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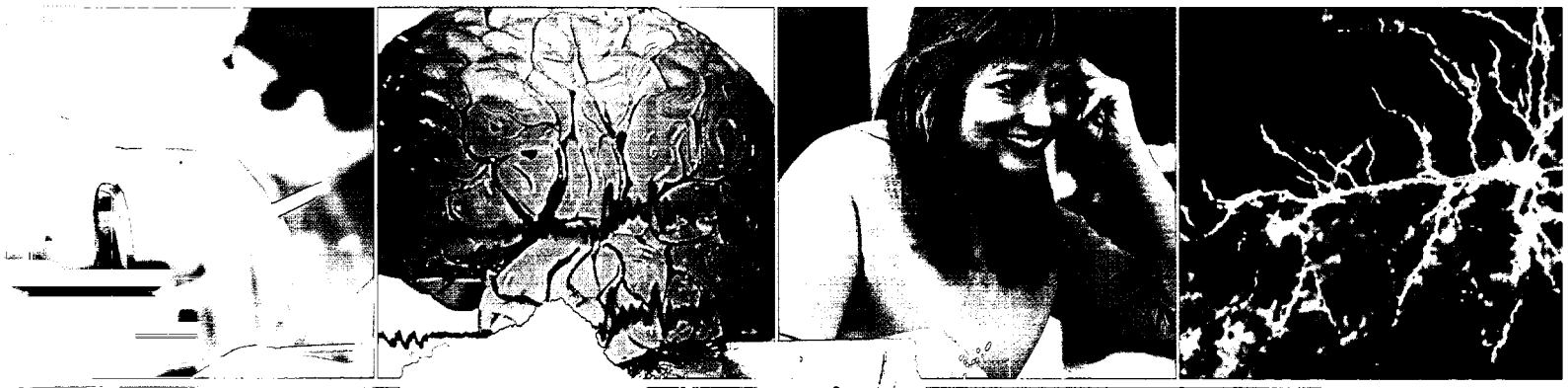
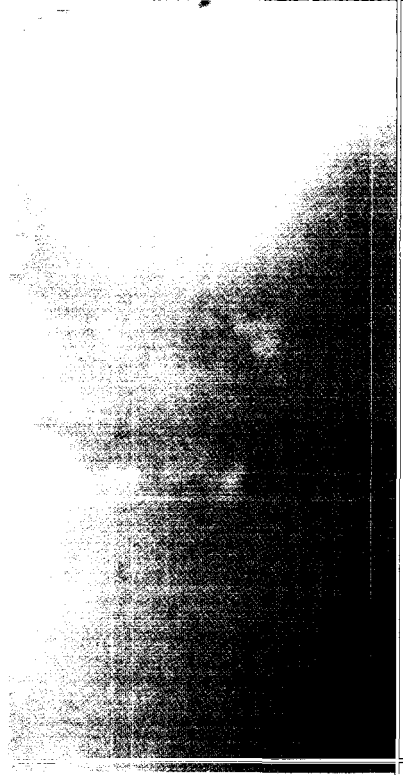
neuromodulation

company for the future



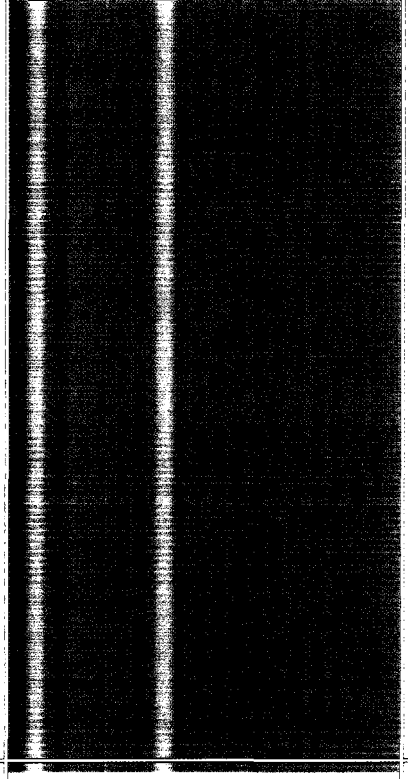
Cyberonics INC.

2005 Annual Report



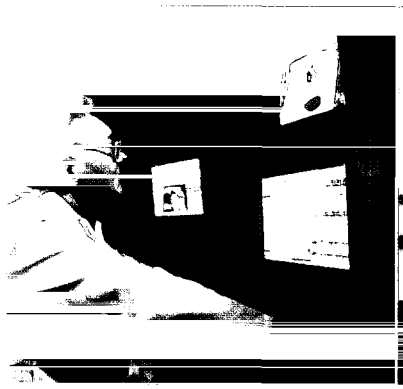
Treatment-Resistant Depression

20% - 30% of people with major depressive disorder, or approximately four million people experience chronic or recurrent treatment-resistant depression that has failed to respond to multiple treatments.



Anxiety Disorders/OCD

3.3 million adults suffer from anxiety disorders/OCD and approximately 650,000 adults who have severe, treatment-resistant OCD who are unresponsive to multiple treatments.



Pharmaco-Resistant Epilepsy

Approximately **2.5 million** individuals in the United States and in excess of **3.1 million** individuals in Western Europe and Japan have epilepsy. About **425,000** in the U.S. and **900,000** worldwide have pharmaco-resistant epilepsy.

Bulimia Nervosa

Five million people are afflicted with some type of eating disorder. Approximately **one million** have refractory bulimia nervosa.

Profile

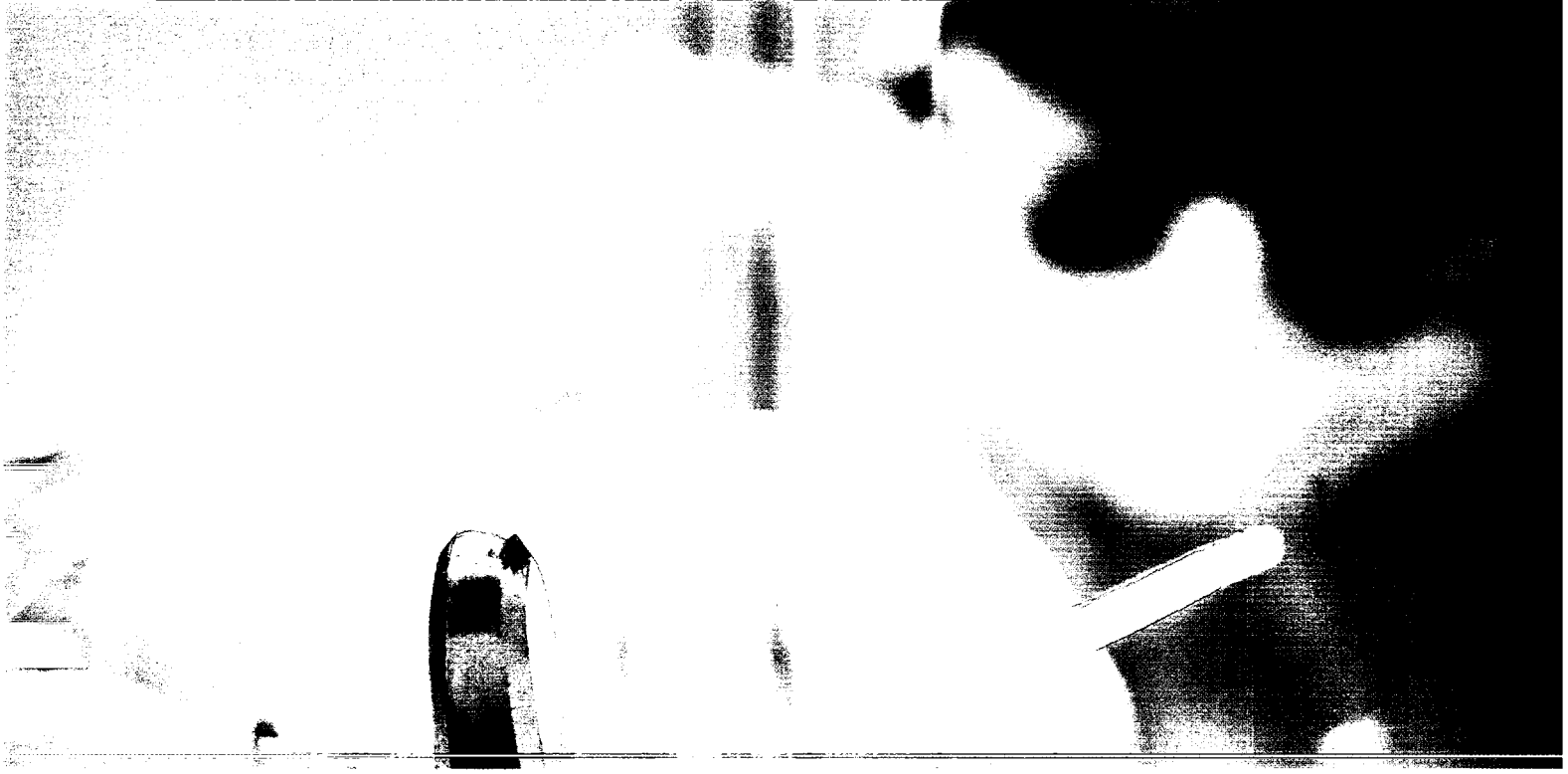
Cyberonics, Inc. (NASDAQ: CYBX) pioneered the Vagus Nerve Stimulation (VNS Therapy™) System. Founded in 1987 to design, develop and market implantable medical devices for the treatment of epilepsy and other debilitating neurological disorders, Cyberonics has emerged as a leader in the neuromodulation industry.

The VNS Therapy System uses a surgically implanted medical device that delivers electrical pulsed signals to the vagus nerve in the left side of the neck. This therapy has proven effective in significantly reducing the number and/or intensity of seizures in many people suffering from epilepsy and has the potential for use in the treatment of other inadequately treated, chronic disorders.

In 1997, Cyberonics received approval from the Food and Drug Administration (FDA) to market VNS Therapy for the treatment of epilepsy. Since that time, more than 32,000 patients worldwide have been implanted with the device. These patients have accumulated in excess of 100,000 patient years of experience using this life-enhancing therapy.

The remarkable success of VNS Therapy in the treatment of epilepsy has served as a platform for continued innovation. On July 15, 2005, after seven years of extensive study and clinical trials, VNS Therapy was approved by the FDA as a long-term adjunctive treatment for treatment-resistant depression. It is also at various levels of study as a potential treatment for other chronic disorders, including anxiety, Alzheimer's, bulimia, and migraine headaches.

Headquartered in Houston, Texas, Cyberonics has additional offices in Brussels, Belgium. The Company markets the VNS Therapy system in selected markets worldwide.



neuromodulation company for the future

Dear Shareholders: The date July 15, 2005 will be remembered at Cyberonics as the dawning of a new era. After seven years of clinical research and development and almost two years of rigorous review by the Food and Drug Administration (FDA), the VNS Therapy System was approved by FDA "for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments."

The approval of VNS Therapy for TRD is a transforming event—for patients, the neuromodulation industry and for Cyberonics. As a result of the FDA's decision:

- An estimated 4.4 million Americans with treatment-resistant depression (TRD) will now get their first and only FDA-Approved long-term treatment option.
- An estimated 200,000 Americans with pharmacoresistant epilepsy and comorbid TRD will have their first treatment option that is approved for both illnesses.
- The neuromodulation industry is expected to expand from a $1 billion market today to a multi-billion dollar "next frontier" market for medical devices.
- Cyberonics is uniquely positioned to become a dominant market leader in neuromodulation with the opportunity to improve the quality of life for more than 10 million people worldwide who suffer from chronic, treatment-resistant illnesses.

FDA's approval of the first and only treatment developed, studied, approved and labeled specifically for patients with treatment-resistant depression is a tribute to the more than 400 Americans who participated in the VNS studies and who made their voices heard during the approval process as well as the psychiatric thought leaders who provided invaluable leadership, guidance and support over the past seven years. The approval is also a testament to Cyberonics' dedication and unwavering commitment to its mission of improving the lives of people touched by epilepsy, depression and other chronic, treatment-resistant illnesses that may prove to be treatable with VNS Therapy.

A pioneering journey

We began this pioneering journey more than 18 years ago when we embarked on the seemingly impossible quest to develop the first device-based therapy for the treatment of epilepsy. Nine years after the first patient was implanted and after completing pivotal studies including approximately 450 patients, the FDA approved VNS Therapy as a adjunctive therapy for reducing the frequency of seizures in patients over 12 years of age with partial onset seizures that are resistant to antiepileptic drugs.

The Company, the therapy and the VNS device that was approved as a treatment for TRD have not only survived, but have thrived during eight years of commercial use and seven years of rigorous studies. VNS Therapy has been approved in Europe as a treatment for medically refractory epilepsy since 1994 and in the U.S and Canada since 1997. It was also approved as a treatment for TRD in Europe and Canada in 2001. Since that time, the safety and effectiveness of VNS has been well established with physicians, surgeons, hospitals, payers and patients. Over 32,000 patients worldwide have now accumulated over 100,000 patient years of experience.

The epilepsy and TRD studies and epilepsy commercial experience confirm that VNS offers a unique value proposition and benefit-to-risk ratio that is sustained or improves over time. In 1998, one year after the approval of VNS Therapy for the treatment of epilepsy, the first pilot study for its use in treatment-resistant depression began after clinical observations revealed that VNS Therapy appeared to have a positive effect on the mood of epilepsy patients who often also suffer from depression.

