satisfy NASDAQ Global Market listing requirements may result in our common stock being delisted from the NASDAQ Global Market.

Our common stock is currently listed on the NASDAQ Global Market under the symbol “NSTR.” For continued inclusion on the NASDAQ Global Market, we must maintain, among other requirements, shareholders’ equity of at least \$10 million, a minimum bid price of \$1.00 per share and a market value of our public float of at least \$5 million; or market capitalization of at least \$50 million, a minimum bid price of \$1.00 per share and a market value of our public float of at least \$15 million. If we fail to meet a closing bid price of our common stock of \$1.00 for 30 consecutive business days, our common stock could be at risk of being delisted. In the event that we fail to satisfy any of the listing standards on a continuous basis, our common stock could be removed from listing on the NASDAQ Global Market. If our common stock were delisted from the NASDAQ Global Market, our common stock may be transferred to the NASDAQ Capital Market if we satisfy the listing criteria for the NASDAQ Capital Market, or trading of our common stock, if any, may be conducted in the over-the-counter market in the so-called “pink sheets” or, if available, the National Association of Securities Dealer’s “Electronic Bulletin Board.” Consequently, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Additionally, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, our common stock. A delisting would likely also make it more difficult for us to raise funds through the sale of our securities.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock or other securities, and we do not anticipate paying any cash dividends in the foreseeable future. Accordingly, our shareholders will not realize a return on their investment unless the trading price of our common stock appreciates. Our common stock may not appreciate in value and may not maintain the price at which investors purchased shares.

ITEM 2. PROPERTIES

As of December 31, 2007, we leased approximately 37,000 square feet of office space in Seattle, Washington for our headquarters and principal research and development facility, of which approximately 9,500 square feet was sublet to another company. Our lease expires on August 31, 2012, with an option to renew for two successive five-year periods. During each option period the rent will be adjusted to reflect the fair market rate. The sublease, which was amended in February 2007, is scheduled to expire on March 31, 2008. We believe that our current facilities will be sufficient to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not involved in any material legal proceedings.

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the NASDAQ Global Market under the symbol “NSTR”. As of January 31, 2008, there were approximately 2,500 holders of record of our common stock. No cash dividends have ever been paid on the common stock. We intend to retain all future income to fund the development and growth of our business and do not anticipate paying any cash dividends in the foreseeable future.

The following table sets forth, for the periods indicated, the range of high and low quarterly closing sales prices of our common stock:

	<u>High</u>	<u>Low</u>
Year ended December 31, 2007		
4th Quarter	\$ 13.25	\$ 8.72
3rd Quarter	12.32	9.89
2nd Quarter	14.20	11.33
1st Quarter	14.39	10.92
Year ended December 31, 2006		
4th Quarter	\$ 16.75	\$ 11.68
3rd Quarter	13.66	10.94
2nd Quarter (from May 4, 2006)	16.60	8.65

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-132135), which was declared effective by the Securities and Exchange Commission on May 4, 2006, and a Registration Statement on Form S-1 filed pursuant to Rule 462 (File No. 333-133827) that also was effective on May 4, 2006.

We received net proceeds of \$112.0 million from the offering and, as of December 31, 2007, \$83.5 million remains invested in money market accounts and investment securities, and we have used \$28.5 million:

- for direct costs to complete our ongoing and future research and clinical trials;
- to continue the development of our *Renova* Cortical Stimulation System; and
- for working capital and other general corporate purposes.

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and the related notes thereto included in this annual report.

	Year Ended December 31,					Period from Inception (May 18, 1999) to December 31, 2007
	2007	2006	2005	2004	2003	
	(in thousands, except share and per share data)					
Statements of Operations Data:						
Revenue (1)	\$ —	\$ —	\$ —	\$ —	\$ 316	\$ 463
Cost of goods sold (1)	—	—	—	—	366	956
Gross margin	—	—	—	—	(50)	(493)
Operating expenses:						
Research and development	19,422	18,277	11,763	12,367	8,703	84,763
Selling, general and administrative	9,441	6,153	3,257	3,127	6,128	41,219
Other operating expenses, net	—	2,500	794	—	650	4,788
Total operating expenses	28,863	26,930	15,814	15,494	15,481	130,770
Operating loss	(28,863)	(26,930)	(15,814)	(15,494)	(15,531)	(131,263)
Interest income, net	5,010	3,287	558	446	398	11,173
Other (expenses) income, net	—	(1,440)	682	1,637	954	1,832
Net loss	(23,853)	(25,083)	(14,574)	(13,411)	(14,179)	(118,258)
Preferred stock accretion	—	(2,062)	(5,653)	(4,979)	(3,749)	(21,406)
Net loss applicable to common shareholders	\$ (23,853)	\$ (27,145)	\$ (20,227)	\$ (18,390)	\$ (17,928)	\$ (139,664)
Basic and diluted net loss per share applicable to common shareholders	\$ (0.92)	\$ (1.54)	\$ (10.53)	\$ (10.36)	\$ (11.25)	
Share used to compute basic and diluted net loss per share applicable to common shareholders	25,840,292	17,622,609	1,921,170	1,775,309	1,593,488	

(1) Represents revenue and cost of goods sold from the sale of PNT product to customers.

	December 31,				
	2007	2006	2005	2004	2003
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investment securities	\$83,450	\$105,347	\$ 20,187	\$ 27,258	\$ 19,036
Other current assets	1,017	1,138	327	529	529
Property and equipment, net	949	865	935	1,068	1,297
Other assets	93	93	296	93	93
Total assets	\$85,509	\$107,443	\$ 21,745	\$ 28,948	\$ 20,955
Accounts payable and accrued liabilities	\$ 3,658	\$ 3,861	\$ 1,541	\$ 1,762	\$ 1,576
Other liabilities	601	844	2,266	1,400	3,212
Long-term debt	—	—	5,811	—	—
Redeemable convertible preferred stock	—	—	99,860	94,207	66,228
Shareholders' equity (deficit)	81,250	102,738	(87,733)	(68,421)	(50,061)
Total liabilities and shareholders' equity (deficit)	\$85,509	\$107,443	\$ 21,745	\$ 28,948	\$ 20,955

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our audited financial statements and notes thereto that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this report.

The statements contained in this Annual Report on Form 10-K, including statements under this section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include those factors described in greater detail in Item 1A of Part I, "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those anticipated in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Overview

Management's discussion and analysis provides additional insight into Northstar Neuroscience, Inc. and is provided as a supplement to, and should be read in conjunction with, our audited financial statements and accompanying footnotes thereto.

We are a development stage medical device company focused on developing and commercializing innovative neurostimulation therapies to restore function and quality of life for people suffering from neurological diseases and disorders. We incorporated in the State of Washington on May 18, 1999, and since inception we have devoted substantially all of our resources to the development and commercialization of medical technologies utilizing electrical stimulation to treat neurological diseases and disorders.

We are currently conducting, or plan to initiate, clinical trials using our proprietary *Renova*TM Cortical Stimulation System for the treatment of major depressive disorder and stroke motor recovery. We continue to explore additional applications for our cortical stimulation platform and monitor relevant research activities on other neurological diseases and disorders. We have completed enrollment and are actively treating patients in our PROSPECT trial, which is our initial feasibility trial using cortical stimulation to treat major depressive disorder and in our SAHALE feasibility trial for tinnitus. We also have completed enrolling patients in the EVEREST pivotal trial for stroke motor recovery and announced the primary endpoint data in January of 2008.

From 2004 to 2007, we conducted the EVEREST pivotal trial to investigate whether cortical stimulation in conjunction with rehabilitation therapy would lead to improved hand and arm function and activities of daily living compared to the control group which received rehabilitation therapy alone. On January 22, 2008, we announced that the EVEREST trial did not meet its primary efficacy endpoint and we do not expect ongoing or

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subsequent analysis, once completed, will demonstrate sufficient evidence of efficacy to pursue marketing approval from the FDA based on EVEREST data alone. We have commenced planning next steps, including additional clinical work and an analysis of the business opportunity for a potentially optimized therapy for stroke motor recovery.

On February 15, 2008, we announced and began implementing restructuring actions with the objective of streamlining our business in response to the announcement of the results of the EVEREST trial. The restructuring actions include a workforce reduction of approximately 32%. We intend to focus our ongoing resources on the evaluation and development of our *Renova* Cortical Stimulation System for the treatment of major depressive disorder, while also pursuing focused research on stroke motor recovery. We will continue to conduct research on the feasibility of our system for the treatment of other neurological diseases and disorders consistent with our financial and operational resources.

To date, we have not generated any revenue from the sale of cortical stimulation products, and we have incurred net losses in each year since our inception. The limited revenue we have generated since inception has been from the commercial sale of an earlier product, which was sold to a third party in 2003. We expect our net losses to continue, though at a reduced magnitude relative to recent losses, as we continue our clinical trial activities, our research and development efforts, and continue to operate as a public held company. To date, we have financed our operations primarily through public and private placements of equity securities.

Critical Accounting Policies and Significant Judgments and Estimates

Our analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including, but not limited to those related to share-based compensation and clinical trial accruals. We base our estimates on historical experience and on other factors that we believe are 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 materially from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 1 to our audited financial statements for the year ended December 31, 2007. We believe that the following accounting policies relating to research, development and clinical trial accruals and share-based compensation are the most critical to understanding and evaluating our reported financial results.

Research, Development and Clinical Trial Accruals

Research and development costs are expensed as incurred or paid. We record accruals for estimated clinical trial costs, comprised primarily of services rendered under contract by our clinical trial sites, based on patient enrollment and progression through the clinical trial protocol. Clinical trial costs are a significant component of our research and development expenses.

Share-based Compensation Pursuant to SFAS 123(R)

Through December 31, 2005, we accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board Opinion No. 25, or APB 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* an interpretation of APB 25, and related interpretations. We had adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, as amended.

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Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (R), *Share-Based Payment*, or SFAS 123(R), which requires the recognition of share-based compensation expense at fair value. We adopted SFAS 123(R) under the prospective transition method and, therefore, we did not restate results for prior periods.

Pursuant to SFAS 123(R), our estimate of share-based compensation expense requires a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, and future forfeitures. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes over its term because of the greater possibility of significant increases in stock price. We have determined the implied volatility of future periods based primarily on the historical volatility of our common stock subsequent to our initial public offering. The expected term of options granted represents the period of time that options granted are expected to remain outstanding. The expected term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, longer option terms provide more opportunity to exploit market highs. Historical data, however, demonstrates that employees typically do not wait until the end of the contractual term of a nontransferable option to exercise. When establishing an estimate of the expected term of an award, we continue to use the simplified method of determining expected term as permitted by SEC Staff Accounting Bulletins 107 and 110, as we do not have sufficient exercise experience on which to base a determination of expected term. We review our valuation assumptions at each grant date and from time to time we will likely change the valuation assumptions used to estimate the value of future share-based awards granted.

Pursuant to Financial Accounting Standards Board Staff Position No. 123(R)-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*, we have adopted the simplified method to calculate our additional paid-in-capital, or APIC, pool of excess tax benefit. This method was used to calculate our beginning APIC pool and to determine the subsequent effect on the APIC pool for stock-based compensation awards that were outstanding upon our adoption of SFAS 123(R).

Income Taxes

Effective January 1, 2007, we adopted the provisions of the Financial Accounting Standards Board, or FASB, Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes. Based on the implementation guidance set forth in the pronouncement and our review of our tax positions leading up to and subsequent to adoption, FIN 48 did not have a material impact on our financial position, results of operations, or cash flows.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. We adopted SFAS No. 157 on January 1, 2008, and we do not expect the adoption to have a material impact on our financial position, results of operations, or cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits companies to choose to measure many financial instruments and

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certain other items at fair value. We adopted SFAS No. 159 on January 1, 2008, and we do not expect the adoption to have a material impact on our financial position, results of operations, or cash flows.

In June 2007, FASB's Emerging Issues Task Force, or EITF reached a consensus on Issue No. 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The consensus will require us to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period in which the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and early adoption is not permitted. Subsequent to our adoption of EITF 07-1 on January 1, 2008, a change in accounting policy will occur whereby nonrefundable prepayments for research and development services will be deferred and recognized as the services are rendered. Under our existing accounting policy such payments are charged to research and development expense as paid. This accounting policy change may impact our financial condition and the results of operations in the future.

Results of Operations for the Years Ended December 31, 2007, 2006 and 2005

Research and Development Expenses

Our research and development expenses primarily consist of costs incurred to conduct clinical trials, engineering development costs associated with our *Renova* Cortical Stimulation System, and regulatory compliance activities. Research and development expenses are comprised of direct clinical trial costs, employee compensation, including share-based compensation, supplies and materials, consultant services, information technology support, travel, and facilities. We expensed research and development costs at the earlier of when they were incurred, or when they were paid and non-refundable. From our inception through December 31, 2007, we have incurred \$84.8 million in research and development expenses.

Research and development expenses were \$19.4 million in 2007, \$18.3 million in 2006, and \$11.8 million in 2005. The \$1.1 million, or 6%, increase in 2007 was primarily due to increased compensation and benefits, including stock compensation, of \$1.6 million for additional staffing to support clinical trials and planning for commercialization efforts associated with our *Renova* system. Greater expenses associated with commercialization efforts in 2007 can be attributed to prototypes of commercial product and expenses related to engineering consultants increasing in the aggregate by \$1.2 million. The increases were partially offset by a reduction in clinical trial costs of \$2.0 million, primarily due to the completion of the EVEREST clinical trial enrollment in 2007, and a net increase of other development expenses of \$300,000.

The increase of \$6.5 million, or 55%, in 2006 compared to 2005 was due to substantial increases in expenses related to the EVEREST clinical trial of \$5.2 million and increased headcount-related expenses of \$1.5 million, partially offset by a net decrease in other development costs of \$200,000.

We expect our research and development expenses to decrease in 2008 principally due to lower overall clinical trial costs since we have no further pivotal trials scheduled for 2008. We also expect to experience decreases in activity associated with the commercialization efforts of the *Renova* system. Our research and development efforts will be focused on the treatment of depression, as well as research relating to the viability of treatment of other indications with our *Renova* Cortical Stimulation System.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include compensation for executive, finance, intellectual property, marketing and administrative personnel, including share-based compensation, and facilities expenses. Other significant expenses include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our cortical stimulation system.

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Selling, general and administrative expenses were \$9.4 million in 2007, \$6.2 million in 2006, and \$3.3 million in 2005. The \$3.2 million, or 52%, increase in 2007 compared to 2006 was primarily due to a \$1.2 million increase in compensation and benefits, including stock compensation, for additional staffing to support operating as a publicly-held company, infrastructure development, and initial marketing efforts related to commercialization planning. The 2007 expenses also included a \$1.2 million increase in professional services for accounting, investor relations, and legal services relating to public company matters and intellectual property, a \$520,000 increase in consultant expenses related to reimbursement and IT infrastructure development, and a \$320,000 net increase in other general and administrative expenses, primarily relating to insurance, recruiting, relocation and travel associated with increased personnel.

The increase of \$2.9 million, or 88%, in 2006 over 2005 was primarily due to increased personnel costs of \$1.2 million, increased professional service costs of \$1.1 million for accounting, investor relations, legal services relating to public company matters and intellectual property, and net increases in other general and administrative expenses of \$600,000, primarily relating to consultants, board of directors fees and expenses, insurance, market research and reimbursement planning.

We expect our selling, general and administrative expenses to decrease in 2008 due to a decrease in activity related to commercialization and marketing efforts associated with the stroke-motor recovery application of our system, and overall lower headcount-related costs as a result of our February 2008 reduction in force.

Other Operating Expenses

Since inception, other operating expenses have included severance expenses, losses on subleases of our facilities, and intellectual property settlements. No other operating expenses were incurred during 2007. During 2006 an expense of \$2.5 million was incurred to settle a potential ownership dispute and secure ownership rights related to one of our issued U.S. patents and six of our U.S. patent applications. The settlement was expensed on the date incurred. In 2005, we had \$794,000 of other operating expenses related to a loss on sublet office space.

Interest Income, Net

Interest income, net was \$5.0 million in 2007, \$3.3 million in 2006, and \$558,000 in 2005. The increase of \$1.7 million in 2007 over 2006 was due to interest earned on a higher average balance of investments over the full year. The increase of \$2.7 million in 2006 over 2005 was due primarily to interest earned on the investment of proceeds received mid-year from our initial public offering.

Other (Expenses) Income, Net

Other (expenses) income, net included \$1.4 million of expense in 2006, and income of \$682,000 in 2005. The expense of \$1.4 million in 2006 was due to losses incurred on debt repayment and non-cash warrant revaluation charges. The other income of \$682,000 in 2005 represents amortization of a gain on assets sold in a prior year.

Liquidity and Capital Resources

We have incurred losses since our inception in May 1999 and, as of December 31, 2007, we had a deficit accumulated during the development stage of \$118.3 million. As of December 31, 2007, we had \$83.5 million in cash, cash equivalents and investments. We have funded our operations to date principally from the sale of equity securities, raising net proceeds of \$192.7 million through December 31, 2007.

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Cash flow information is as follow, in millions:

	Year ended December 31,		
	2007	2006	2005
Cash provided by (used in):			
Operating activities	\$ (23.9)	\$ (20.5)	\$ (13.7)
Investing activities	\$ 26.2	\$ (87.8)	\$ 11.6
Financing activities	\$ 0.1	\$ 105.4	\$ 7.1

Net Cash Used in Operating Activities

Net cash used in operating activities in 2007, 2006, and 2005 primarily reflects the net loss for those periods, offset in part by non-cash operating expenses including share-based compensation, loss on debt repayment, depreciation, and amortization of premiums on investments, and changes in operating assets and liabilities.

Net Cash Provided by and Used in Investing Activities

Net cash provided by and used in investing activities in 2007, 2006, and 2005 primarily reflects the net of purchases and maturities of investments and purchases of fixed assets.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during 2007 reflects the exercises of stock options. Net cash provided by financing activities in 2006 was primarily attributable to the net proceeds from our initial public offering of \$112.0 million, offset by repayment of debt of approximately \$7.0 million. Net cash provided by financing activities in 2005 was primarily from the issuance of debt.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any product based on our cortical stimulation technology and we have not achieved profitability. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, conduct and complete clinical trials, pursue additional applications for our technology platform and expand our clinical development.

We do not anticipate generating any product revenue unless and until we successfully obtain FDA approval for, and begin selling, our *Renova* Cortical Stimulation System. We believe that our cash, cash equivalents, investments, and related interest income will be sufficient to meet our anticipated cash requirements into 2011. If our available cash, cash equivalents and investments are insufficient to satisfy our liquidity requirements, or if we develop additional products or pursue additional applications for our products, we may seek to sell additional equity or issue debt securities before 2011. The sale of additional equity securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We will require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business.

We anticipate spending additional funds over the next year for the development of new applications of our *Renova* system that may also require the expenditure of significant financial resources and take several years to complete, from development to ultimate commercialization. We expect to fund the development of applications for our *Renova* system with our existing cash, cash equivalents and investment balances.