Over the next seven years, we conducted rigorous clinical studies of VNS Therapy for the treatment of chronic or recurrent depression in patients with major depressive episodes that have not responded to standard treatments. The depression study program included acute and long-term clinical studies, acute and long-term mechanism-of-action research and comparative studies with clinical and economic outcomes in patients with TRD receiving conventional medical treatment that did not include VNS. The promising initial results, coupled with the fact that no safe and effective treatments existed for TRD, compelled the FDA to grant VNS Therapy "Expedited Review" status in 1999.

Pioneering the first treatment to be developed, studied, approved and labeled specifically for patients with TRD was neither quick nor easy. The VNS clinical studies were designed specifically to satisfy the unique needs of patients with TRD and collect valid scientific evidence of the safety and effectiveness of VNS Therapy for its proposed use that is consistent with implantable medical device laws, regulations and approval precedents. To achieve this:

- The VNS studies were longer-term than previous studies to satisfy the need for a safe and effective long-term maintenance therapy;
- The studies included patients with the most chronic and resistant depressions ever studied, who are often excluded from other studies of antidepressants, to determine the safety and effectiveness in a true TRD population;
- The D-02 study had an acute sham control to evaluate acute safety and effectiveness;
- Longitudinal patients-as-their-own controls analyses were done to show the long-term, sustained effect and value of VNS as a maintenance therapy;
- Comparative analyses versus a non-randomized, well-matched group of TRD patients treated with any currently available treatment (no VNS) compared adjunctive VNS Therapy to standard medical practices using currently available treatment; and
- Multiple outcome measures, including physician and patient ratings scales, were used to test the consistency of the long-term outcomes.

The results showed that response and remission rates (remission being a complete or near complete absence of depressive symptoms) and clinical benefit increased over one year of adjunctive VNS Therapy and then remained stable over the second year of treatment. After two years of adjunctive VNS Therapy, about 1 in 3 patients had responded with a meaningful mood improvement, and 1 in 6 had achieved remission with a

complete or near complete absence of depressive symptoms. More than 50% of patients at 12 months of adjunctive VNS Therapy reported a meaningful clinical benefit, defined as a 25% or greater improvement in depressive symptoms.

Preparing for launch

Since February 2005, we have been preparing our organization for launch in depression, putting in place the organization, processes and systems needed to satisfy the unmet needs of millions of Americans, their families, psychiatrists and payers. We expanded our sales, customer support and case management organizations to support anticipated demand in both epilepsy and depression by increasing our sales demand organization to 330 personnel and completing comprehensive training programs for all those personnel. We have also taken steps to ensure that our manufacturing operation, regulatory and administration functions are scalable to support increasing product demand.

Fiscal 2005 financial results

In fiscal 2005, Cyberonics' primary objectives were to invest in and improve the people, organization, systems, controls and business processes across all business functions to facilitate a successful TRD launch in the U.S. and support a multiple indication business model while maintaining our core epilepsy business. Despite an increasing investment of time and expenses into TRD pre-launch activities, we accomplished our objectives for the year.

Net sales for the fiscal year ended April 29, 2005, were $103.4 million, including U.S. net sales of $90.3 million and international net sales of $13.1 million. In the U.S., net sales included a major investment of almost six weeks of selling days that were diverted to TRD training and development activities. Internationally, the Company reported an all-time record sales performance.

The net loss of $12.2 million, or $0.51 per fully diluted share, reflects the significant financial resources devoted to clinical and regulatory activities associated with the depression regulatory process and depression scale-up activities.

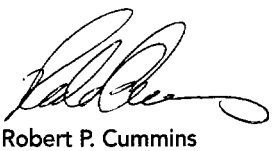
The journey continues

The Cyberonics of today bears little resemblance to the small fledgling company that launched the first device-based treatment approved for epilepsy in 1997. We anticipate even more change in the future.

In fiscal 2006, we will be accelerating the implementation of our long-term strategic plan to become the leader in the neuromodulation industry. Our five-pronged plan includes:

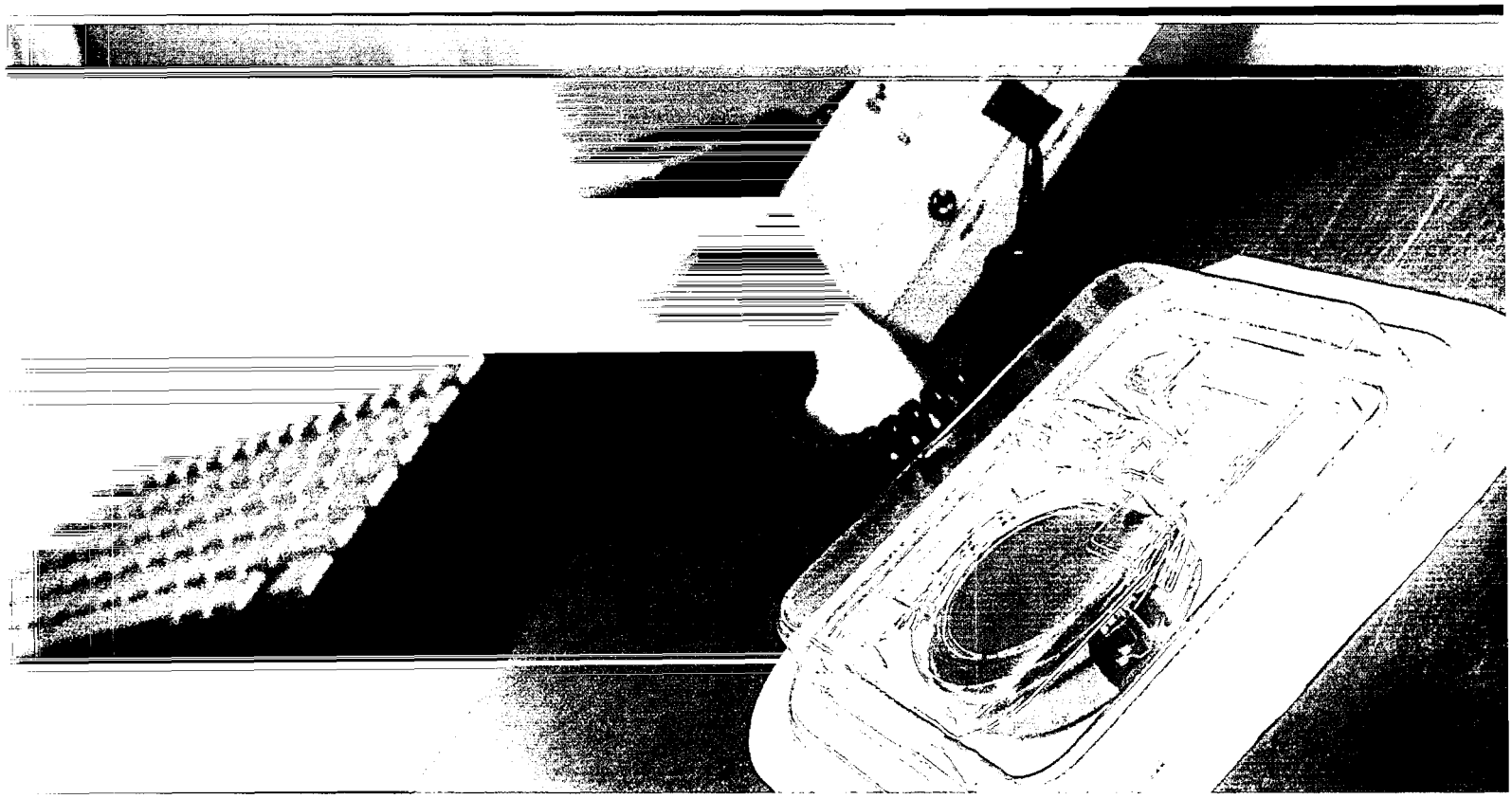
- Accomplishing our mission for TRD in the U.S. market and aggressively developing and expanding our TRD intellectual property, regulatory and market franchise;
- Repositioning and relaunching VNS Therapy in a unique market position in the U.S. epilepsy market;
- Increasing our investment in international markets to accelerate growth and development in global epilepsy and depression markets;
- Developing new, patent-protected VNS indications; and
- Leveraging Cyberonics' core competencies to exploit non-VNS neuromodulation opportunities through strategic partnerships.

Looking ahead, we know that the coming year will not be without challenges. But challenges are nothing new for the people of Cyberonics. The determination and the pioneering spirit of our people and their unwavering commitment to our mission, coupled with our innovative technology and our market position, have enabled us to capitalize on opportunities in the past and create value for our shareholders. While I am proud of the work that we have done, I am even more excited about the future and the journey that lies ahead.



Robert P. Cummins
Chairman of the Board and Chief Executive Officer

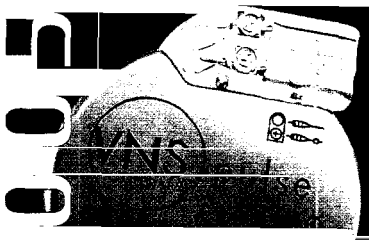
AT CYBERONICS, OUR MISSION IS TO IMPROVE THE LIVES OF PEOPLE TOUCHED BY EPILEPSY, TREATMENT-RESISTANT DEPRESSION AND OTHER CHRONIC DISORDERS THAT MAY PROVE TO BE TREATABLE WITH OUR PATENTED VAGUS NERVE STIMULATION THERAPY SYSTEM.



FDA approval of VNS Therapy for the treatment of chronic, treatment-resistant depression provides Cyberonics with exceptional long-term growth potential.

The approval by the FDA of VNS Therapy as a treatment for chronic, treatment-resistant depression is a watershed event for more than 4.4 million Americans who suffer from this debilitating illness. For most, VNS Therapy is their first safe, effective long-term, non-drug treatment option that provides antidepressant and quality-of-life efficacy without the side effects typically experienced with medications and electro-convulsive treatment.

The need is enormous. Around the world, millions suffer from depression, and in the U.S., depression is a leading cause of disability. Over the past 10 years, the number of patients diagnosed with Major Depressive Disorder has risen 350%, to more than 17.2 million adults, and the number of patients with treatment-resistant depression has risen by almost 700%, to more than 4 million patients, or about 20% of the depressed population.



2005

FDA approves VNS Therapy as a long-term adjunctive treatment for chronic, treatment-resistant depression on July 15, 2005.

By May, all FDA conditions are met, including fully-informative labeling and post-market protocols for a 460-patient dosing study and a 2,000-patient five-year TRD registry.

In April, Cyberonics is informed by FDA's Dallas District office that its responses to the Current Good Manufacturing Practice Warning Letter have been accepted.

In February, FDA deems Cyberonics' Expedited Review PMA-S approvable with conditions.

Depression is more than the "blues." It is a devastating affliction that interferes with an individual's ability to function in everyday life. It is life long and life threatening. Depressed patients are 35 times more likely to commit suicide and many suffer from related medical conditions such as heart disease and stroke.

The costs are staggering. Total annual costs for the treatment of depression in the U.S. are more than $80 billion, including $30 billion in annual direct treatment costs. The average annual healthcare cost for a person suffering with TRD exceeds $42,000 per patient.

The approval of VNS Therapy for use in treating depression will have an enormous impact on the future of Cyberonics. The Company's VNS Therapy intellectual property, regulatory and market franchise will expand considerably as the Company has the opportunity to create the first neuromodulation company with more than $1 billion in annual sales.

As the industry leader, Cyberonics will be able to leverage its core competencies to expand into other non-VNS neuromodulation markets and treatment modalities, allowing it to widen its position as the market leader.

The people of Cyberonics have been preparing for the approval and launch into the depression market. The Company has expanded its sales and case management organizations from approximately 139 to 330 to support anticipated sales demand in both epilepsy and depression. In addition, Cyberonics' proven demand creation organization and model has been enhanced and scaled to simultaneously accomplish its mission and satisfy the needs of physicians, hospitals, payers, patients and their families. VNS Therapy's track record of delivering solid value to all customers in epilepsy combined with the fundamentals of VNS Therapy in depression, create a favorable opportunity for continued success.

FDA's Neurological Devices Panel of the Medical Devices Advisory Committee votes 5 to 2 to recommend approval, with conditions, of Cyberonics' VNS Therapy System "as an adjunctive long-term treatment of chronic or recurrent depression for patients over the age of 18 who are experiencing a major depressive episode that has not had an adequate response to four or more adequate antidepressant treatments."

In September 2004 Cyberonics submits important 2-year data from the depression pivotal study to the FDA. The 2-year data demonstrates that efficacy improves over time and is sustained long-term in patients with treatment-resistant depression.

2004

Now that final FDA approval has been received, the Company is moving quickly to get formal coverage policies in place with the most important payers. It will also fund a comprehensive post-market study program in treatment-resistant depression to build clinical knowledge of VNS Therapy and TRD.

Today, coverage in epilepsy is virtually universal and the fundamentals suggest that Cyberonics will be as successful in obtaining coverage for TRD. There is substantially more data available on the high costs of treating depression and payers are aware not only of the costs but of the enormous need for treatment. The long-term safety, effectiveness and cost effectiveness data from the Company's TRD studies are compelling.

In 2005, Cyberonics is much better prepared to accomplish its mission than it was in 1997 when VNS Therapy was approved for the treatment of epilepsy. The Company's experienced management team has successfully developed new device therapies and has pioneered new markets and new pharmaceuticals and the demand creation organization and model is larger and better prepared. The TRD market is also much better prepared for VNS Therapy since this treatment is already a widely accepted standard treatment in epilepsy. Insurance companies are already educated about VNS Therapy and physicians and surgeons are experienced in its use.

Cyberonics is committed to enhancing the information available to help physicians and patients make informed decisions about VNS Therapy for the treatment of depression. The Company has committed to the FDA to undertake a 460-patient post-approval dosing study and a 2,000-patient five-year TRD registry that will include patients treated with adjunctive VNS Therapy. Cyberonics will also support or sponsor additional clinical research in TRD to enhance knowledge and facilitate well-informed decisions as well as ongoing medical education.

Cyberonics is a pioneer for disorders of the central nervous system.

Since Cyberonics was formed in 1987, the Company has created a legacy of innovation based on its pioneering efforts in utilizing VNS Therapy in the treatment of disorders of the central nervous system. The challenges have been enormous. Not only has Cyberonics pioneered a new nerve stimulation system, a revolutionary new therapy and a new FDA approval process for devices that treat neurological disorders, but it has also had to develop a sales and marketing organization and business model to create awareness, acceptance and demand for a device-based therapy among important customer groups. Cyberonics has spearheaded the growth and acceptance of VNS Therapy and has educated clinicians, surgeons, hospital administrators, insurance companies, patients and their families about its benefits.

New solutions don't come easily. Developing new, innovative treatments is a long-term process requiring skill, tenacity and the highest level of commitment. At Cyberonics, the investment in research and development has yielded important results for people touched by treatment-resistant, chronic disorders.

2003

FDA formally notifies Cyberonics that its depression PMA Supplement application for the VNS Therapy System is suitable for filing. FDA begins in-depth review of Cyberonics' depression PMA-S.

Cyberonics submits an 87-volume panel-track, Expedited Review PMA Supplement to the FDA seeking approval to market the VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression.

Today, VNS therapy is the only approved medical device alternative for treating epilepsy, the second most prevalent neurological disorder. Traditionally, drug therapy, surgery, and the ketogenic diet were the only courses of treatment available to people with epilepsy. The effectiveness of drug treatments depend on many variables, but they are generally less effective for those with partial onset seizures, which are more resistant to traditional therapies, and many people with epilepsy are not good candidates for surgery or the ketogenic diet. Since VNS Therapy was approved in 1997 for use as an adjunctive therapy in reducing the frequency of seizures in patients with partial onset seizures, more than 32,000 patients have successfully accumulated in excess of 100,000 patient years of treatment experience.

Cyberonics supports an aggressive internal research and development program and has formed alliances with leading research institutions, universities and clinicians to develop new solutions that address unmet medical needs. The Company is currently studying new indications for VNS Therapy such as anxiety, Alzheimer's, bulimia and migraine headaches.

Most recently, the Company joined with a consortium comprising The Cleveland Clinic, Case Western Reserve University, the University of Cincinnati and several other medical device firms, to establish an Atrial Fibrillation Innovation Center at The Cleveland Clinic. The Center will implement a five-part program to ensure that new atrial fibrillation research and therapies are developed and commercialized. VNS Therapy is among the therapies being investigated.

In March 2005, Cyberonics also announced the results of a promising pilot study of VNS Therapy in patients with bulimia nervosa at the University of Minnesota's Neuroscience Research Center. The study was designed to evaluate whether or not VNS Therapy reduces episodes of binging and purging that are the hallmark of bulimia by reversing the physiological changes that occur in the function of the vagus nerve. To date, all patients participating in the study who have been treated with VNS Therapy have reported dramatic results.

As of April 2003, 22,000 patients had been implanted with VNS Therapy as an adjunctive treatment for pharmaco-resistant epilepsy.

Study results find that 28 percent of patients with pharmacoresistant epilepsy have a particular gene expression against 16 percent in the drug responsive group. These pharmacogenomic results identify a genetic factor associated with resistance to antiepileptic medications.

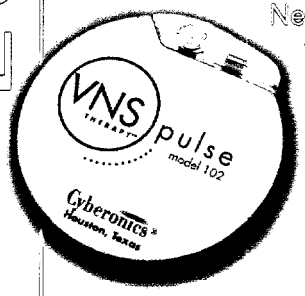
FDA approves new labeling regarding use of VNS Therapy in women of child bearing age. Animal studies reveal no evidence of impaired fertility or harm to the fetus due to VNS Therapy.

Statistically and clinically significant results are announced in one-year D-02 depression pivotal study compared to baseline. Approximately half of all patients experienced improvement after one year of VNS Therapy.

2002

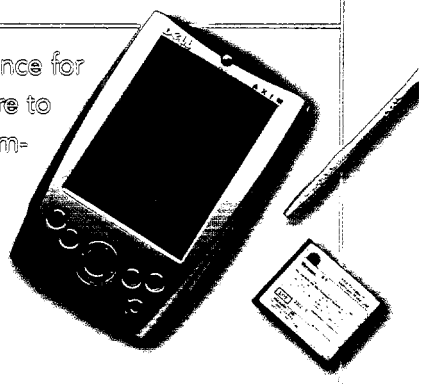
Cyberonics submits revised, prospective long-term pivotal study analysis plan to FDA designed to determine the statistical and clinical significance of the long-term improvements from baseline in all D-02 depression study patients treated over a one-year period with VNS Therapy compared with D-04 study patients.

Favorable results of depression pilot study show that after one year of VNS Therapy, 42 percent of the patients experienced at least a 50 percent improvement and 26 percent achieved remission and were free of depressive systems.

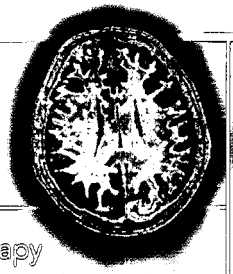


New Pulse Model 102 VNS Therapy for epilepsy launches in the U.S. four months ahead of schedule.

FDA grants market clearance for new VNS Therapy software to support handheld programming computer launch.



2001



fMRI scans show VNS Therapy increases activity in brain regions implicated in mood regulation.

Study results reveal that VNS Therapy effectively reduces the need for antiepileptic drugs in patients with pharmacoresistant epilepsy.

Canadian approval received for VNS Therapy as a treatment for depression in patients with treatment-resistant or treatment intolerant major depressive episodes including unipolar depression and bipolar disorder (manic depression).

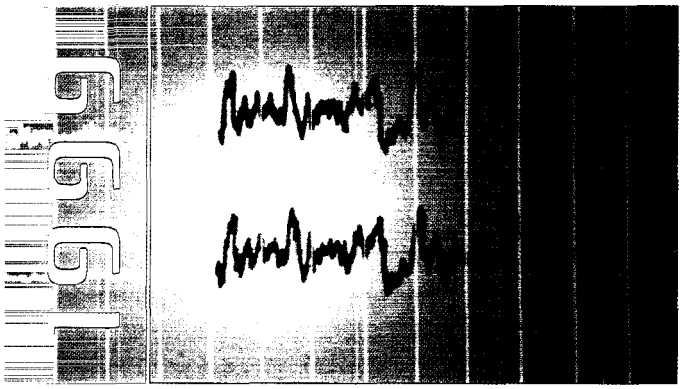
First patient is treated with VNS Therapy to initiate the European D-03 clinical study of VNS therapy for depression.

In August, first enrollment for the pivotal clinical study of VNS Therapy for depression begins.

Cyberonics announces that research shows mortality and sudden unexplained death in epilepsy rates drop significantly among epilepsy patients treated with VNS Therapy.

2000

Depression pilot study investigators report that acute results from the first 30 patients show a significant response to VNS Therapy — a potential new treatment modality for chronic or recurrent treatment-resistant depression.



Results from an open-label, long-term efficacy study show that VNS Therapy provides seizure reduction.

American Academy of Neurology task-force assessment indicates that VNS Therapy is safe and effective based on a preponderance of Type I data (one or more controlled studies).

As of April 1999, 4,500 patients have been implanted with VNS Therapy as an adjunctive treatment for pharmaco-resistant epilepsy.

Cyberonics is transforming the neuromodulation industry worldwide.

Cyberonics is redefining the way in which neurological disorders are treated. In developing innovative neuromodulation therapies, Cyberonics is at the forefront, introducing the world's first device-based therapy for chronic, treatment-resistant epilepsy and depression and continuing its focus on new applications for a variety of disorders involving the central nervous system.

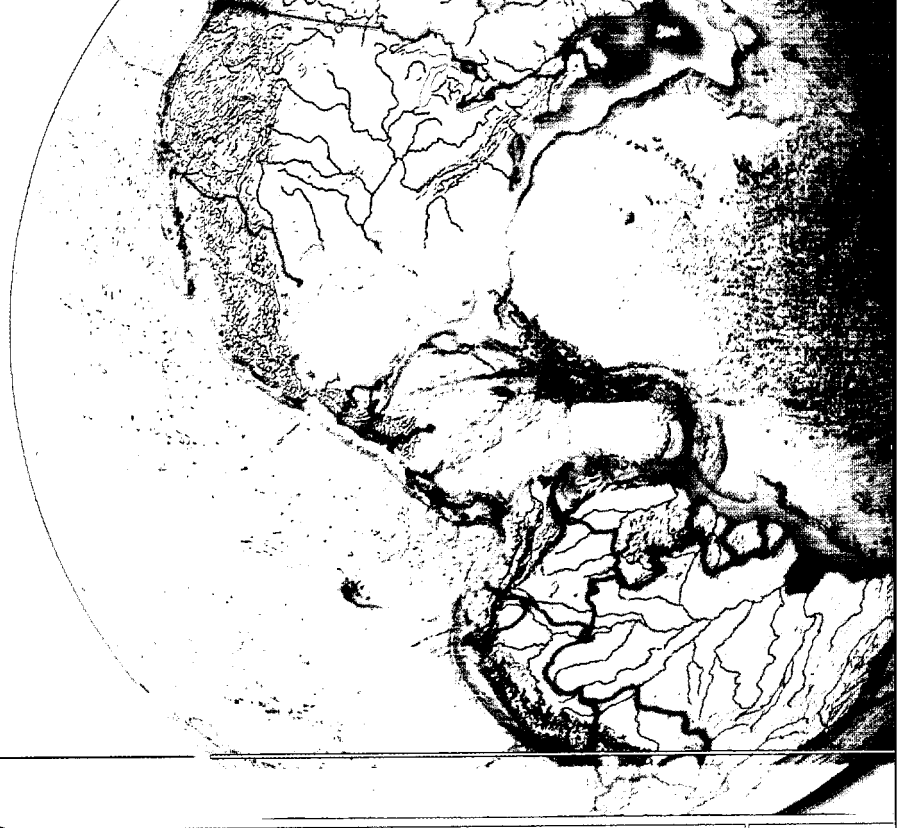
The Company has exclusive rights to 14 U.S. device and 22 U.S. method patents that provide Cyberonics with a strong intellectual property franchise in neuromodulation. The methods patents expire beginning in 2011 and give Cyberonics the exclusive right to manufacture or sell a product that applies a pulsed electrical signal to the vagus, trigeminal or glossopharynegeal nerves to treat a variety of neurological disorders.

The Company's epilepsy patent was extended by five years following FDA approval in epilepsy. An application to extend the depression patent to 2015 was filed immediately following final approval of VNS Therapy in the treatment of treatment-resistant depression. The method patents and high regulatory barriers to entry suggest that Cyberonics will have no direct therapeutic competition for at least the next six years in a variety of indications in the U.S.

In addition to the U.S., patients in 24 countries around the world have benefited from VNS Therapy in the treatment of epilepsy. The VNS Therapy System is approved for sale as a treatment for epilepsy in all the member countries of the European Union, Australia, Canada, South America, South Africa, India and several countries in Eastern Asia. In addition to its recent approval in the U.S., VNS Therapy is also approved as a treatment for depression in the European Union and in Canada.

Cyberonics is continually working to accelerate the development of new higher value products with new features designed to improve efficacy, functionality and longevity. In February 2005, the Company received FDA approval to market the VNS Therapy Version 7.0 Programming Software in the U.S., which was specifically designed to support the programming of smaller, more fully featured future systems. In March 2005, regulatory agencies in Korea and Brazil approved the VNS Therapy Models 102 and 102R Generators and the VNS Therapy Model 302 Leads for treatment of pharmaco-resistant epilepsy.

As VNS Therapy becomes a reality for the treatment of chronic depression, Cyberonics is moving ahead with the development of additional indications. The Company currently has preclinical or pilot studies underway or completed for 11 potential new VNS indications, most of which are in its core neurology and psychiatry markets. A pivotal study for a third VNS Therapy indication is planned in the next year.