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Our forecast of the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the “Risk Factors” section of this Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our *Renova* Cortical Stimulation System, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete ongoing clinical trials and successfully deliver a commercial product to market. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, and cost of our clinical trials and other research and development activities;
- clinical trial results;
- the costs and timing of regulatory approvals;
- the working capital required for general and administrative expenses;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and potential commercial supplies of our *Renova* Cortical Stimulation System and any other products that we may develop;
- the rate of market acceptance of our device;
- the effect of competing products and market developments;
- any revenue generated by sales of our future products;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third party patent or other intellectual property rights;
- the cost of defending other litigation or disputes with third parties; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Off-Balance Sheet Arrangements

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

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2007 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years (in thousands)	3-5 Years	More than 5 Years
Operating leases	5,127	1,043	2,204	1,880	—
Total	<u>\$5,127</u>	<u>\$ 1,043</u>	<u>\$ 2,204</u>	<u>\$ 1,880</u>	<u>\$ —</u>

The table above reflects payment obligations that are fixed and determinable. Our commitments for operating leases primarily relate to the lease for our corporate headquarters in Seattle, Washington.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates primarily due to our investment portfolio. We maintain an investment portfolio consisting mainly of money market, federal and state government obligations, municipal obligations, corporate obligations, auction rate securities, and asset-backed securities. We have the intent and ability to hold our fixed income investments until maturity; therefore, we do not anticipate that changes in market interest rates will have a material impact on our operating results or cash flows.

Our investment strategy is governed by a Cash and Investment policy that strives to preserve capital and is reviewed with our Board of Directors periodically. The provisions of our cash and investment policy as of December 31, 2007 include, among other provisions:

- all investments must be rated as investment grade by a recognized rating agency;
- investment securities from a single issuer that is not guaranteed by the good faith and credit of the United States government is limited to 5%;
- expected maturity is limited to 36 months and the average maturity of the portfolio is limited to 18 months; and
- derivatives, synthetics or similar instruments and instruments accounted for off balance sheet are specifically prohibited without prior authorization from the Board of Directors.

Consistent with general market conditions, our investment portfolio is subject to credit and interest rate risks with the investment securities held. We manage our investments pursuant to provisions of our Cash and Investment Policy, in an effort to minimize exposures to credit quality, changes in credit quality, and individual security positions. Since our portfolio is comprised of income-generating securities yielding returns based on stated interest rates, as interest rates change our portfolio value may change materially and future rates of return may diminish as interest rates decline. We do not use derivative or other instruments to hedge our risks associated with changes in interest rates.

Management has reviewed the composition of the investment portfolio and believes that as of December 31, 2007, the portfolio was in compliance with the Cash and Investment Policy. Additionally, subsequent to December 31, 2007, all auction rate securities were liquidated at regularly scheduled auctions, and no losses were realized.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15 (a)1 and (a)2 of Part IV and included in this Form 10-K Annual Report.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed under the Securities Exchange Act of 1934, as amended, or 1934 Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to ensure that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the quarter ended December 31, 2007 we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and the chief financial officer, as required by the rules and regulations under the 1934 Act, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the 1934 Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2007, our disclosure controls and procedures were effective.

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Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability, preparation, and fair presentation of published financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems of internal control determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2007. In conducting this evaluation, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework. Based on its evaluation, our management, with the participation of the Chief Executive Officer and Chief Financial Officer, believes that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by Ernst & Young LLP our independent Public Registered Accounting firm, as stated in their report which is included herein.

The certifications of our Chief Executive Officer and Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act have been filed as Exhibits 31.1 and 31.2 to this report.

Changes in Internal Control Over Financial Reporting

There were no changes that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the quarter ended December 31, 2007.

Limitations on Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Northstar Neuroscience, Inc.

We have audited Northstar Neuroscience, Inc.'s (a development stage company) internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Northstar Neuroscience, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Northstar Neuroscience, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Northstar Neuroscience, Inc. as of December 31, 2007 and 2006, and the related statements of operations, redeemable convertible preferred stock and shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007, and the period from inception (May 18, 1999) to December 31, 2007 of Northstar Neuroscience, Inc. and our report dated March 14, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington
March 14, 2008

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and director nominees is incorporated by reference to our definitive Proxy Statement for our 2008 Annual Meeting of Shareholders under the captions “Election of Directors” and “Corporate Governance.” Information regarding Section 16(a) beneficial ownership reporting compliance is incorporated by reference to the material under the heading “Security Ownership of Certain Beneficial Owners and Management” in the 2008 Proxy Statement. Information relating to our executive officers is contained in Item 12 of this Annual Report on Form 10-K.

We have adopted a written code of conduct that applies to all employees, including our Chief Executive Officer, Chief Financial Officer and Controller, which is a “code of ethics” as defined by applicable rules of the SEC. This code of conduct is publicly available on our website at www.northstarneuro.com in the Investor Relations/Corporate Governance section. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K. If we make any amendments to this code of conduct other than technical, administrative or other non-substantive amendments, or grant any waivers, including implicit waivers, from a provision of this code to our Chief Executive Officer, Chief Financial Officer, or Controller, we will disclose the nature of the amendment or waiver, its effective date and to whom it applies on our website or in a report on Form 8-K filed with the SEC.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the 2008 Proxy Statement under the caption “Executive Compensation.”

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by this item is incorporated by reference to the 2008 Proxy Statement under the captions “Principal Shareholders and Stock Ownership by Management” and “Equity Compensation Plan Information.”

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the 2008 Proxy Statement under the captions “Certain Relationships and Related Transactions” and “Corporate Governance.”

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to the 2008 Proxy Statement under the caption “Principal Accounting Fees and Services.”

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Financial Statements

The financial statements required by this item are included herein:

[Index to Financial Statements](#)

[Report of Independent Registered Public Accounting Firm](#)

Audited Financial Statements:

[Balance Sheets](#)

[Statements of Operations](#)

[Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity \(Deficit\)](#)

[Statements of Cash Flows](#)

[Notes to Financial Statements](#)

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(a)3. Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Incorporated by Reference</u>			<u>Exhibit Number</u>	<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Date of First Filing</u>		
3.1	Amended and Restated Articles of Incorporation of the registrant	S-1	333-132135	3/1/2006	3.4	
3.2	Amended and Restated Bylaws of the registrant	S-1	333-132135	3/1/2006	3.6	
10.1*	Form of Indemnification Agreement entered into between the registrant and each of its directors and officers	S-1	333-132135	3/1/2006	10.1	
10.2*	Amended and Restated 1999 Stock Option Plan and related agreements	S-1	333-132135	3/1/2006	10.5	
10.3*	2006 Performance Incentive Plan and related agreements	S-1	333-132135	3/1/2006	10.6	
10.4	Lease Agreement, dated July 5, 2000, between the registrant and Selig Real Estate Holdings Eight	S-1	333-132135	3/1/2006	10.7	
10.5	First Amendment to Lease dated July 5, 2000, dated as of July 2, 2002, between the registrant and Selig Real Estate Holdings Eight	S-1	333-132135	3/1/2006	10.8	
10.6	Manufacturing Agreement, dated April 9, 2004, between the registrant and Texcel LLC	S-1	333-132135	3/1/2006	10.9	
10.7	Manufacturing Agreement, dated April 9, 2004, between the registrant and SMTEK International, Inc., as amended (SMTEK International, Inc. has been acquired by CTS Electronics Manufacturing Solutions, Inc.)	S-1	333-132135	3/1/2006	10.10	
10.8	Manufacturing Agreement, dated August 30, 2004, between the registrant and Avail Medical Products, Inc.	S-1	333-132135	3/1/2006	10.11	
10.9	Manufacturing Agreement, dated April 8, 2004, between the registrant and Oscor, Inc.	S-1	333-132135	3/1/2006	10.12	

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<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Incorporated by Reference</u>			<u>Exhibit Number</u>	<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Date of First Filing</u>		
10.10*	Consultant Agreement between the registrant and Alan J. Levy, Ph.D.	8-K	0-51951	7/2/2007	10.2	
10.11*	Amended and Restated Executive Employment Agreement between the registrant and John S. Bowers Jr.	8-K	0-51951	7/2/2007	10.1	
10.12*	Form of Employment Agreement between the registrant and Raymond N. Calvert	S-1	333-132135	3/1/2006	10.15	
10.13*	Form of Employment Agreement between the registrant and Nawzer Mehta, Ph.D.	S-1	333-132135	3/1/2006	10.17	
10.14*	Form of Employment Agreement between the registrant and Bradford E. Gliner	S-1	333-132135	3/1/2006	10.18	
10.15*	Executive Management Cash Bonus Program	8-K	0-51951	4/6/2007	10.1	
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

* Denotes a compensatory plan, contract or arrangement, in which the Registrant's directors or executive officers may participate.

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NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)
INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Northstar Neuroscience, Inc.