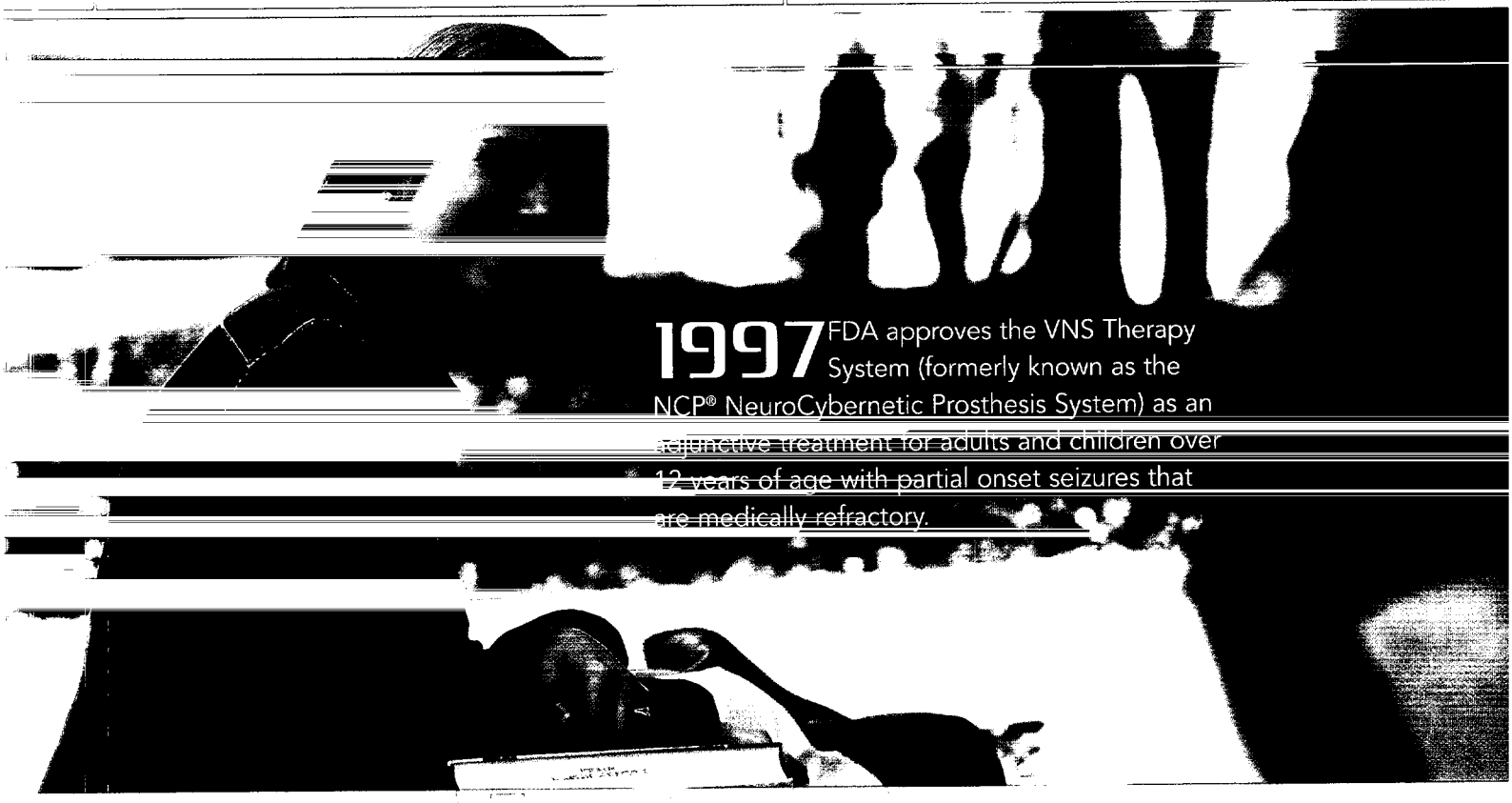


Cyberonics announces study results indicating that VNS Therapy enhances memory in humans.

FDA grants approval for pilot study of VNS Therapy for depression.

Cyberonics announces Health Care Finance Administration (HCFA) provides national Medicare coverage for VNS Therapy.

1996



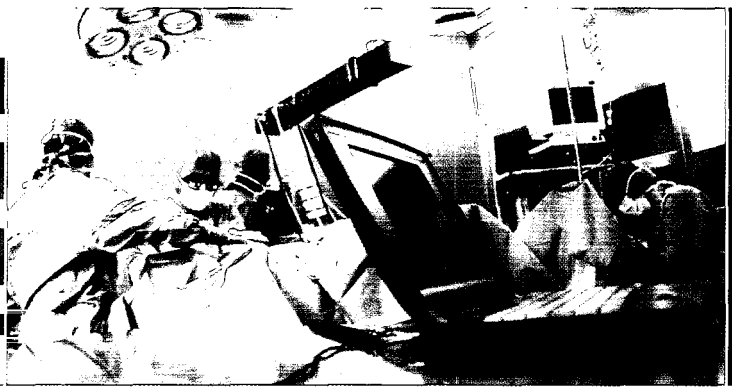
1997 FDA approves the VNS Therapy System (formerly known as the NCP® NeuroCybernetic Prosthesis System) as an adjunctive treatment for adults and children over 12 years of age with partial onset seizures that are medically refractory.

Cyberonics is a champion to people whose lives have been disrupted by chronic disorders of the Central Nervous System.

Cyberonics is committed to being a champion for people whose lives have been disrupted by chronic disorders of the Central Nervous Systems—disorders such as epilepsy and TRD that are so severe that there previously has been no approved long-term treatment option.

VNS Therapy has been approved for use in the U.S. for eight years as an adjunctive therapy for reducing the frequency of epileptic seizures that are resistant to drugs in patients over the age of 12. Epilepsy is the second most prevalent neurological disorder in the world today. Approximately 2.5 million people in the U.S. have epilepsy and approximately 181,000 new cases are diagnosed each year. There are also more than 3.1 million individuals living with epilepsy in Western Europe

1988

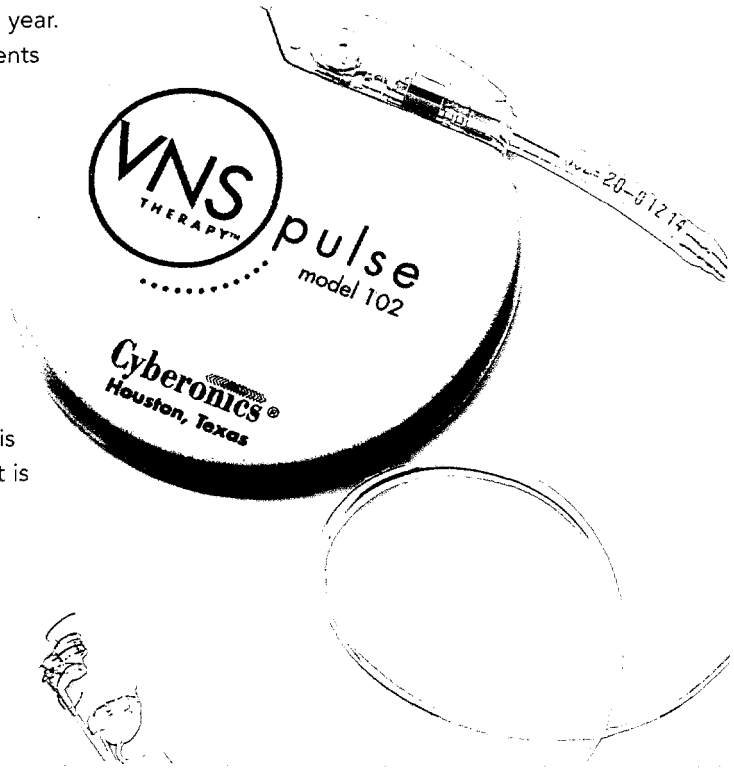


First human implant of the VNS Therapy System by Dr. J. Kiffen Penry (neurologist), William Bell (neurosurgeon) at Wake Forest Bowman Gray Medical School.

and Japan, with more than 345,000 new cases diagnosed each year. Pharmacoresistant epilepsy is estimated to effect 425,000 patients in the U.S. and more than 900,000 patients worldwide.

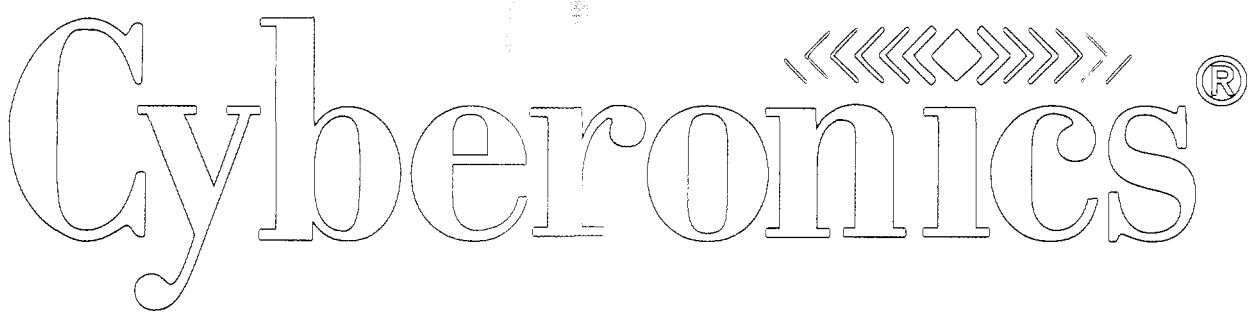
For patients suffering from epilepsy, VNS Therapy means life without the constant intrusion of debilitating seizures that can strain personal and family relations and render the individual incapable of keeping a job or a driver's license.

In the future, patients experiencing TRD will also be able to experience the benefits of VNS Therapy. These patients will have access to a safe, effective, long-term treatment that has been shown to succeed where other treatments have failed. It is a momentous opportunity and a tremendous responsibility that is shared by everyone at Cyberonics.



We believe that neuromodulation is the next frontier for medical devices, and our goal is to be the market leader in the neuromodulation industry. To achieve that goal, we plan to:

- Satisfy the urgent, unmet medical need in treatment-resistant depression and aggressively develop and expand our intellectual property, regulatory and market franchise in the U.S. TRD market.
- Rejuvenate growth and accelerate penetration for VNS Therapy in the U.S. epilepsy market by repositioning core messages in connection with the depression launch.
- Increase our investment around the world to accelerate growth and development for VNS Therapy in the treatment of epilepsy and depression in global markets.
- Develop new, patent-protected VNS Therapy indications in refractory markets with unmet needs.
- Leverage our core competencies to exploit non-VNS neuromodulation opportunities through strategic partnerships.


Cyberonics®

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 April 29, 2005

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: 0-19806

Cyberonics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**76-0236465**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

Cyberonics Building
100 Cyberonics Blvd.
Houston, Texas
77058-2072
(Address of principal executive offices)
(Zip Code)

Registrant's telephone number, including area code:
(281) 228-7200

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 Par Value
(Title of Class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☑ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 126-2). Yes ☑ No ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of October 29, 2004, the last business day of the registrant's most recently completed second fiscal quarter, was based upon the last sales price reported for such date on the NASDAQ National Market, approximately $244 million. For purposes of this disclosure, shares of common stock held by persons who hold more than 5% of the outstanding shares of common stock and shares held by officers and directors of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination is not necessarily conclusive.

At May 20, 2005, 24,781,665 shares of common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report on Form 10-K will be incorporated by reference to certain sections of Cyberonics' definitive proxy statement for its annual meeting of stockholders in 2005. To the extent that such proxy statement is not filed within 120 days of the registrant's fiscal year end, the registrant will file an amendment to this Annual Report on Form 10-K to include such information.

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In this Annual Report on Form 10-K, "Cyberonics," "we," "us" and "our" refer to Cyberonics, Inc.

CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. These statements relate to future events or our future financial performance. We have attempted to identify forward-looking statements by terminology such as "expect," "may," "will," "intend," "anticipate," "believe," "estimate," "could," "possible," "plan," "project," "forecast," and similar expressions. Our forward-looking statements generally relate to our growth strategies, financial results, reimbursement programs, product acceptance programs, product development programs, clinical and new indication development programs, regulatory approval programs, manufacturing processes and sales and marketing programs. Forward-looking statements should be carefully considered as involving a variety of risks and uncertainties. These risks and uncertainties include, but are not limited to:

- continued market acceptance of the Cyberonics VNS Therapy System™ and sales of our product;
- the development and satisfactory completion of clinical trials and/or market tests of the Cyberonics VNS Therapy System™ for the treatment of epilepsy, depression or other indications;
- adverse changes in coverage or reimbursement amounts by third parties;
- intellectual property protection and potential infringement claims;
- maintaining compliance with government regulations;
- obtaining necessary government approvals for new applications;
- product liability claims and potential litigation;
- reliance upon single suppliers and manufacturers for certain components, and
- the accuracy of management's estimates of future sales, expenses, and capital requirements.

Consequently, no forward-looking statements can be guaranteed to be accurate and actual outcomes may vary materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K to conform these statements to actual results, unless required by law.

PART I

Item 1. *Business*

General

Cyberonics, Inc. was founded in 1987 to design, develop, manufacture and market the Cyberonics VNS Therapy System™, an implantable medical device for the treatment of epilepsy and other debilitating chronic disorders. Our mission is to improve the lives of people touched by epilepsy, depression and other disorders that may prove to be treatable with our patented therapy, Vagus Nerve Stimulation (VNS). To accomplish that mission, we have pioneered new medical science regarding the vagus nerve and its impact on neurotransmitters and brain function, a new device-based therapy, a unique sales and marketing model to profitably create awareness, acceptance and demand for a revolutionary device-based therapy among six different customer constituencies in a traditional pharmaceutical market, a new consensus on pharmacoresistant epilepsy and its treatment, and a totally new device market.

The VNS Therapy System has been approved by the United States Food and Drug Administration (FDA) for marketing in the U.S. as an adjunctive therapy for reducing the frequency of seizures in patients over 12 years of age with partial onset seizures that are refractory to antiepileptic drugs. The VNS Therapy System has also received regulatory approval in numerous other markets, including Europe, Australia, Canada, South America, Africa, India and certain countries in Eastern Asia for the treatment of refractory epilepsy.