We have audited the accompanying balance sheets of Northstar Neuroscience, Inc. (a development stage company) as of December 31, 2007 and 2006, and the related statements of operations, redeemable convertible preferred stock and shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007, and the period from inception (May 18, 1999) to December 31, 2007. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Northstar Neuroscience, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, and the period from inception (May 18, 1999) to December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the Company adopted Financial Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, effective January 1, 2007; and the Company adopted Statement of Financial Accounting Standard No. 123 (revised 2004), *Share-Based Payment*, effective January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Northstar Neuroscience Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington
March 14, 2008

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NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)

BALANCE SHEETS
(in thousands, except share and per share data)

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,212	\$ 7,853
Investments, short-term	66,043	72,794
Other current assets	<u>1,017</u>	<u>1,138</u>
Total current assets	77,272	81,785
Investments, long-term	7,195	24,700
Property and equipment, net	949	865
Other assets	<u>93</u>	<u>93</u>
Total assets	<u>\$ 85,509</u>	<u>\$ 107,443</u>
Liabilities, Redeemable Convertible Preferred Stock and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 719	\$ 889
Accrued liabilities	2,939	2,972
Other current liabilities	<u>99</u>	<u>336</u>
Total current liabilities	3,757	4,197
Other long-term liabilities	502	508
Commitments and contingencies	—	—
Shareholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized, 25,884,871 and 25,788,256 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively	26	26
Additional paid-in capital	199,393	197,385
Deferred share-based compensation	(52)	(239)
Deficit accumulated during the development stage	(118,258)	(94,405)
Accumulated other comprehensive gain (loss)	<u>141</u>	<u>(29)</u>
Total shareholders' equity	81,250	102,738
Total liabilities and shareholders' equity	<u>\$ 85,509</u>	<u>\$ 107,443</u>

See accompanying notes

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NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)
STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	<u>Year Ended December 31,</u>			<u>Period from Inception (May 18, 1999) to December 31, 2007</u>
	<u>2007</u>	<u>2006</u>	<u>2005</u>	
Revenue	\$ —	\$ —	\$ —	\$ 463
Cost of goods sold	<u>—</u>	<u>—</u>	<u>—</u>	<u>956</u>
Gross margin	—	—	—	(493)
Operating expenses:				
Research and development	19,422	18,277	11,763	84,763
Selling, general and administrative	9,441	6,153	3,257	41,219
Other operating expenses	<u>—</u>	<u>2,500</u>	<u>794</u>	<u>4,788</u>
Total operating expenses	<u>28,863</u>	<u>26,930</u>	<u>15,814</u>	<u>130,770</u>
Operating loss	(28,863)	(26,930)	(15,814)	(131,263)
Interest income, net	5,010	3,287	558	11,173
Other (expenses) income, net	<u>—</u>	<u>(1,440)</u>	<u>682</u>	<u>1,832</u>
Net loss	(23,853)	(25,083)	(14,574)	(118,258)
Preferred stock accretion	<u>—</u>	<u>(2,062)</u>	<u>(5,653)</u>	<u>(21,406)</u>
Net loss applicable to common shareholders	<u>\$ (23,853)</u>	<u>\$ (27,145)</u>	<u>\$ (20,227)</u>	<u>\$ (139,664)</u>
Basic and diluted net loss per share applicable to common shareholders	<u>\$ (0.92)</u>	<u>\$ (1.54)</u>	<u>\$ (10.53)</u>	
Shares used in computation of basic and diluted net loss per share applicable to common shareholders	<u>25,840,292</u>	<u>17,622,609</u>	<u>1,921,170</u>	

See accompanying notes

NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Share-based Compensation	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Issuance of common stock to founders and employees for services, technology and cash of \$0.00 to \$0.015 per share	—	\$ —	1,479,166	\$ 2	\$ 187	\$ (163)	\$ —	\$ —	\$ 26
Exercise of stock options at various times during the year for cash of \$0.015 per share	—	—	27,333	—	—	—	—	—	—
Non-employee share-based compensation	—	—	—	—	2	—	—	—	2
Amortization of deferred share-based compensation	—	—	—	—	—	28	—	—	28
Issuance of Series A redeemable convertible preferred stock for cash of \$1.00 per share (June)	3,050,000	3,050	—	—	—	—	—	—	—
Preferred stock offering costs	—	—	—	—	(16)	—	—	—	(16)
Preferred stock accretion	—	95	—	—	(95)	—	—	—	(95)
Net loss	—	—	—	—	—	—	(1,237)	—	(1,237)
Balance at December 31, 1999	3,050,000	3,145	1,506,499	2	78	(135)	(1,237)	—	(1,292)
Repurchase of common stock at various times during the year from terminated employees for cash of \$0.015 per share	—	—	(118,055)	—	(13)	11	—	—	(2)
Exercise of stock options at various times during the year for cash of \$0.15 to \$0.42 per share	—	—	160,442	—	32	—	—	—	32
Non-employee share-based compensation	—	—	—	—	8	—	—	—	8
Amortization of deferred share-based compensation	—	—	—	—	—	80	—	—	80
Issuance of Series B redeemable convertible preferred stock for cash of \$2.80 per share (February)	3,085,714	8,640	—	—	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock for cash of \$4.00 per share (December)	1,750,000	7,000	—	—	—	—	—	—	—
Preferred stock offering costs	—	—	—	—	(30)	—	—	—	(30)
Preferred stock accretion	—	663	—	—	(663)	—	—	—	(663)
Net loss	—	—	—	—	—	—	(4,930)	—	(4,930)
Balance at December 31, 2000	7,885,714	19,448	1,548,886	2	(588)	(44)	(6,167)	—	(6,797)
Repurchase of common stock at various times during the year from terminated employees for cash of \$0.15 to \$0.42 per share	—	—	(26,833)	—	(3)	—	—	—	(3)
Exercise of stock options at various times during the year for cash of \$0.15 to \$0.60 per share	—	—	15,900	—	3	—	—	—	3
Non-employee share-based compensation	—	—	—	—	121	—	—	—	121
Amortization of deferred share-based compensation	—	—	—	—	—	27	—	—	27
Issuance of Series C redeemable convertible preferred stock for cash of \$4.00 per share (April)	515,000	2,060	—	—	—	—	—	—	—
Preferred stock offering costs	—	—	—	—	(6)	—	—	—	(6)
Preferred stock accretion	—	1,250	—	—	(1,250)	—	—	—	(1,250)
Unrealized gain on investments	—	—	—	—	—	—	—	3	3
Net loss	—	—	—	—	—	—	(7,804)	—	(7,804)
Comprehensive loss	—	—	—	—	—	—	—	—	(7,801)
Balance at December 31, 2001	8,400,714	\$ 22,758	1,537,953	\$ 2	\$ (1,723)	\$ (17)	\$ (13,971)	\$ 3	\$ (15,706)

NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)
(In thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Share-based Compensation	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at January 1, 2001	8,400,714	\$ 22,758	1,537,953	\$ 2	\$ (1,723)	\$ (17)	\$ (13,971)	\$ 3	\$ (15,706)
Exercise of stock options at various times during the year for cash of \$0.15 to \$1.20 per share	—	—	84,103	—	50	—	—	—	50
Non-employee share-based compensation	—	—	—	—	74	—	—	—	74
Amortization of deferred share-based compensation	—	—	—	—	—	13	—	—	13
Issuance of Series D redeemable convertible preferred stock for cash of \$4.00 per share (April/May)	9,191,248	36,765	—	—	—	—	—	—	—
Preferred stock offering costs	—	—	—	—	(612)	—	—	—	(612)
Preferred stock accretion	—	2,956	—	—	(2,956)	—	—	—	(2,956)
Unrealized gain on investments	—	—	—	—	—	—	—	34	34
Net loss	—	—	—	—	—	—	(13,187)	—	(13,187)
Comprehensive loss	—	—	—	—	—	—	—	—	(13,153)
Balance at December 31, 2002	17,591,962	\$ 62,479	1,622,056	\$ 2	\$ (5,167)	\$ (4)	\$ (27,158)	\$ 37	\$ (32,290)
Repurchase of common stock at various times during the year from terminated employees for cash of \$0.42 to \$1.20 per share	—	—	(7,153)	—	(6)	—	—	—	(6)
Exercise of stock options at various times during the year for cash of \$0.15 to \$1.20 per share	—	—	101,787	—	64	—	—	—	64
Non-employee share-based compensation	—	—	—	—	54	—	—	—	54
Employee share-based compensation	—	—	—	—	78	—	—	—	78
Deferred share-based compensation	—	—	—	—	36	(36)	—	—	—
Amortization of deferred share-based compensation	—	—	—	—	—	10	—	—	10
Preferred stock accretion	—	3,749	—	—	(3,749)	—	—	—	(3,749)
Unrealized loss on investments	—	—	—	—	—	—	—	(43)	(43)
Net loss	—	—	—	—	—	—	(14,179)	—	(14,179)
Comprehensive loss	—	—	—	—	—	—	—	—	(14,222)
Balance at December 31, 2003	17,591,962	\$ 66,228	1,716,690	\$ 2	\$ (8,690)	\$ (30)	\$ (41,337)	\$ (6)	\$ (50,061)

NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)
(In thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Share-based Compensation	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amounts					
Balance at January 1, 2004	17,591,962	\$ 66,228	1,716,690	\$ 2	(8,690)	\$ (30)	\$ (41,337)	\$ (6)	\$ (50,061)
Exercise of stock options at various times during the year for cash of \$0.15 to \$1.20 per share	—	—	179,660	—	115	—	—	—	115
Non-cash issuance of common stock warrants at fair value as consideration for a technology licensing agreement	—	—	—	—	15	—	—	—	15
Non-employee share-based compensation	—	—	—	—	30	—	—	—	30
Deferred share-based compensation	—	—	—	—	24	(24)	—	—	—
Amortization of deferred share-based compensation	—	—	—	—	—	22	—	—	22
Issuance of Series E redeemable convertible preferred stock for cash of \$4.77 per share (April)	4,821,803	23,000	—	—	—	—	—	—	—
Preferred stock offering costs	—	—	—	—	(61)	—	—	—	(61)
Preferred stock accretion	—	4,979	—	—	(4,979)	—	—	—	(4,979)
Unrealized loss on investments	—	—	—	—	—	—	—	(91)	(91)
Net loss	—	—	—	—	—	—	(13,411)	—	(13,411)
Comprehensive loss	—	—	—	—	—	—	—	—	(13,502)
Balance at December 31, 2004	22,413,765	94,207	1,896,350	2	(13,546)	(32)	(54,748)	(97)	(68,421)
Repurchase of common stock at various times during the year from terminated employees for cash of \$0.90 to \$1.20 per share	—	—	(6,778)	—	(7)	—	—	—	(7)
Exercise of stock options at various times during the year for cash of \$0.15 to \$2.25 per share	—	—	201,514	—	176	—	—	—	176
Non-employee share-based compensation	—	—	—	—	108	—	—	—	108
Deferred share-based compensation	—	—	—	—	1,185	(1,185)	—	—	—
Amortization of deferred share-based compensation	—	—	—	—	—	564	—	—	564
Preferred stock accretion	—	5,653	—	—	(5,653)	—	—	—	(5,653)
Unrealized gain on investments	—	—	—	—	—	—	—	74	74
Net loss	—	—	—	—	—	—	(14,574)	—	(14,574)
Comprehensive loss	—	—	—	—	—	—	—	—	(14,500)

NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)
(In thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Share-based Compensation	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amounts					
Balance at December 31, 2005	22,413,765	99,860	2,091,086	2	(17,737)	(653)	(69,322)	(23)	(87,733)
Proceeds from initial public offering, net	—	—	8,165,000	8	111,971	—	—	—	111,979
Exercise of stock options at various times during the year for cash of \$0.15 to \$2.25 per share	—	—	503,066	1	424	—	—	—	425
Non-employee share-based compensation	—	—	—	—	171	—	—	—	171
Amortization of deferred share-based compensation	—	—	—	—	—	414	—	—	414
Employee share-based compensation under SFAS 123R	—	—	—	—	1,331	—	—	—	1,331
Preferred stock accretion	—	2,062	—	—	(2,062)	—	—	—	(2,062)
Conversion of preferred stock to common stock	(22,413,765)	(101,922)	14,942,499	15	101,907	—	—	—	101,922
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	1,380	—	—	—	1,380
Net exercise of common stock warrants	—	—	86,605	—	—	—	—	—	—
Unrealized gain on investment securities	—	—	—	—	—	—	—	(6)	(6)
Net loss	—	—	—	—	—	—	(25,083)	—	(25,083)
Comprehensive loss	—	—	—	—	—	—	—	—	(25,089)
Balance at December 31, 2006	—	\$ —	25,788,256	\$ 26	\$ 197,385	\$ (239)	\$ (94,405)	\$ (29)	\$ 102,738
Exercise of stock options at various times during the year for cash of \$0.42 to \$11.48 per share	—	—	93,615	—	102	—	—	—	102
Non-employee share-based compensation	—	—	3,000	—	122	—	—	—	122
Amortization of deferred share-based compensation	—	—	—	—	—	63	—	—	63
Employee share-based compensation under SFAS 123R	—	—	—	—	1,908	—	—	—	1,908
Reversal of deferred Stock-based compensation for terminated employees	—	—	—	—	(124)	124	—	—	—
Unrealized gain on investment securities	—	—	—	—	—	—	—	170	170
Net loss	—	—	—	—	—	—	(23,853)	—	(23,853)
Comprehensive loss	—	—	—	—	—	—	—	—	(23,683)
Balance at December 31, 2007	—	\$ —	25,884,871	\$ 26	\$ 199,393	\$ (52)	\$ (118,258)	\$ 141	\$ 81,250

See accompanying notes

NORTHSTAR NEUROSCIENCE, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS
(in thousands)

	<u>Year Ended December 31,</u>			<u>Period from Inception (May 18, 1999) to December 31, 2007</u>
	<u>2007</u>	<u>2006</u>	<u>2005</u>	
Operating activities				
Net loss	\$ (23,853)	\$ (25,083)	\$ (14,574)	\$ (118,258)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	274	251	272	2,084
Share-based compensation	2,093	1,916	672	5,224
Amortization of securities (discount) premium	(2,128)	(451)	371	(1,198)
Non-cash loss on debt repayment	—	871	—	871
Accretion of debt original issuance discount	—	318	—	318
Revaluation of preferred stock warrants to fair value	—	290	—	290
Amortization of gain on sale of PNT assets	—	—	(682)	(4,096)
Lease incentive	—	—	—	902
Other non-cash items	13	(12)	—	42
Changes in operating assets and liabilities:				
Other assets	121	(608)	(1)	(1,110)
Other liabilities	(446)	1,988	237	3,357
Net cash used in operating activities	<u>(23,926)</u>	<u>(20,520)</u>	<u>(13,705)</u>	<u>(111,574)</u>
Investing activities				
Purchases of property and equipment	(360)	(181)	(139)	(3,675)
Proceeds from sale of PNT assets	—	—	—	4,750
Purchases of investment securities	(148,482)	(149,710)	(13,940)	(404,832)
Maturities of investment securities	175,025	62,095	25,686	332,934
Net cash provided (used in) by investing activities	26,183	(87,796)	11,607	(70,823)
Financing Activities				
Proceeds from initial public offering, net of offering costs	—	111,979	—	111,979
Proceeds from sale of redeemable convertible preferred stock, net of offering costs	—	—	—	79,790
Proceeds from exercise of stock options, net of common stock repurchases	102	425	169	975
Proceeds from issuance of debt, net of offering costs	—	—	5,811	5,811
Issuance of warrants	—	—	1,090	1,090
Principal payments on debt and capital lease obligations	—	(7,000)	—	(7,036)
Net cash provided by financing activities	<u>102</u>	<u>105,404</u>	<u>7,070</u>	<u>192,609</u>
Net increase (decrease) in cash and cash equivalents	2,359	(2,912)	4,972	10,212
Cash and cash equivalents at beginning of period	7,853	10,765	5,793	—
Cash and cash equivalents at end of period	<u>\$ 10,212</u>	<u>\$ 7,853</u>	<u>\$ 10,765</u>	<u>\$ 10,212</u>
Supplemental schedule of non-cash activities:				
Conversion of redeemable convertible preferred stock and warrants to common stock and warrants	\$ —	\$ 103,302	\$ —	\$ 103,302
Preferred stock accretion	—	2,062	5,653	21,406
Deferred share-based compensation	(124)	—	1,185	1,284
Interest paid	—	438	—	438

See accompanying notes

1. Organization and Summary of Significant Accounting Policies

Business

Northstar Neuroscience, Inc. is a development stage medical device company headquartered in Seattle, Washington, focused on developing novel neurostimulation therapies for a broad range of neurological diseases and disorders. We incorporated in the State of Washington on May 18, 1999 and have devoted substantially all of our resources to development and commercialization of medical technologies utilizing electrical stimulation to treat neurological diseases and disorders.

We continue to report as a development stage company, since planned principal operations have not commenced. We operate in a single segment and management uses one measure of financial performance and does not segment its business for internal reporting.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used for, but not limited to, accruals for clinical trial activities and the assumptions used in determining share-based compensation expenses. Actual results could differ from management's estimates and assumptions.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standard, or SFAS, No. 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. We will adopt SFAS No. 157 as of January 1, 2008, and we do not expect the adoption to have a material impact on our financial position, results of operations, or cash flows.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS No. 159 permits companies to choose to measure many financial instruments and certain other items at fair value. We will adopt SFAS No. 159 as of January 1, 2008, and we do not expect the adoption to have a material impact on our financial position, results of operations, or cash flows.

In June 2007, FASB's Emerging Issues Task Force, or EITF reached a consensus on Issue No. 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The consensus will require us to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period in which the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and early adoption is not permitted. Subsequent to our adoption of EITF 07-1 on January 1, 2008, a change in accounting policy will occur whereby nonrefundable prepayments for research and development services will be deferred and recognized as the services are rendered. Under our existing accounting policy such payments are charged to research and development expense as paid. This accounting policy change may impact our financial condition and the results of operations in the future.

Liquidity

We have incurred losses since our inception in May 1999 and, as of December 31, 2007, we had a deficit accumulated during the development stage of \$118.3 million. We have funded our operations to date from public and private placements of equity securities and stock option exercises, raising net proceeds of \$192.7 million through December 31, 2007.

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Cash and Cash Equivalents

We consider cash equivalents to be those money market accounts and investments, which are highly liquid, readily convertible to cash, and which have original maturities within three months of the date of purchase.

Investments

We invest in marketable debt securities as part of our cash management program. Classification of investment securities is determined at the time of purchase and is re-evaluated as of each balance sheet date. Investments in securities that mature or are expected to be liquidated in less than one year are classified as short-term.

Investments in debt securities are classified and accounted for as available-for-sale. Investments are recorded at fair value in both short-term and long-term investments, with the unrealized gains and losses reported as a separate component of shareholders' equity. Amortization, accretion, interest and dividends, and realized gains and losses are included in interest income. The cost of securities sold is determined using the specific-identification method.

Investments are considered impaired when a decline in fair value is deemed to be other-than-temporary. We periodically review our investments for potential impairment. If cost exceeds fair value, we consider, among other factors, the duration and extent to which cost exceeds fair value, the financial strength of the issuer, and our intent and ability to hold the investment to maturity. Once a decline in value is deemed to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established. No impairment losses were recognized during 2007, 2006, or 2005.

Concentration of Credit Risk and Certain Other Risks

Financial instruments that potentially subject us to significant concentrations of credit risk consist of our holdings of cash, cash equivalents, and investments. We attempt to reduce our credit risk by investing in high-quality market instruments, securities of U.S. government agencies, and high-quality corporate issuers. Our investment guidelines limit the investment holdings in any one issuer to 5% of the total portfolio, except for investments in U.S. treasury and agency obligations and money market funds.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, ranging from three to seven years. Leasehold improvements are amortized over the shorter of the useful life or the underlying lease term. Amortization expense related to leasehold improvements is included in depreciation expense.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or any other significant adverse change that would indicate that the carrying amount of an asset is not recoverable.

For long-lived assets used in operations, impairment losses are only recorded if the asset's carrying amount is not recoverable through its undiscounted, probability-weighted cash flows. Impairment losses are measured based on the difference between the carrying amounts and estimated fair value. No impairment losses have been recognized to date.

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Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense accrued and amounts paid under the lease agreement is recorded as deferred rent.