Since 1998, we have been conducting clinical studies of the VNS Therapy System for the adjunctive treatment of patients 18 years of age and older with chronic or recurrent treatment-resistant depression (TRD) in a major depressive episode. The depression study program includes pilot and pivotal acute and long-term clinical studies, acute and long-term mechanism-of-action research and clinical and economic outcome studies in patients with TRD receiving standard medical treatment that does not include VNS Therapy. The VNS Therapy System was approved in 2001 in the European Union countries and in Canada for the treatment of chronic or recurrent depression in patients who are in a treatment-resistant or treatment-intolerant depressive episode. On July 15, 2005, FDA approved the VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.

We have also been conducting or providing support for small pilot studies for the treatment of Alzheimer's Disease, anxiety, chronic migraine headache and bulimia. These studies are being conducted to determine the safety and effectiveness of VNS Therapy and to determine which new indications should be considered for pivotal studies and, therefore, are a principal component of our clinical research activities.

Our plan is to become the market leader in neuromodulation, the next frontier for medical devices. Our plan includes the following objectives:

- satisfy the urgent unmet medical need in TRD and aggressively develop and expand our intellectual property, regulatory and market franchise in the U.S. TRD market;
- reposition VNS Therapy in a unique, defensible market position in epilepsy to rejuvenate growth and accelerate penetration of the U.S. epilepsy market;
- increase our investment in rest-of-world markets to accelerate growth and development of epilepsy and depression in global markets;
- develop new, patent-protected VNS indications; and
- leverage our core competencies to exploit non-VNS neuromodulation opportunities through strategic partnerships.

Epilepsy

The VNS Therapy System has been approved by FDA for marketing in the U.S. as an adjunctive therapy for reducing the frequency of seizures in patients over 12 years of age with partial onset seizures that are refractory to antiepileptic drugs. The VNS Therapy System has also received regulatory approval in numerous other markets, including Europe, Australia, Canada, South America, Africa, India and certain countries in Eastern Asia for the treatment of refractory epilepsy.

Epilepsy Market Overview

Epilepsy is a disorder of the brain characterized by recurrent seizures that are categorized as either partial or generalized at onset. Generalized seizures that involve the entire brain from the onset usually result in the loss of consciousness and are typically manifested by convulsions. Partial onset seizures initiate in a localized region of the brain, and may or may not result in an alteration in consciousness. Partial onset seizures can also progress to generalized seizures. Patients who continue to have unsatisfactory seizure control or intolerable side effects after treatment with appropriate antiepileptic therapies for a reasonable period of time are said to suffer from refractory epilepsy. For reasons that are not clear, partial onset seizures are generally more refractory to existing therapies than generalized seizures.

Epilepsy is the second most prevalent neurological disorder. It is estimated that approximately 2.8 million individuals in the U.S. have epilepsy, with approximately 150,000 new cases diagnosed each year, and that there are in excess of 3.3 million individuals with epilepsy in Western Europe and Japan, with over 210,000 new cases diagnosed each year. In addition, it is estimated that approximately 50% of patients with epilepsy suffer from partial onset seizures and that over 20% of these patients continue to suffer from seizures in spite of treatment with antiepileptic drugs. The medical, psychological, sociological and financial implications of refractory epilepsy can be profound for individuals and their families. Seizures can be severely debilitating and may result in major irreversible morbidity which consists of lasting complications or side effects. Medical consequences may include brain damage from recurrent seizures, injuries and accidents associated with the loss or impairment of consciousness and death as the result of severe seizures. Personal implications of epilepsy may include suffering the side effects of antiepileptic drugs, strained personal and family relations, and the inability to obtain and hold meaningful employment or a driver's license.

Up to 50% of refractory epilepsy patients also suffer from co-morbid major depressive disorder, which is largely undiagnosed and untreated. As the first and only treatment that is approved for both medically refractory epilepsy and treatment-resistant depression, VNS Therapy is uniquely positioned to meet this medical need for many patients.

Traditional Epilepsy Therapies

Traditionally, there have been two courses of treatment available to persons suffering from epilepsy: drug therapy and surgery. The efficacy of these treatments depends in part upon the type of seizures from which a patient suffers. The efficacy of drugs and surgery for patients suffering from partial onset seizures is highly variable.

Drug Therapy. Antiepileptic drugs serve as a first-line treatment and are prescribed for virtually all individuals being treated for epilepsy. Lack of patient compliance, which is typical of chronic drug therapy, inherently reduces the efficacy of a drug therapy regimen. In addition, side effects are common with antiepileptic drugs. Side effects range from debilitating central nervous system conditions such as drowsiness, confusion and cognitive impairment to life-threatening hematologic reactions or liver failure. Women taking antiepileptic drugs are more likely to bear infants with birth defects than the general population. Children receiving antiepileptic drug therapy often experience learning difficulties.

Surgical Treatment. When drug therapy is not effective, the other traditional treatment alternative has been surgical removal of the portion of the brain where seizures originate. Surgical treatment of epilepsy has been proven safe and beneficial for a limited number of patients. Approximately 2,500 epilepsy surgeries are performed per year in the U.S. We believe that the low number of surgeries is attributable to several factors,

including: the extensive evaluation and testing required to screen candidates for surgery and to localize the source of the seizures; the relatively small percentage of patients who have a clearly identifiable and surgically accessible focus for their seizures; the risks of morbidity and mortality associated with brain surgery; the uncertainty of long-term benefits; the non-reversible nature of the procedure; and the cost of evaluation, testing and surgery, which is reported to be approximately $60,000 in many cases.

Other Treatments currently under investigation. Researchers are currently exploring the use of other treatments to control epilepsy, including direct deep brain stimulation (DBS). This treatment involves implanting electrodes in discrete focal areas of the basal ganglia and delivering a current via a computer controlled impulse generator implanted beneath the skin. Another treatment under investigation is the Responsive Neurostimulator System (RNS™), which is designed to suppress seizures before symptoms appear. The neurostimulator is surgically implanted in the patient's skull and is connected to electrode wires that are either implanted within the patient's brain or placed on the brain surface in the area of presumed seizure origin. The device monitors brain waves and, upon identifying the "signature" of a seizure onset, delivers an electric current to the patient's brain to suppress the seizure. These treatments are in the investigation stage and do not currently compete with VNS Therapy.

VNS Therapy In Epilepsy

Clinically Proven. To date, over 32,000 patients in 24 countries have accumulated in excess of 94,000 patient years of treatment experience with the VNS Therapy System. In July 1997, FDA approved the VNS Therapy System for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures that are refractory to antiepileptic drugs. The product is approved for sale as a treatment for refractory epilepsy in all member countries of the European Union, Canada, Australia and other markets.

Improvements in Disease Symptoms. In our two randomized, parallel, double-blind active control studies, the treatment groups reported a mean seizure reduction of approximately 24% and 28% during the three-month acute phase of the studies. Additionally, many patients, including some who reported no change or an increase in seizure frequency, also reported a reduction in seizure severity. Long-term follow-up data, derived from an uncontrolled protocol, on the 440 patients in our first five studies suggest that efficacy is maintained and, for many patients, improves over time when the VNS Therapy System is used as an adjunctive therapy with drugs as part of a patient's optimized long-term treatment regimen. Analysis of this pooled data showed that the median percent seizure reduction increased from 20% in the first three months to 44% after 24 months of treatment and was sustained at that level at 36 months.

Well-tolerated Side Effects. In the treatment of refractory epilepsy the side effects associated with the VNS Therapy System are generally mild, localized and related to the period of time in which stimulation is activated. They include hoarseness, coughing, a feeling of shortness of breath, difficulty swallowing and throat or neck discomfort. The VNS Therapy System has not typically been associated with the debilitating central nervous system side effects that frequently accompany antiepileptic drugs. Additionally, side effects typically decrease over time.

Improvements in Quality of Life. The Cyberonics VNS Patient Outcome Registry contains acute and long-term follow-up data on patients treated with VNS Therapy post-FDA approval. Global changes were measured in important quality-of-life areas such as alertness, verbal communication, memory, school/professional achievements, mood changes, postictal state and cluster seizures. To date, the registry includes data on over 7,200 patients, of which approximately 4,500 patients are at three-months follow-up and over 2,700 patients are at 12-months follow-up. Compared to pre-implant, approximately half of patients in both the acute and long-term follow-up exhibit improvements in at least two quality of life areas. Less than 6% of patients exhibit a worsening of any effect in both the acute and long-term patient populations.

Easy to Use. The implantation procedure is a straightforward, reversible procedure that takes between 30 and 90 minutes to complete, does not involve the brain and has been performed by surgeons with a variety of specializations. Infection and nerve damage are the chief risks related to the surgery. The VNS Therapy System does not interact with existing therapies. Because the VNS Therapy System provides therapy without

patient (or caregiver) administration, compliance is high. Moreover, a patient can use a magnet to override temporarily the pre-programmed stimulation cycle to activate on-demand therapy if the patient senses the onset of a seizure or to eliminate temporarily stimulation side effects.

Depression

On July 15, 2005, FDA approved VNS Therapy as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression in a major depressive episode and have not responded to at least four adequate antidepressant treatments. Chronic treatment-resistant depression is defined as being in the current depressive episode for more than two years. Recurrent treatment-resistant depression is defined as having a history of multiple prior episodes of depression. The approved indication for use includes patients with unipolar or bipolar depression in a major depressive episode.

Depression Market Overview

Major depressive disorder (MDD) is one of the most prevalent and serious illnesses in the U.S. It affects nearly 19 million Americans 18 years of age or older every year. Depression is the second leading cause of disability for the general population and is the leading cause of disability for American women. Approximately 20% of Americans who are depressed, or approximately 4 million people, experience chronic or recurrent treatment-resistant depression that has failed to respond to multiple antidepressant treatments. Depression interferes with a person's ability to function, feel pleasure or maintain interest in everyday living. It is associated with increased mortality due to suicide and co-morbid general medical conditions, including heart disease and lung disease. Depressed patients use twice the healthcare services as non-depressed patients. Total annual costs for depression in the U.S. exceed $80 billion, including $30 billion in annual direct treatment costs. A person with depression is 35 times more likely to commit suicide than a person not experiencing depression and 15% of previously hospitalized depressed patients do ultimately commit suicide.

Treatment-resistant depression is defined by most psychiatrists as a major depressive episode that has not had an adequate response to two or more adequate antidepressant treatments at appropriate dose and duration. For those patients, treatments such as psychotherapy, antidepressant medications and electroconvulsive therapy produce an incomplete response or may not sustain their effectiveness over time. Studies have shown that annual healthcare costs for severe TRD can exceed $40,000 per patient, approximately six times the cost of depressed patients who are not treatment resistant.

The exact causes of depressive disorders are unknown, although both biological abnormalities and psychological factors are thought to precipitate this disease. Diminished synaptic concentrations of neurotransmitters, especially serotonin and norepinephrine, are implicated in the pathogenesis of depression. Most current standard therapies are thought to affect either one or both of these neurotransmitter systems: selective serotonin reuptake inhibitors (SSRIs) drugs and serotonin-norepinephrine reuptake inhibitors (SNRIs) increase synaptic concentrations by blocking reabsorption of these neurotransmitters while monoamine oxidase inhibitors drugs (MAOIs) work by decreasing the breakdown of norepinephrine and serotonin. It is of interest to note that several antiepileptic compounds, such as carbamazepine, valproate and lamotrigine, are also used as mood stabilizers.

Traditional Depression Therapies

The goals of treatment of depression are to achieve remission of symptoms, prevent relapse and recurrence and to improve the quality of life and functional capacity of the patient. Treatment of depression is typically viewed in terms of acute, continuation and maintenance phases of treatment. The acute treatment phase is considered to be six to 12 weeks, the continuation phase is four to nine months and the maintenance phase is greater than nine to 12 months. For well-established recurrent depressions, the rate of recurrence may exceed 75%. In the U.S., it is estimated that approximately 100,000 patients are treated annually with electroconvulsive therapy (ECT). ECT typically involves general anesthesia and multiple treatments that can cost from $8,000 to as high as $20,000 per patient per year. Morbidity associated with ECT includes the risks of general anesthesia, as well as short and long-term cognitive deficits, including memory loss.

Although there are many safe and effective antidepressant treatments including medications, psychotherapy and ECT, there are no FDA-approved, informed-use, safe and effective long-term treatments for TRD, other than VNS Therapy. Multiple medication combinations are used to treat TRD without evidence of long-term safety and efficacy. ECT, the most effective acute antidepressant, is often declined, and is of limited long-term value due to cognitive side effects and high relapse/recurrence rates within six months of treatment.

VNS Approval History in Treatment-Resistant Depression

On July 15, 2005, FDA approved VNS Therapy as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression in a major depressive episode that has not responded to at least four adequate antidepressant treatments. Chronic treatment-resistant depression is defined as being in the current depressive episode for more than two years. Recurrent treatment-resistant depression is defined as having a history of multiple prior episodes of depression. The approved indication for use includes patients with unipolar or bipolar depression in a major depressive episode.

Since June 1998, we have been conducting clinical studies of the VNS Therapy System for the treatment of depression in patients with major depressive episodes that have not responded to standard treatments. The depression study program includes acute and long-term clinical studies, acute and long-term mechanism-of-action research and clinical and economic outcome studies in patients with treatment-resistant depression receiving standard medical treatment that does not include VNS. These studies are being conducted to determine the safety, clinical effectiveness and cost effectiveness of VNS Therapy in the treatment of depression, support regulatory approvals and support post-approval psychiatrist, patient and payer acceptance.