Research and Development Expenses

Research and development expenses include payroll, employee benefits, share-based compensation, clinical studies performed by third parties, materials and supplies to support ongoing clinical programs, contracted research, product development and related manufacturing of prototype and trial units, consulting arrangements, and other expenses incurred to sustain our overall research and development programs. Internal research and development costs are expensed as incurred. Through December 31, 2007, third-party research and development costs were expensed at the earlier of when the contracted work was performed or as nonrefundable upfront payments were made.

Clinical trial costs are a significant component of our research and development expenses and are accrued based on patient enrollment and progression through the clinical trial protocol. Clinical trial costs are comprised primarily of services rendered under contract by our clinical trial sites.

In June 2007, the FASB ratified Emerging Issues Task Force, Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF No. 07-3. This consensus requires that nonrefundable contractual prepayments related to future research and development activities be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. We will adopt EITF No. 07-3 as of January 1, 2008, and it is not expected to have a material impact on our financial position, results of operations, or cash flows.

Patents

We generally apply for patent protection on our processes and products. Patent application costs are expensed as incurred, as recoverability of such expenditures is uncertain. Patent costs are classified as a component of selling, general and administrative expenses.

Income Taxes

On January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—An Interpretation of SFAS No. 109, Accounting for Income Taxes*, or FIN 48. Deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances have been established to reduce deferred tax assets to the amounts expected to be realized.

The newly adopted interpretation clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of uncertain tax positions taken or expected to be taken in a tax return. As a result of implementing FIN 48, we did not have any deferred tax benefits that would impact our effective tax rate and therefore, there was no material effect on our financial position, results of operations, or cash flows.

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss includes certain changes in equity that are excluded from net loss. Our accumulated other comprehensive loss represents unrealized gains and losses on investments.

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Share-Based Compensation

Share-based Compensation Pursuant to SFAS 123(R)

Through December 31, 2005, we accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board Opinion No. 25, or APB 25, *Accounting for Stock Issued to Employees*, FASB No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB 25, and related interpretations. We had adopted the disclosure-only provisions of SFAS 123, *Accounting for Stock-Based Compensation*, as amended.

Effective January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment*, which requires the recognition of share-based compensation expense at fair value. We adopted SFAS 123(R) under the prospective transition method and, therefore, we did not restate results for prior periods.

Pursuant to FASB Staff Position No. 123(R)-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*, we have adopted the simplified method to calculate our additional paid-in-capital, or APIC, pool of excess tax benefit. This method was used to calculate our beginning APIC pool and to determine the subsequent effect on the APIC pool for stock-based compensation awards that were outstanding upon our adoption of FAS 123(R).

Pursuant to SFAS 123(R), our estimate of share-based compensation expense requires a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, and future forfeitures. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes over its term because of the greater possibility of significant increases in stock price. We have determined the implied volatility of future periods based primarily on the historical volatility of our common stock subsequent to our initial public offering. The expected term of options granted represents the period of time that options granted are expected to remain outstanding. The expected term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, longer option terms provide more opportunity to exploit market highs. Historical data, however, demonstrates that employees typically do not wait until the end of the contractual term of a nontransferable option to exercise. When establishing an estimate of the expected term of an award, we continue to use the simplified method of determining expected term as permitted by SEC Staff Accounting Bulletins 107 and 110, as we do not have sufficient exercise experience on which to base a determination of expected term. We review our valuation assumptions at each grant date and from time to time we will likely change the valuation assumptions used to estimate the value of future share-based awards granted.

Presentation

Certain prior period amounts have been presented to conform to our current financial statement period presentation. These presentation changes did not impact the net increase (decrease) in cash flows, net loss, or total assets, liabilities, or shareholders' equity.

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2. Investments

Information regarding our investments is as follows (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Investment Securities Fair Value</u>	<u>Cash Equivalents</u>	<u>Short-term Investments</u>	<u>Long-term Investments</u>
Year ended December 31, 2007							
Money market funds	\$ 5,975	\$ —	\$ —	\$ 5,975	\$ 5,975	\$ —	\$ —
Government and agency debt	6,199	9	(4)	6,204	—	3,002	3,202
Domestic corporate debt	45,010	131	(14)	45,127	—	41,134	3,993
Auction rate securities	15,450	—	—	15,450	—	15,450	—
Asset-backed securities	10,174	19	—	10,193	3,736	6,457	—
Total	<u>\$ 82,808</u>	<u>\$ 159</u>	<u>\$ (18)</u>	<u>\$ 82,949</u>	<u>\$ 9,711</u>	<u>\$ 66,043</u>	<u>\$ 7,195</u>
Year ended December 31, 2006							
Money market funds	\$ 5,764	\$ —	\$ —	\$ 5,764	\$ 5,764	\$ —	\$ —
Government and agency debt	16,477	7	(12)	16,472	—	3,999	12,473
Domestic corporate debt	59,997	18	(43)	62,972	—	50,745	12,227
Auction rate securities	18,050	—	—	18,050	—	18,050	—
Asset-backed securities	2,999	1	—	3,000	—	3,000	—
Total	<u>\$ 103,287</u>	<u>\$ 26</u>	<u>\$ (55)</u>	<u>\$ 103,258</u>	<u>\$ 5,764</u>	<u>\$ 72,794</u>	<u>\$ 24,700</u>

Investments by expected year of maturity at December 31, 2007 are as follows (in thousands):

	<u>Amortized Cost</u>	<u>Fair Market Value</u>
2008	\$ 65,937	\$ 66,043
2009	5,170	5,200
2010	2,000	1,995
	<u>\$ 73,107</u>	<u>\$ 73,238</u>

The unrealized losses on the investment securities held at December 31, 2007 and 2006 are primarily attributable to changes in interest rates and are considered to be temporary in nature. As of December 31, 2007, no investments have had unrealized losses for greater than twelve months. No investment losses have been incurred and no impairment losses have been recorded during the periods presented.

3. Property and Equipment

Property and equipment consists of the following (in thousands):

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Office and lab equipment	\$ 797	\$ 794
Furniture, fixtures, and leasehold improvements	1,201	1,168
Software	192	234
	2,190	2,196
Accumulated depreciation and amortization	(1,241)	(1,331)
	<u>\$ 949</u>	<u>\$ 865</u>

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4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2007	2006
Clinical trial expenses	\$ 1,827	\$ 2,394
Professional services	257	104
Employee compensation	797	373
Other	58	101
	<u>\$ 2,939</u>	<u>\$ 2,972</u>

5. Lease Agreements

We entered into a non-cancelable operating lease agreement in July 2000 for office and research facilities, and amended the lease in July 2002. The amended lease commenced September 1, 2002, continues through August 2012, and includes two five-year renewal periods, at our option, at the then-market rate for comparable facilities. In addition, the lease provided for a rent credit of \$420,000 to be applied to specified future periods and a tenant improvement allowance of \$902,000. In accordance with SFAS No. 13, the rent credit has been factored into our straight-line rent expense calculation as a reduction of overall lease expense during the term of the lease. We utilized the tenant improvement incentive prior to occupancy, and reflect that incentive on the balance sheet both as a leasehold improvement in property and equipment and as deferred rent. The leasehold improvement is being amortized over the term of the lease. Rent expense under this lease for the years ended December 31, 2007, 2006, and 2005 was \$763,000, \$643,000, and \$680,000, respectively.

Future minimum lease payments for non-cancelable operating leases are as follows (in thousands):

Years ending December 31:	
2008	\$1,043
2009	1,134
2010	1,070
2011	1,134
2012	746
Thereafter	<u>—</u>
	<u>\$5,127</u>

During February 2005, we executed a three-year sublease for a portion of the facilities covered by our amended lease and recorded a loss at the commencement of the sublease representing the difference between the sublease proceeds and the lease expense over the term of the sublease. The accrued loss is reduced monthly as rent is paid, and at December 31, 2007 was \$65,000. During 2007, the sublease was amended to return a portion of the facilities to us in exchange for reductions and elimination of sublease payments. Total payments received under all subleases during 2007, 2006, and 2005 were \$23,000, \$173,000, and \$269,000, respectively. The sublease will terminate in 2008.

6. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2007, we have recorded a valuation allowance equal to our total net deferred tax assets due to the uncertainty of ultimately realizing tax benefits of approximately \$42.8 million. We are subject to audit by the IRS for all years since inception.

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In June 2006 the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, or FIN 48. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, or SFAS 109. This interpretation prescribes 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. FIN 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition.

On January 1, 2007, we adopted the provisions of FIN 48, Accounting for Uncertainty in Income Taxes. We did not have any unrecognized tax benefits that would require an adjustment to the January 1, 2007 beginning balance of retained earnings, and adoption did not impact our financial position, results of operations or cash flows. We did not have any unrecognized tax benefits at January 1, 2007 or at December 31, 2007. Our policy is to classify any interest and penalties as a component of tax expense. To date, there have been no interest or penalties charged to us in relation to the underpayment of income taxes.

Significant components of the our deferred tax assets and liabilities approximated the following (in thousands):

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 39,457	\$ 31,864
Research and development tax credits	2,479	1,997
Book expense in excess of tax	976	626
Total deferred tax assets	42,912	34,487
Deferred tax liability:		
Tax expense in excess of book	(104)	(149)
Total deferred tax assets and liabilities	42,808	34,338
Less valuation allowance	(42,808)	(34,338)
Net deferred tax assets and liabilities	\$ —	\$ —

We recognized a valuation allowance equal to the total deferred tax assets and liabilities due to the uncertainty of realizing the benefits of the assets. The valuation reserve increased by \$8.5 million in 2007, \$10.2 million in 2006, and \$4.6 million in 2005, primarily due to the increase in net operating loss carryforwards.