In July 1999, FDA granted Expedited Review status for a future PMA for our VNS Therapy System for the treatment of major depression in patients with unipolar and bipolar depressive disorder. During fiscal 1999, we launched a pilot safety and efficacy study of vagus nerve stimulation using our VNS Therapy System in patients with refractory chronic or recurrent severe depression. In October 1999, FDA granted unconditional approval for a pivotal clinical study of VNS Therapy for treatment-resistant depression to include up to 20 institutions and up to 240 patients.

In March 2001, the VNS Therapy System was approved by N.V. KEMA, an official notified body representing the European Union countries, for the treatment of chronic or recurrent depression in patients who are in a treatment-resistant or treatment-intolerant depressive episode. This CE Mark approval, by definition, includes the treatment of depression in patients with depressive disorder, or so-called unipolar depression, as well as patients with bipolar disorder or manic depression. In April 2001, the VNS Therapy System was approved by Health Canada for the treatment of chronic or recurrent depression in patients who are in a treatment-resistant or treatment-intolerant depressive episode. The Canadian approval is similar to CE Mark European approval in that depressed patients with unipolar depression and bipolar depression are included.

On October 27, 2003, we filed a Premarket Approval Supplement (PMA-S) with FDA for approval to market the VNS Therapy System for the adjunctive long-term treatment of chronic or recurrent depression in patients experiencing a major depressive episode that has not had an adequate response to two or more antidepressant treatments. In April 2004, we were notified by FDA that a meeting of FDA's Panel had been scheduled for June 15, 2004 to review our PMA-S seeking approval to market the VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression.

On June 15, 2004, the Neurological Devices Panel of FDA's Medical Devices Advisory Committee voted 5 to 2 to recommend approval with conditions of Cyberonics' VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode that has not had an adequate response to four or more adequate antidepressant treatments. The Panel recommended several labeling changes: that the VNS depression prescribers and implanting surgeons have appropriate experience and adequate training in the implantation and programming of the VNS Therapy System; that patients receive adequate education and that Cyberonics implement a long-term depression patient registry following approval.

On August 11, 2004, FDA determined that notwithstanding the recommendation of the Neurological Devices Panel, our PMA-Supplement, absent additional information, was considered not approvable. FDA's stated reasons included observations of worsening depression in some patients, potential biases stemming from a non-randomized control and an inability to distinguish one-year VNS effects from placebo and concomitant treatment effects.

On September 23, 2004, we submitted to FDA an amendment to our Expedited Review PMA Supplement (PMA-S) to address the safety and effectiveness concerns expressed in FDA's not-approvable letter, and to obtain approval to market the VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression for patients who are experiencing a major depressive episode and have not had an adequate response to four or more antidepressant treatments, as recommended by the FDA's specially chosen Advisory Panel on June 15, 2004. The amendment augmented the original PMA-S, which included comprehensive one-year data and analyses on over 400 patients, with two-year safety and effectiveness data and analyses on over 240 patients with chronic or recurrent TRD treated with adjunctive VNS Therapy. The amendment also included updated, informative and transparent labeling for physicians and patients and a formal response to FDA's not-approvable letter.

On February 2, 2005, FDA deemed the VNS Therapy System approvable as an adjunctive treatment for treatment-resistant depression. In the approvable letter, FDA indicated that final approval was conditional on reaching agreement on final labeling and final protocols for a post-approval dosing optimization study and patient registry, satisfactory compliance with Quality System Regulations (QSR) and satisfactory resolution of any outstanding bioresearch monitoring issues.

In February 2005, FDA notified us that the bioresearch monitoring condition of approval was satisfied. On April 6, 2005 FDA's Dallas District Office notified us that our response to FDA's Warning Letter dated December 22, 2004 was found to be complete and adequate and that the Warning Letter was officially closed.

On June 2, 2005, we received an FMD 145 letter from FDA's Dallas District Office notifying us that the inspection and Warning Letter dated December 22, 2004 were officially closed under 21 C.F.R. 20.64(d)(3). We also were informed that FDA's Center for Devices and Radiological Health (CDRH) was nearing completion of its final review of the conditions of TRD approval and that CDRH had requested that the Dallas District Office conduct a follow-up facility inspection at our headquarters to confirm the QSR corrective and preventative actions implemented in response to the Warning Letter observations. That follow-up inspection was concluded on June 10, 2005 with no observations.

VNS Therapy Depression Clinical Study Overview

Since June 1998, we have been conducting clinical studies of the VNS Therapy System for the treatment of depression in patients with major depressive episodes that have not responded to standard treatments. The clinical component consists of four studies: a 60-patient open-label pilot study (D-01) which was initiated in fiscal year 1999 and includes long-term follow-up, with all continuing patients exceeding three years of follow-up; a 235-patient randomized, double-blind, placebo-controlled study (D-02) with long-term open-label follow-up; an open-label post-marketing study in Europe (D-03); and a 127-patient observational study of treatment-resistant depressed patients receiving standard-of-care treatment but no VNS Therapy (D-04).

Clinical Study Designs and Controls. The VNS clinical studies were designed specifically to satisfy the unique needs of patients with TRD and collect valid scientific evidence of the safety and effectiveness of VNS Therapy for the proposed indication for use consistent with implantable medical device laws, regulations and approval precedents.

- The VNS studies were longer-term to satisfy the need for a safe and effective long-term maintenance therapy;
- Inclusion and exclusion criteria were designed to include patients with the most chronic and resistant depressions ever studied, who are excluded from other studies of antidepressants, to determine the safety and effectiveness in a true TRD population;

- Blinded videotape ratings were done by Columbia University to preserve the blind and ensure consistency of ratings;
- The D-02 study had an acute sham control to evaluate acute safety and effectiveness;
- Consistent with most device precedents, longitudinal patients-as-their-own controls analyses were done to show long-term, sustained effect and the value of VNS as a maintenance therapy;
- Comparative analyses versus a non-randomized, well-matched, active control group of TRD patients treated with any currently available treatment (no VNS) compared adjunctive VNS Therapy to standard medical practices using currently available treatment; and
- Multiple outcome measures and analyses including physician and patient ratings scales were used to test the consistency of the long-term outcomes.

Chronic, Treatment-Resistant Depression Study Patients. The patients in the VNS studies were suffering from among the most chronic and treatment-resistant depressions ever studied. The average lifetime depressive illness was 25 years with average duration in the current depressive episode of four years. Patients averaged 20 failed treatments lifetime, including 53% of patients treated with ECT and ten failed treatments in the current episode alone. As episode duration and number of failed adequate treatments in the current episode are the best predictors of response and relapse in ECT studies, the probability of response, complete response and sustained response among the patients in the VNS studies was very low.

Clinical Study Results. The depression clinical study results showed that response and remission rates (remission being a complete or near complete absence of depressive symptoms) and clinical benefit increased over one year of adjunctive VNS Therapy and then remained stable over the second year of treatment. After one year of adjunctive VNS Therapy, about 1 in 3 patients had responded and 1 in 6 had achieved remission. More than 50% of patients at 12 months of adjunctive VNS Therapy reported at least a meaningful prospectively-defined clinical benefit as measured by the Hamilton Rating Scale for Depression (HRSD) and defined as a 25% or greater improvement in depressive symptoms. Response and remission rates for the patients in the D-02, D-01 and combined study results were as follows:

3, 12 and 24 Month HRSD Response and Remission Rates for Patients Treated with VNS

	D-02	D-01	Combined
3 Mo. Responders	15%	31%	18%
1 Yr. Responders	30%	46%	34%
2 Yr. Responders	33%	43%	35%
3 Mo. Remitters	7%	15%	9%
1 Yr. Remitters	17%	27%	20%
2 Yr. Remitters	17%	21%	18%

A significant finding of the pivotal study (D-02) was that most patients who responded while receiving adjunctive VNS Therapy maintained that response at the one- and two-year evaluations; 60% of the patients who responded after three months of adjunctive VNS Therapy were still responders at one year; and 70% of these three-month responders were responders at the two-year evaluation. For patients who were responders at the one-year evaluation, 69% were still responders at two years.

Effectiveness was further demonstrated by comparing the pivotal depression study outcomes over 12 months of adjunctive VNS Therapy with outcomes from a large group of non-randomized control patients who were treated for 12 months with standard antidepressant treatments but no VNS. Both the patients in this control study group (D-04), and the patients receiving adjunctive VNS Therapy in the pivotal depression study could receive any FDA-approved antidepressant treatment, but only the pivotal depression study patients, designated as the D-02 group, received VNS Therapy. The results comparing adjunctive VNS Therapy and standard antidepressant treatment (sometimes referred to as treatment as usual) showed that the patients receiving adjunctive VNS Therapy had significantly more improvement in depressive symptoms,

significantly higher response rates, significantly higher rates of remission, and a significantly higher rate of maintained response than did the patients who received treatment as usual without VNS Therapy.

Although the TRD patients enrolled in the VNS studies were at a relatively high risk of suicide, the rates of suicide attempts and suicides in the depression clinical studies were comparable to those observed in a large published database of non-resistant depressed patients treated in antidepressant drug studies. The number of suicide attempts in the pivotal study has declined the longer the patients have been under treatment with VNS Therapy, consistent with the increasing response over time observed in the TRD studies and consistent with the decline in Sudden Unexplained Death in Epilepsy Patients, or SUDEP, rates over time observed in the post-approval clinical use of VNS in epilepsy. Similarly, incidences of significant worsening of depression declined over time in the pivotal study, again consistent with the observation of increasing response as patients continue to receive adjunctive VNS Therapy over longer periods of time.

VNS Therapy was generally well-tolerated in the VNS clinical studies. The most commonly reported adverse events in the pivotal depression trial are well-known side effects of the therapy and include voice alteration, increased cough, neck pain, and shortness of breath. The common side effects of the therapy tend to occur during stimulation, tend to be reported as mild or moderate, and tend to be reported less frequently over time.

The tolerability of VNS Therapy was demonstrated by high therapy continuation rates. During 12 months of VNS Therapy in the pivotal depression clinical study, only 10% of study patients dropped out. Furthermore, at the time of the PMA-S submission when all remaining pivotal study patients had received VNS Therapy for at least 12 months, only 3% of the patients had dropped out due to adverse events. After 24 months, over 80% of the pivotal study patients continued in the study, with only 6% of patients discontinuing therapy due to adverse effects during 24 months (or longer) of therapy.

VNS Therapy Product Labeling and Post Market Surveillance in Depression

The product labeling approved by FDA for the TRD indication is comprehensive and fully informative and includes labeling for both physicians and patients. Importantly, the approved labeling provides not just short-term effectiveness results, but also includes results for patients treated with adjunctive VNS Therapy over a 2-year time period. The labeling contains all the relevant safety data known about VNS Therapy, including detailed contraindications, warnings, and precautions to assist physicians and patients in making informed treatment decisions, safety data from the depression studies and epilepsy studies, as well as commercial epilepsy safety data from Cyberonics' Medical Device Reporting (MDR) reports and FDA's Maude database derived from over 32,000 patients with over 80,000 patient years of experience as of October 2004.

As part of our commitment to enhance the information that is available to physicians and patients to make informed decisions about the use of VNS Therapy, Cyberonics has committed to FDA as part of post-market surveillance to undertake a 460-patient post-approval dosing study and a 2,000-patient five-year TRD registry, to include 1,000 patients treated with adjunctive VNS Therapy. The dosing study will randomize patients to one of three different VNS dosages to help determine the optimum VNS dosage settings for patients. The patient registry will follow VNS Therapy-treated patients for 5 years. One of the primary objectives of the registry will be to help determine if there are specific predictors for which patients benefit most (or least) from VNS Therapy.

Other Indications Development

Based on its known central nervous system effects and observed clinical effects, VNS Therapy may be useful for treating a variety of disorders. Accordingly, our patent portfolio includes many potential additional uses for VNS Therapy. We currently have small pilot studies underway for the treatment of Alzheimer's Disease, anxiety, bulimia and chronic headache/migraine. In fiscal 2006, we intend to invest considerable financial and human resources to expand clinical study activities in new applications of VNS Therapy.

VNS Therapy System

VNS Therapy is the first treatment that is approved by FDA for medically refractory epilepsy and treatment-resistant depression. The VNS Therapy product and the implant procedure are similar for refractory epilepsy and TRD indications.

The safety profiles for VNS Therapy and the VNS Therapy System, including the implant procedure, are well established in clinical studies of refractory epilepsy and TRD and in commercial use in over 32,000 patients with over 94,000 total patient years of experience. The safety profile in the depression studies was similar to that observed in earlier epilepsy clinical studies and subsequent post-approval clinical experience. As a non-pharmacologic treatment, VNS Therapy has some unique benefits:

- VNS Therapy does not cause pharmacokinetic interactions with drugs;
- VNS Therapy has not been found to produce cognitive impairment common with electroconvulsive therapy and certain pharmaceutical therapies;
- VNS Therapy does not require active administration by the physician or patient and therefore patients experience a high treatment compliance;
- VNS Therapy has no risk of overdose;
- VNS Therapy requires a surgical procedure and cannot be used without the unanimous agreement of a patient, prescribing physician, surgeon, hospital, and payer. As a result, VNS Therapy is not likely to be used without careful and deliberate consideration as to its potential risks and benefits for each and every patient.