At December 31, 2007, we had net operating loss carryforwards of approximately \$112.8 million and research and development tax credits of approximately \$2.5 million. These net operating loss carryforwards and tax credits will expire from 2019 to 2027. In accordance with Section 382 of the Internal Revenue Code, a change in ownership of greater than 50% within a three-year period will place an annual limitation on our ability to utilize existing net operating loss carryforwards. Due to redeemable convertible preferred stock issuances as well as our initial public offering, we may be subject to these annual limitations and, therefore, unable to fully utilize the net operating loss carryforwards and research and development tax credits.

Under SFAS 123(R), excess tax benefits related to stock option deductions incurred after December 31, 2005, are recognized in the period in which the tax deduction is realized as a reduction of income taxes payable. As a result, we have not recorded deferred tax assets for certain stock option deductions included in its net operating loss carryforwards and research and development tax credits. At December 31, 2007, deferred tax assets have not been recorded on federal net operating loss carryforwards of approximately \$5.8 million. These stock option tax benefits will be recorded as an increase in additional paid-in capital when realized.

7. Shareholders' Equity (Deficit)

Redeemable Convertible Preferred Stock Warrants

In connection with the a loan and security agreement executed in December 2005, we issued warrants to purchase shares of our Series E redeemable convertible preferred stock, which, as of May 4, 2006, converted into warrants to purchase 118,798 shares of common stock at \$7.155 per share. Pursuant to the terms of the warrants, the warrant holders, at their sole discretion, may net exercise the warrants based upon the fair value of the common stock at the date of exercise.

Prior to the conversion of the Series E redeemable convertible preferred stock warrants into common stock warrants, the preferred stock warrants were classified as a liability on the balance sheet pursuant to SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and related FASB Staff Position 150-5, *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*. The warrants were subject to re-measurement at each balance sheet date and changes in fair value were recognized as a component of other expense.

Management determined that the fair value of the warrants was \$1,090,000 at issuance and at December 31, 2005. We determined the fair value of the warrants at May 4, 2006 was \$1,380,000 using the Black-Scholes option pricing model with the following assumptions, on an as converted basis: risk-free interest rate of 5.2%; contract term of 9.7 years; volatility of 45.0%; and a common stock value of \$15.00 per share. The \$290,000 change in value from December 31, 2005 to May 4, 2006 is reflected in the statement of operations for 2006 as other expense.

Common Stock Warrants

During 2006, holders of warrants to purchase 134,185 shares of common stock at prices ranging from \$1.20 to \$7.155 per share elected to net-exercise their warrants in exchange for 86,605 shares of common stock. The determination of the net shares to issue to the warrant holders was based on the fair value of the common stock on the dates of exercise. The fair value on the dates of exercise ranged from \$15.00 to \$16.45. No cash was received or paid in conjunction with these transactions.

As of December 31, 2007 and 2006, a warrant to purchase 71,279 shares of common stock at \$7.155 per share was outstanding.

Preferred Stock

As of December 31, 2007, we were authorized to issue 5,000,000 shares of preferred stock. Our Board of Directors has the authority, without action by the shareholders, to designate and issue shares of preferred stock in one or more series. The Board of Directors may also designate the rights, preferences and powers of each series of preferred stock, any or all of which may be greater than the rights of the common stock including restrictions of dividends on the common stock, dilution of the voting power of the common stock, reduction of the liquidation rights of the common stock, and delaying or preventing a change in control without further action by the shareholders. The Board of Directors has not designated any rights, preference or powers of any preferred stock and no preferred shares have been issued subsequent to our IPO.

Since inception, we have issued Series A through E redeemable convertible preferred stock. In connection with the completion of our IPO on May 4, 2006, all shares of then-outstanding redeemable convertible preferred stock converted into 14,942,499 shares of common stock. As of December 31, 2007 no shares of redeemable convertible preferred stock were outstanding.

Prior to the conversion to common stock, the holders of the outstanding redeemable convertible preferred stock, voting as a group, could have requested redemption at any time, on or after June 30, 2008, at a redemption

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price equal to the original purchase price per share of Preferred Stock plus a rate of return equal to 6%, compounded annually, plus any accrued and unpaid dividends. The difference between the original net proceeds and the redemption value of the redeemable convertible preferred stock was accreted over the period from the date of issuance until conversion to common stock.

A summary of the redeemable convertible preferred stock activity for the years ended December 31, 2007, 2006 and 2005, is as follows (in thousands):

	Series A Redeemable Convertible Preferred Stock	Series B Redeemable Convertible Preferred Stock	Series C Redeemable Convertible Preferred Stock	Series D Redeemable Convertible Preferred Stock	Series E Redeemable Convertible Preferred Stock	Total
Balance at December 31, 2004	4,208	11,483	11,413	43,097	24,006	94,207
Accretion to redemption value	253	689	685	2,586	1,440	5,653
Balance at December 31, 2005	4,461	12,172	12,098	45,683	25,446	99,860
Accretion to redemption value	92	251	250	943	526	2,062
Conversion to common shares on May 4, 2006	(4,553)	(12,423)	(12,348)	(46,626)	(25,972)	(101,922)
Balance at December 31, 2006	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Balance at December 31, 2007	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

Stock Option Plans

As of December 31, 2007, we had one active share-based compensation plan, the 2006 Performance Incentive Plan (2006 Plan). Prior to the 2006 Plan becoming effective, we granted options under the 1999 Stock Option Plan (1999 Plan). Upon the 2006 Plan becoming effective on May 4, 2006, the 1999 Plan terminated. Shares subject to outstanding options as of the date of the 1999 Plan termination will continue to be outstanding and subject to the terms of the 1999 Plan, and, to the extent such options expire or terminate without being exercised in full, will be rolled into the 2006 Plan.

For options granted through December 31, 2005, we elected to follow APB 25, and related interpretations, including FIN 44, *Accounting for Certain Transactions Involving Stock Compensation*, to account for employee stock options, rather than the alternative fair value accounting that was permitted under SFAS 123. Under APB 25, compensation expense related to employee stock option grants is recognized using the intrinsic value method. Accordingly, for those grants made through December 31, 2005, we recognized compensation expense for stock options granted to employees with an exercise price below the estimated fair value of our common stock on the grant date. Through December 31, 2005, the fair value of our options was estimated for disclosure purposes at the grant date using the minimum value option-pricing model.

Options granted under the 2006 Plan become exercisable upon vesting which occurs over a service period ranging from immediate vesting to four years. Options outstanding under the 1999 Plan generally are immediately exercisable, but the underlying shares are then subject to our repurchase upon exercise. In the event that the optionee terminates employment or providing service, we have the option to repurchase the shares at the price originally paid at exercise by the optionee. These repurchase rights generally lapse over the service period of four years at a rate of 25% per year from the optionee's date of hire, or another date specified at the time the option was granted. Options granted under the 2006 Plan and 1999 Plan expire no later than 10 years from the date of grant.

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Through December 31, 2005, the fair value of our common stock was determined by our board of directors in consultation with management. During the year ended December 31, 2005, we granted stock options with exercise prices ranging from \$1.20 to \$2.25 per share. In consideration of the guidance set forth in the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and a valuation of the our common stock by an independent third party, we subsequently determined that the fair value of its common stock during 2005 ranged from \$1.20 to \$8.69 per share. In accordance with APB 25, deferred share-based compensation of \$1.2 million was recorded during the year ended December 31, 2005, of which, net of reversals for terminated employees, \$1,041,000 has been expensed through December 31, 2007. Deferred share-based compensation is amortized to expense using graded vesting over the related vesting terms of the options. The remaining deferred share-based compensation will be amortized fully during 2008.

In January 2007, we entered into employment agreements with certain of our newly promoted executive officers. These employment agreements provide for acceleration of vesting of outstanding stock options and other outstanding stock awards upon the occurrence of certain events, including certain change in control and termination of employment. These agreements and the underlying modification of vesting terms of the grants did not result in additional compensation, as the vesting terms did not impact the value of the options.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R) using the prospective transition method as required by the pronouncement. In accordance with the prospective transition method of SFAS 123(R), we did not restate results for prior periods as a result of adopting the new standard. The prospective transition method provides for the recognition of compensation expense for share-based payments made prior to adoption pursuant to the historical APB 25 intrinsic value accounting treatment, in which share-based compensation expense is recognized using graded vesting. Compensation expense for share-based payments made subsequent to adoption is based on the fair value requirements of SFAS 123(R) and recognized on a straight-line basis over the vesting period of the grant.

The provisions of SFAS 123(R) retain the previous accounting practices of share-based payments made to non-employees pursuant to Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which requires measuring the stock options at fair value and remeasuring such stock options to the current fair value until the performance date has been reached.

We recorded total share-based compensation expense as follows (in thousands):

	Research and Development	Selling, General and Administrative	Total
Year ended December 31, 2007			
Employee stock options granted prior to January 1, 2006	\$ 62	\$ 1	\$ 63
Employee stock options granted on or subsequent to January 1, 2006	703	1,205	1,908
Non-employee stock options	69	53	122
	<u>\$ 834</u>	<u>\$ 1,259</u>	<u>\$ 2,093</u>
Year ended December 31, 2006			
Employee stock options granted prior to January 1, 2006	\$ 341	\$ 73	\$ 414
Employee stock options granted on or subsequent to January 1, 2006	662	669	1,331
Non-employee stock options	171	—	171
	<u>\$ 1,174</u>	<u>\$ 742</u>	<u>\$ 1,916</u>
Year ended December 31, 2005			
Employee stock options	\$ 400	\$ 164	\$ 564
Non-employee stock options	60	48	108
	<u>\$ 460</u>	<u>\$ 212</u>	<u>\$ 672</u>

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As of December 31, 2007 unrecognized share-based compensation expense related to unvested share options totaled \$4.7 million. We expect to recognize this compensation expense over a weighted average period of 2.8 years.