VNS Therapy is a proprietary, integrated system consisting of an implantable device that delivers an electrical signal to an implantable lead that is attached to the left vagus nerve. The vagus nerve is the longest of the cranial nerves, extending from the brain stem through the neck to organs in the chest and abdomen. The left vagus nerve has been shown to have influence over numerous areas of the brain. Preclinical studies and mechanism of action research suggest that intermittent stimulation of the left vagus nerve in the neck modulates a number of structures and alters blood flow bilaterally in several areas of the brain. These studies have also shown that stimulation of the left cervical vagus nerve is effective in blocking seizures and results in persistent or carryover antiepileptic effects, which increase with chronic intermittent stimulation. The mechanism of action research associated with our TRD studies has shown stimulation of the left vagus nerve results in modulation of areas of the brain thought to be important in the regulation of mood.

The VNS Therapy System consists of the VNS Therapy Pulse Generator, the Bipolar Lead, the programming wand and software and the tunneling tool. The VNS Pulse Generator and Bipolar Lead are surgically implanted in a procedure that takes from 30 to 90 minutes, during which time the patient is under general, regional or local anesthesia. The VNS Pulse Generator is surgically implanted in a subcutaneous pocket in the upper left chest. The Bipolar Lead is connected to the VNS Pulse Generator and attached to the vagus nerve in the lower left side of the patient's neck. The patient is generally admitted to the hospital the day of surgery and discharged the same or following day.

The VNS Therapy System delivers VNS on a chronic, intermittent basis. The initial standard stimulation parameters that we typically recommend are a 30-second period of stimulation which we refer to as ON time, followed by a five-minute period without stimulation which we refer to as OFF time. To optimize patient treatment, the pulse width, amplitudes, frequency and stimulation ON and OFF intervals of the VNS Pulse Generator can be noninvasively programmed and adjusted by the treating physician with a personal or handheld computer using our programming wand and software. In addition, the patient can use a small, handheld magnet that is provided with the VNS Pulse Generator to manually activate or deactivate stimulation. On-demand therapy can be useful for those epilepsy patients who sense an oncoming seizure and has been reported by a number of patients to abort or reduce the severity or duration of seizures. The magnet can also be used to provide patient control of stimulation side effects by allowing the patient to deactivate stimulation temporarily.

VNS Pulse Generator. The VNS Pulse Generator is an implantable, programmable signal generator designed to be coupled with the bipolar lead to deliver electrical signals to the vagus nerve. The VNS Pulse Generator is a battery powered device. Upon depletion of the battery, the VNS Pulse Generator is removed and a new generator is implanted in a short, outpatient procedure using local anesthesia.

Bipolar Lead. The VNS Bipolar Lead conveys the electrical signal from the VNS Pulse Generator to the vagus nerve. The lead incorporates electrodes, which are self-sizing and flexible, minimizing mechanical trauma to the nerve and allowing body fluid interchange within the nerve structure. The lead's two electrodes and anchor tether wrap around the vagus nerve and the connector end is tunneled subcutaneously to the chest where it attaches to the VNS Pulse Generator. The leads are available in two sizes of inner spiral diameter to ensure optimal electrode placement on different size nerves.

Programming Wand and Software. Our programming wand and proprietary software are used to interrogate the device and to transmit programming information from a personal or handheld computer to the VNS Pulse Generator via electromagnetic signals. Programming capabilities include modification of the VNS Pulse Generator's programmable parameters (pulse width, amplitude frequency and ON and OFF intervals) and storage and retrieval of telemetry data.

Tunneling Tool. The tunneling tool is a single use, sterile, disposable surgical tool designed to be used during surgical placement of the bipolar lead. The tool is used for subcutaneous tunneling of the lead assembly between the nerve site in the neck and the VNS Pulse Generator site in the chest.

Accessory Pack. The Accessory Pack includes one resistor assembly used to test the function of the device prior to implantation, the VNS Bipolar Lead tie-downs, one hex screwdriver, two setscrews and setscrew plugs.

The VNS Therapy System implant procedure, including device costs, hospital charges and physician fees, costs between $20,000 and $35,000. The current list price for the VNS Therapy System is approximately $15,900 for the Model 102 System.

Manufacturing and Sources of Supply

Our manufacturing operations are required to comply with FDA's Quality System Regulations, commonly referred to as QSR, which incorporate the agency's former Good Manufacturing Practices regulations. QSR addresses the design, controls, methods, facilities and quality assurance controls used in product design, manufacturing, packaging, labeling, storing and installing medical devices. In addition, certain international markets have regulatory, quality assurance and manufacturing requirements that may be more or less rigorous than those in the U.S. Specifically, we are subject to the compliance requirements of International Standards Organization (ISO) 9001:1994 and 13485:1996, CAN/CSA ISO 13485:1998 certifications and CE Mark directives. We are audited by KEMA, Quality USA on a semiannual basis and by KEMA, The Netherlands on an annual basis, respectively, for such compliance.

The VNS Therapy Pulse Generator Model 102 is similar in design and manufacture to a cardiac pacemaker. The Model 102 is comprised of one printed circuit board and a battery which is hermetically sealed in a titanium case. Standard components are assembled on printed circuit boards using surface-mount technology. The circuit boards are next assembled and tested. The assembled circuit boards and battery are then placed in a titanium case that is laser welded. A header to which the bipolar lead connects is added to all sealed units. Each unit is subject to final release testing prior to being sterilized by a third-party vendor.

We continue to rely on sole source suppliers for certain materials and services used in manufacturing the VNS Therapy System for reasons of quality assurance, availability or cost effectiveness. We periodically experience discontinuation or unavailability of components, materials and contract services. Any such interruption in this availability of components, materials or services might necessitate the qualification of alternative sources or the redesign of specific components of the VNS Therapy System, which could consume significant resources and require regulatory submissions and approvals. Although we believe that any such changes will be made without disruption, extended delays in or an inability to secure alternative sources for components, materials and contract services could result in product supply interruptions. In addition, in an

effort to reduce potential product liability exposure, certain suppliers have terminated or may terminate sales of certain materials and parts to manufacturers of implantable medical devices. The Biomaterials Access Assurance Act was adopted in 1998 to help ensure the availability of raw materials and component parts essential to the manufacture of medical devices. We cannot estimate the impact of this law on supplier arrangements. Any supply or manufacturing disruption could significantly harm our business.

Marketing and Sales

United States. We market and sell our products for refractory epilepsy and treatment-resistant depression through a direct sales force in the U.S. As of May 20, 2005, our U.S. sales and case management organization consisted of approximately 300 full-time employees, including about 235 in field sales, specialty surgical and account management personnel and 65 in case management.

Our sales and marketing plan focuses on creating awareness and demand for the VNS Therapy System among targeted epileptologists and neurologists who treat refractory epilepsy, implanting surgeons, nurses, third-party payers, and patients and their families. In fiscal 2006, our efforts will expand to create awareness of VNS Therapy for treatment-resistant depression among targeted psychiatrists and patients with TRD.

To reach each of these groups, we are using a specialized sales force consisting of sales personnel with medical device, pharmaceutical, or nursing experience; reimbursement specialists experienced in obtaining third-party coverage and payments for new medical technologies; surgical sales specialists and field clinical engineers experienced in obtaining, training and maintaining adequate surgical capacity for implanting the VNS Therapy System; marketing teams experienced in educational and promotional marketing programs; and case managers experienced in patient education and insurance verification and authorization issues. The same demand creation organization and model that was developed for the refractory epilepsy market over the past seven years will be used for the treatment-resistant depression market. In addition to our direct selling activities, we facilitate and support peer-to-peer interactions such as symposia, conference presentations, journal articles and patient support groups to provide experienced clinicians and patients the opportunity to share their perspectives on the VNS Therapy System with others.

On July 15, 2005, FDA approved VNS Therapy as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression in a major depressive episode and have not responded to at least four adequate antidepressant treatments. Since February 2005, we have intensified the preparation of our organization for approval and launch in depression and we have recently expanded our sales and case management organization from approximately 140 to over 300 demand creation personnel to support anticipated sales demand in both epilepsy and depression markets. While we expect to achieve significant revenue growth in fiscal 2006 related to sales of VNS Therapy in the U.S. for TRD, the scale-up of our sales organization is substantial and improvements in sales force productivity are not expected in fiscal 2006, as we will support product launch activities in depression throughout fiscal 2006. Furthermore, our expectations for sales demand in a completely new device market for TRD will likely change as we complete our physician targeting programs and promote awareness and acceptance of VNS Therapy among new psychiatric prescribers. Accordingly, while we expect to achieve revenue growth as a result of this approval, we can provide no assurance as to the size or timing of such growth, particularly, because FDA's approval was so recently received.

International. We market and sell our products through a combination of a direct sales force in certain European countries and distributors elsewhere. As of May 20, 2005, our international organization consisted of 34 full-time equivalent employees and a number of independent distributors. The VNS Therapy System is currently sold by a direct sales force in Austria, Belgium, Denmark, France, Germany, Italy, Luxemburg, The Netherlands, Norway, Sweden, Switzerland, and the United Kingdom. We have distribution agreements with independent distributors covering a number of other countries, principally in Europe, Asia, South Africa, Australia, Mexico, South America and Canada. The distribution agreements generally grant the distributor exclusive rights for the particular territory for a period of three years. The distributor generally assumes responsibility for obtaining regulatory and reimbursement approvals for such territory and agrees to certain minimum marketing and sales expenditures and purchase commitments. Under the terms of the distributor

agreements, no product return rights are granted to the distributor and no additional product performance issues exist for the Company after shipment to the distributor. Pricing is generally fixed under the terms of the distribution agreements, but may change, at the Company's election, with as little as thirty days prior notice, under most agreements. Sales incentives, if provided, are recorded as a reduction of net sales in the same period revenue is recognized.

Third-Party Reimbursement

Our ability to successfully expand the commercialization of the VNS Therapy System depends on obtaining and maintaining favorable coverage, coding and reimbursement for the implant procedure and follow-up care. Currently, more than 99% of requests for VNS Therapy coverage and reimbursement for epilepsy are approved. VNS Therapy has been recommended and/or adopted by most payers across the U.S. for the treatment of epilepsy, including Aetna, Blue Cross/Blue Shield Technology Evaluation Center, CHAMPUS, Kaiser Permanente, Centers for Medicare & Medicaid Services (CMS) and most state Medicaid programs. The favorable coverage, coding and reimbursement decisions for VNS Therapy in the treatment of refractory epilepsy have established a strong foundation for obtaining future favorable reimbursement decisions for VNS Therapy for treatment-resistant depression. Universal coverage for VNS Therapy for refractory epilepsy, existing coding for the VNS Therapy System, payment rates for surgeons and prescribing physicians are already in place. Additionally, the hospitals that purchase the VNS Therapy System and the implanting surgeons are largely the same for both refractory epilepsy and treatment-resistant depression. We intend to actively pursue similar favorable coverage decisions to expand reimbursement to include VNS Therapy for the treatment of treatment-resistant depression, but can provide no assurance as to the timing of obtaining such coverage.

In deciding to cover a new therapy, payers base their initial coverage decisions on several factors including, but not limited to, the status of FDA's review of the product, CMS coverage decision, Blue Cross/Blue Shield Technology Evaluation Center recommendations, the product's safety and efficacy, the number of studies performed and peer-reviewed articles published with respect to the product and how the product and therapy compares to alternative therapies. The Cyberonics Reimbursement Department is available to assist hospitals and physicians with reimbursement questions. Regional Alliance Managers and Reimbursement Case Managers are available through our Reimbursement Hotline, to help with coverage, coding and reimbursement issues on a case-by-case basis and/or policy level.

The success of any new medical device therapy also depends on specific codes that physicians, surgeons and hospitals use to bill for their services. Medical services provided in conjunction with VNS Therapy have specifically approved codes for physicians, surgeons and hospitals to submit claims for their services. In making decisions about reimbursement amounts, payers typically reimburse for the costs of newly covered devices and services using the standard methods they employ for other products and services already covered. Many private insurers and managed care plans use a variety of payment mechanisms including, but not limited to, discounted charges, per diem amounts, resource-based payment scales, medical surgical case rates, contracted amounts and reimbursement of costs. We have found that many of these same payment mechanisms have provided reimbursement levels for VNS Therapy and related services that physicians and hospitals view as adequate to support use of VNS Therapy.

Medicare

Effective July 1, 1999, CMS (formerly the Healthcare Financing Administration, or HCFA), issued National Coverage Policy Transmittal 144 (Section 60-22). This policy is in accordance with FDA-labeled usage for the device. Currently, Medicare accounts for a total of 20% to 25% of the epilepsy patients implanted with VNS Therapy. The Medicare program uses different payment mechanisms to reimburse for procedures performed in different settings. For outpatient implants, Medicare introduced on August 1, 2000 a new prospective payment system based on Ambulatory Payment Classifications (APCs). Effective January 1, 2004, Medicare approved a new APC Code 0039 for implantation of Neurostimulators. For inpatient implants, Medicare uses a fixed-payment method, which is an all-inclusive prospective amount known as Diagnosis Related Groups (DRG). Under current DRG groupings, hospital inpatient procedures for implanting the

VNS Therapy are assigned to one of two different DRGs based on whether or not the patient has complications or coexisting severe medical problems, also referred to as co-morbidities. In our experience, 90% of the VNS Therapy implants are implanted in the outpatient setting. Reimbursement codes are already in place to pay for the cost of the device implantation and the surgeon implant fees, both of which are identical in the treatment of refractory epilepsy and treatment-resistant depression. Existing prescriber codes for device interrogation and dosage adjustment currently cover medical professionals in the epilepsy medical community. We intend to actively pursue expansion of existing prescriber codes to include psychiatrists and other mental health care professionals, but can provide no assurance as to the obtaining of such codes.