The fair value of share-based payments made to employees, including non-employee directors, during 2006 through 2007, and non-employees for 2005 through 2007, was estimated on the measurement date using the Black-Scholes option-pricing model. Prior to 2006, the fair value of employee options for pro-forma disclosure purposes was determined using the minimum value. For the applicable years, the following assumptions were used to determine the fair value using the Black-Scholes option-pricing model:

	2007		2006		2005
	Employees	Non-Employees	Employees	Non-Employees	Non-Employees
Average risk free interest rate	3.8-4.7%	3.8-4.7%	4.6-5.0%	4.6-5.0%	3.8-4.4%
Dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%
Expected/contractual term (in years)	5.0-6.1	7.8-9.9	5.0-6.1	6.1-10.0	7.9
Volatility	40%	40%	40-50%	40-50%	60%

A summary of our stock option activity and related information for the years ended December 31, 2007, 2006 and 2005 is as follows (in thousands, except share and per share data):

	2007		2006		2005	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Outstanding at beginning of year	1,774,317	\$ 5.73	1,595,910	\$ 1.01	1,461,066	\$ 0.87
Granted at fair value	978,353	12.04	704,826	12.87	133,333	1.20
Granted below fair value	—	—	—	—	318,102	1.44
Exercised	(103,074)	1.13	(503,059)	0.85	(201,514)	0.87
Cancelled	(105,359)	10.64	(23,360)	3.93	(115,077)	0.95
Outstanding at end of year	<u>2,544,237</u>	\$ 8.13	<u>1,774,317</u>	\$ 5.73	<u>1,595,910</u>	\$ 1.01
Intrinsic value of options outstanding	<u>\$ 2,977</u>		<u>\$ 15,348</u>		<u>\$ 12,257</u>	
Outstanding options vested and exercisable, but not subject to repurchase at year-end	1,215,905	\$ 4.61	994,144	\$ 3.26	1,026,695	\$ 0.88
Intrinsic value of outstanding options vested and exercisable, but not subject to repurchase	<u>\$ 5,703</u>		<u>\$ 11,055</u>		<u>\$ 8,018</u>	
Weighted-average fair value of options granted during the period	<u>\$ 5.55</u>		<u>\$ 6.58</u>		<u>\$ 3.12</u>	

The total intrinsic value of options exercised, determined as of the date of exercise, during the years ended December 31, 2007 and December 31, 2006 were \$1.1 million and \$5.4 million, respectively.

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Exercise prices for options outstanding at December 31, 2007 are as follows:

<u>Range of Exercises Prices</u>	<u>Number of Shares</u>	<u>Weighted-Average Remaining Contractual Life (in years)</u>	<u>Outstanding Options Vested and Exercisable, but Not Subject to Repurchase</u>	<u>Weighted-Average Remaining Contractual Life (in years)</u>
\$0.15-\$0.90	402,987	5.2	394,305	5.2
\$1.20-\$2.25	544,499	6.3	456,349	6.1
\$9.10-\$11.80	591,727	9.0	130,331	8.4
\$11.81-\$13.15	659,738	9.2	52,648	8.9
\$13.20-\$16.60	<u>345,286</u>	8.6	<u>182,272</u>	<u>8.4</u>
	<u>2,544,237</u>	7.8	<u>1,215,905</u>	<u>6.5</u>

8. Net Loss Per Common Share

Basic net loss per share applicable to common shareholders is calculated by dividing the net loss applicable to common shareholders by the weighted-average number of unrestricted common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share applicable to common shareholders is computed by dividing the net loss applicable to common shareholders by the weighted-average number of unrestricted common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method and the as if converted method. For purposes of this calculation, redeemable convertible preferred stock, stock options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share applicable to common shareholders (in thousands, except share and per share data):

Historical	Year Ended December 31,		
	2007	2006	2005
Numerator:			
Net loss applicable to common shareholders	<u>\$ (23,853)</u>	<u>\$ (27,145)</u>	<u>\$ (20,227)</u>
Denominator:			
Weighted average shares used in computation of basic and diluted net loss per share applicable to common shareholders	<u>25,840,292</u>	<u>17,662,609</u>	<u>1,921,170</u>
Basic and diluted net loss per share applicable to common shareholders	<u>\$ (0.92)</u>	<u>\$ (1.54)</u>	<u>\$ (10.53)</u>
Antidilutive securities excluded from diluted net loss applicable to common shareholders:			
Preferred stock	—	4,939,326	14,942,499
Warrants and options outstanding	2,615,516	1,899,314	1,735,280

Non-GAAP Pro Forma Net Loss per Share Applicable to Common Shareholders

The additional non-GAAP disclosure below shows what basic and diluted net loss per share would have been if the conversion of our shares of redeemable convertible preferred stock, that occurred on May 4, 2006, had occurred at the beginning of the respective periods being reported using the as-if-converted method. In connection with the completion of our initial public offering on May 4, 2006, all shares of then-outstanding redeemable convertible preferred stock converted into 14,942,499 shares of common stock. We believe that this

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non-GAAP pro forma information provides meaningful supplemental information that helps users of our financial statements compare current results to those of prior periods. Our non-GAAP pro forma net loss per share applicable to common shareholders is as follows (in thousands, except share and per share data):

	2007	2006	2005
Numerator:			
Net loss applicable to common shareholders, as reported	\$ (23,853)	\$ (27,145)	\$ (20,227)
Reversal of accretion to redemption value of redeemable convertible preferred stock	—	2,062	5,653
Non-GAAP pro forma net loss applicable to common shareholders	<u>\$ (23,853)</u>	<u>\$ (25,083)</u>	<u>\$ (14,574)</u>
Denominator:			
Shares used to compute basic and diluted net loss per share applicable to common shareholders	25,840,292	17,662,609	1,921,170
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock on January 1, 2005	—	4,939,326	14,942,499
Non-GAAP pro forma shares used in basic and diluted pro forma net loss per share	<u>25,840,292</u>	<u>22,601,935</u>	<u>16,863,669</u>
Non-GAAP pro forma basic and diluted net loss per share applicable to common shareholders	<u>\$ (0.92)</u>	<u>\$ (1.11)</u>	<u>\$ (0.86)</u>

9. Shares Reserved

At December 31, 2007, common stock is reserved for the following purposes:

Stock Options	
Options outstanding	2,544,237
Shares reserved for future grants	2,129,332
Warrants to purchase common stock	71,279
	<u>4,744,848</u>

10. Defined Contribution Plan

We sponsor a defined contribution 401(k) plan (401(k) Plan), which commenced in 2000, in which employees may contribute pretax earnings, up to the maximum allowed by law. The 401(k) Plan permits discretionary contributions, however, we have made no contributions to date.

11. Subsequent Events

On January 22, 2008 we announced that our EVEREST pivotal clinical trial evaluating cortical stimulation for the treatment of stroke-related hand and arm impairment failed to meet its primary endpoint. Based on the results of the EVEREST trial, we do not expect to file for marketing approval of our *Renova* Cortical Stimulation System without conducting additional research, including additional clinical trials. Subsequently, on February 15, 2008, we implemented a reduction in our workforce including 19 employees, leaving 58 employees. We took this action to reduce operating costs and align operations with our strategic and clinical development plan. In connection with this action, we recorded expenses in the first quarter, 2008 associated with termination benefits, including severance payments and continuation of medical insurance benefits, of \$775,000, including non-cash share-based compensation of \$95,000 relating to acceleration of option vesting.

[Table of Contents](#)**12. Quarterly Financial Information (Unaudited)**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2007 and 2006 (in thousands):

	For the Three Months Ended			
	December 31	September 30	June 30	March 31
Year ended December 31, 2007				
Total operating expenses	\$ 6,007	\$ 6,640	\$ 8,276	\$ 7,940
Net loss	(4,857)	(5,421)	(6,986)	(6,589)
Basic and diluted net loss per share	(0.19)	(0.21)	(0.27)	(0.26)

	For the Three Months Ended			
	December 31	September 30	June 30	March 31
Year ended December 31, 2006				
Total operating expenses	\$ 6,707	\$ 6,910	\$ 9,100	\$ 4,213
Net loss applicable to common shareholders	(5,272)	(5,414)	(10,625)	(5,834)
Basic and diluted net loss per share applicable to common shareholders	\$ (0.21)	\$ (0.21)	\$ (0.65)	\$ (2.81)

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Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-141408 and 333-135119) pertaining to the Northstar Neuroscience, Inc. 2006 Performance Incentive Plan and 1999 Stock Option Plan and the Registration Statement (Form S-3 333-145944) pertaining to the registration of shares of common stock of Northstar Neuroscience, Inc. and in the related Prospectus, of our reports dated March 14, 2008 with respect to the financial statements of Northstar Neuroscience, Inc. and the effectiveness of internal control over financial reporting included in the Annual Report (Form 10-K) for the year ended December 31, 2007.

/s/ ERNST & YOUNG LLP

Seattle, Washington
March 14, 2008

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C SECTION 1350**

The undersigned, John Bowers, the President and Chief Executive Officer of Northstar Neuroscience, Inc. (the "Company"), pursuant to 18 U.S.C. §1350, hereby certifies that:

- (i) the Annual Report on Form 10-K for the period ended December 31, 2007 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008

/s/ John S. Bowers, Jr.

John S. Bowers, Jr.
President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350**

The undersigned, Raymond Calvert, the Vice President of Finance and Chief Financial Officer, of Northstar Neuroscience, Inc. (the "Company"), pursuant to 18 U.S.C. §1350, hereby certifies:

- (i) the Annual Report on Form 10-K for the period ended December 31, 2007 of the Company (the "Report") fully complies with the requirements of Section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008

/s/ Raymond N. Calvert

Raymond N. Calvert

Vice President of Finance and Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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