Medicaid

Medicaid programs cover hospital inpatient and outpatient services that are medically necessary and appropriate. Currently, Medicaid accounts for 20% to 25% of patients implanted with the VNS Therapy. Most state Medicaid agencies have developed their own coverage policy for VNS Therapy or adopted the National CMS coverage policy. In many cases, prior authorization is required. Medicaid reimbursement mechanisms vary state by state. Medicaid policy and payment methodologies change on a regular basis, so vigilant and ongoing work is necessary to ensure continued access and acceptable reimbursement for patients covered by Medicaid programs. Reimbursement codes are already in place to pay for the cost of the device implantation and the surgeon implant fees, both of which are identical in the treatment of refractory epilepsy and treatment-resistant depression. Existing prescriber codes for device interrogation and dosage adjustment currently cover medical professionals in the epilepsy medical community. We intend to actively pursue expansion of existing prescriber codes to include psychiatrists and other mental health care professionals, but can provide no assurance as to the obtaining of such codes.

Private Payers

Private payers also cover hospital inpatient and outpatient services that are considered to be medically necessary. Currently, private payers (commercial, managed care and other third-party payers) account for 50% to 60% of patients implanted with VNS Therapy. As with other payers, many private payers have developed clinical guidelines for coverage or adopted the National CMS coverage policy for use of VNS Therapy. Reimbursement mechanisms vary by plan.

While we believe the clinical evidence supporting VNS Therapy for treatment-resistant depression is adequate to convince private payers to provide coverage, approval is subject to each payer's assessment program. While we cannot give any assurances that private payers will expand coverage, we will actively work with private payers to gain approval of coverage for VNS Therapy in treatment-resistant depression.

Although the VNS Therapy System has been approved for commercial distribution in European Union countries and Canada for the treatment of chronic or recurrent depression, we do not anticipate significant sales volumes until reimbursement approvals are achieved in these countries. We are continuing to pursue appropriate reimbursement approvals in these countries.

Product Development

Our product development efforts are directed toward improving the VNS Therapy System and developing new products that provide additional features and functionality while improving cost effectiveness. In fiscal year 2003, we received approval for a new family of products represented in the Model 102 System, including the VNS Therapy Pulse Model 102 Generator, VNS Therapy Lead Model 302, Model 250 VNS Therapy System Programming Software Version 4.6 for use with the laptop programming system, the Model 250 VNS Therapy Programming Software 6.1 for use with a handheld programming system, VNS Therapy Tunneler Model 402 and VNS Therapy Accessory Pack Model 502. In fiscal year 2004, we introduced the Model 102R generator with a dual pin connector to provide the current generator technology for end of service replacement patients. On May 19, 2005, we received approval from KEMA Medical, our European Regulatory Notified body, of our VNS Therapy System Model 103 and 104 Generators for sale in the member countries of the European Union for the approved epilepsy and depression indications for use. The Model 103 Generator is the

next generation of single connector VNS generators for use in new patients, and the Model 104 Generator is the next generation of dual connector VNS generators for use in patients that have elected replacement of their previous dual connector generator at the end of its battery life. Both the Model 103 and 104 Generators are considerably more functional, smaller and lighter than the previous models. In December 2004, FDA agreed to review the Model 103/104 PMA-S through the Real-Time Review process. We anticipate submitting that PMA-S by the end of calendar 2005. We are conducting ongoing product development programs to design improvements in the VNS Therapy Pulse Generator, the Bipolar Lead and software enhancements. We will be required to file for the appropriate U.S. and international regulatory approvals, and some projects may require clinical trials, in connection with the introduction of new and improved products.

Competition

We believe that in the fields of refractory epilepsy and TRD, existing and future drug therapies are and will continue to be the primary competition for the VNS Therapy System. We may also face competition from other medical device companies for the treatment of partial seizures and TRD. Medtronic, Inc., for example, continues to assess clinically an implantable signal generator used with an invasive deep brain probe, or thalamic stimulator, for the treatment of neurological disorders and has received FDA approval for the device for the treatment of essential tremor and Parkinson's Disease. We could also face competition from other large medical device and pharmaceutical companies that have the technology, experience and capital resources to develop alternative devices for the treatment of epilepsy. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than us. In addition, the healthcare industry is characterized by extensive research efforts and rapid technological progress. Our competitors may develop technologies and obtain regulatory approval for products that are more effective in treating epilepsy than our current or future products. In addition, advancements in surgical techniques could make surgery a more attractive therapy for epilepsy. The development by others of new treatment methods with novel antiepileptic and depression drugs, medical devices or surgical techniques for epilepsy could render the VNS Therapy System non-competitive or obsolete.

We believe that the primary competitive factors within the epilepsy treatment market are the efficacy and safety of the treatment relative to alternative therapies, physician and patient acceptance of the product and procedure, availability of third-party reimbursement, quality of life improvements and product reliability. We also believe that the VNS Therapy System compares favorably with competitive products as to these factors.

While no other therapies have been specifically approved for TRD, a well-established array of antidepressant drugs, typically combined with other antidepressants of complimentary action or with atypical antipsychotic drugs and/or mood stabilizers, are frequently used for refractory patients. For severe patients or those at acute risk for suicide, ECT is often used for rapid response, although the effects of ECT are not generally sustained and relapse is common. These treatment modalities may pose a competitive threat in the near term, to the extent that they may delay a decision to offer VNS Therapy to TRD patients. As other forms of neurostimulation are investigated and developed for TRD, these may emerge in years to come as competition for VNS patient candidates. Less invasive procedures like rTMS (repetitive transcranial magnetic stimulation) and MST (magnetic seizure therapy) may compete for a similar place in the TRD treatment algorithm. More invasive technology like DBS (deep brain stimulation) is also being investigated for TRD. Finally, ECT is undergoing refinements in technique to increase specificity and reduce the cognitive deficit side effects; if successful, the tolerability and patient acceptance of ECT could improve in the future. These neurostimulation techniques could prove to be more effective, more predictable, or have a more rapid onset of antidepressant activity than VNS Therapy.

We face similar competition with respect to the development and sale of VNS Therapy as a treatment for the other indications we are evaluating, including, but not limited to Alzheimer's Disease, anxiety disorders and bulimia.

Patents, Licenses and Proprietary Rights

Proprietary protection for our products is important to our business. We maintain a policy of seeking method and device patents on our inventions, acquiring licenses under selected patents of third parties, and entering into invention and confidentiality agreements with our employees and consultants with respect to technology that we consider important to our business. We also rely on trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position.

We have an exclusive license agreement with Jacob Zabara, Ph.D., a co-founder and consultant to us, pursuant to which we received exclusive licenses on five U.S. method patents (and such international counterparts as have been or may be issued) covering the VNS Therapy System for vagus nerve and other cranial nerve stimulation for the control of movement disorders, including epilepsy, neuropsychiatric disorders, including depression, and other disorders. We believe that these patents give us an advantage. The license agreement runs for the term of licensed patents, which will give us coverage through 2011 for movement and neuropsychiatric disorders. Pursuant to the license agreement, we are obligated to pay Dr. Zabara a royalty equal to 3.0% of net sales through 2011.

We have an agreement with Mitchell S. Roslin, M.D. on two U.S. patents that we co-own with Dr. Roslin for bilateral VNS for the treatment of obesity. Pursuant to the agreement, we are obligated to pay Dr. Roslin a royalty rate of 1.0% of the first $10 million of net obesity sales covered by one of the patents and 0.5% of net obesity sales thereafter. The agreement also obligates us to pay to Dr. Roslin advances on royalties in the amount of $25,000 per year for five years beginning January 1, 2000 and, upon the completion of certain milestones, up to $325,000 in additional advances on royalties.

In addition to these agreements, as of May 20, 2005, we had approximately 33 issued U.S. patents and 15 pending U.S. patent applications, covering various aspects of the VNS Therapy System and the VNS method of treatment for a variety of disorders. In addition to movement disorders, other method patents cover the fields of eating disorders including obesity and bulimia, endocrine disorders, migraine headaches, dementia, neuropsychiatric disorders, including depression and anxiety disorders, motility disorders, sleep disorders, coma, chronic pain, cardiac disorders and hypertension. We have filed counterparts of certain of our key U.S. patent applications in certain key international jurisdictions and currently have approximately 15 patents issued by the European Patent Office or other international authorities and 17 patent applications pending in the European Patent Office or before other international authorities.

We cannot assure you that patents will be issued from any of the remaining applications or, that if patents are issued, that they will be of sufficient scope or strength to provide meaningful protection of our technology. In addition, we cannot assure you that the TRD patent will be extended or that any patents issued to us will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide proprietary protection or commercial advantage to us. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents.

We believe that the patents we own and license provide us with protection in the U.S. in the field of cranial nerve stimulation, including VNS for the control of epilepsy, and other movement disorders, including Parkinson's Disease and essential tremor, neuropsychiataric disorders, including clinical depression, eating disorders, anxiety disorders, obesity, dementia including Alzheimer's Disease and additional indications for which method patents have been issued. The protection offered by our international patents is not as strong as that offered by our U.S. patents due to differences in patent laws. In particular, European and other countries prohibit patents covering methods for treatment of the human body by surgery or therapy.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. We may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how or to defend us against claims of infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Litigation could be costly and divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the VNS Therapy System, any of which could severely harm our

business. We are not currently a party to any patent litigation or other litigation regarding proprietary rights and are not aware of any challenge to our patents or proprietary rights.

Government Regulation

The preclinical and clinical testing, manufacturing, labeling, sale, distribution and promotion of the VNS Therapy System are subject to extensive and rigorous regulation in the U.S. by federal agencies, primarily FDA, and by comparable state agencies. In the U.S., the VNS Therapy System is regulated as a medical device and is subject to FDA's premarket approval requirements. Under the Food, Drug, and Cosmetic Act, all medical devices are classified into three classes, class I, II or III. New class III devices, such as the VNS Therapy System, are subject to the most stringent FDA review, and require submission and approval of a premarket application before commencement of marketing, sales and distribution in the U.S.

For medical devices, the FDA Modernization Act (FDAMA) was enacted in 1997, one year before we began our TRD studies, to ensure the timely availability of safe and effective medical devices that will benefit the public and ensure that our nation continues to lead the world in medical product innovation and development. Device regulations and approval precedents clearly state that study designs and controls must be matched to the proposed indication for use and the illness and needs of the patients being studied. Industry and FDA are specifically encouraged by device laws, regulations and precedents to find alternatives for randomized controlled trials when potential biases associated with alternative controls can be addressed, parenthetically as they were in the VNS studies. As a result, valid scientific evidence of safety and effectiveness in device laws, regulations and precedents comes from:

- well-controlled investigations;
- partially controlled studies;
- studies and objective trials without matched controls;
- well-documented case histories conducted by qualified experts; and/or
- reports of significant human experience with a marketed device.

In July 1997, we received FDA approval to market the VNS Therapy System in the U.S. for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures that are refractory to antiepileptic drugs. While we have satisfied FDA's requirements to sell our product in the U.S., we continue to be subject to FDA's ongoing requirements to maintain regulatory compliance. We are also required by FDA to continue to provide information about which patients benefit most from the device as well as information on any deaths that occur in patients who have the device implanted. FDA may raise additional concerns in the future, and any such concerns could significantly impact our business prospects. Accordingly, compliance with FDA regulations and requirements is a priority for us and critical for the continued success of our business.

In July 1999, FDA granted Expedited Review status for a future PMA for our VNS Therapy System for the treatment of major depression in patients with unipolar and bipolar depressive disorder. During fiscal 1999, we launched a pilot safety and efficacy study of vagus nerve stimulation using our VNS Therapy System in patients with refractory chronic or recurrent severe depression. In October 1999, FDA granted unconditional approval for a pivotal clinical study of VNS Therapy for treatment-resistant depression to include up to 20 institutions and up to 240 patients.

On June 15, 2004, the Panel voted 5 to 2 to recommend approval with conditions of our VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode that has not had an adequate response to four or more adequate antidepressant treatments. Conditions recommended by the Panel included several labeling changes: that the VNS depression prescribers and implanting surgeons have appropriate experience and adequate training in the implantation and programming of the VNS Therapy System, that patients receive adequate education and that we implement a long-term depression patient registry following approval. FDA's Division of General and Restorative Neurological Devices will consider the deliberations, vote and recommendation of

the Panel and make the final decision on approval of the VNS Therapy System for the proposed indication for use.

On August 11, 2004, FDA's Center for Neurological and Restorative Devices determined that, notwithstanding the Neurological Devices Panel's recommendation for approval with conditions, the PMA-Supplement, absent additional information, must be considered not approvable. FDA's stated reasons included observations of worsening depression in some patients, potential biases stemming from a non-randomized control and an inability to distinguish one-year VNS effects from placebo and concomitant treatment effects.

On September 23, 2004, we filed an Amendment to the PMA-S to address the safety and effectiveness concerns expressed in FDA's not-approvable letter. The Amendment augmented the original PMA-S, which included comprehensive one-year data and analyses on 460 patients, with two-year safety and effectiveness data and analyses on approximately 200 patients with chronic or recurrent treatment-resistant depression (TRD) treated with adjunctive VNS Therapy compared with their baseline depression. The Amendment also included updated, informative and transparent labeling for physicians and patients and a formal response to FDA's not-approvable letter.

On December 22, 2004, FDA issued a Warning Letter regarding nonconformities with Current Good Manufacturing Practice (CGMP) requirements of the QSR for medical devices, as specified in Title 21, Code of Federal Regulation, Part 820. The letter followed an inspection of Cyberonics' Houston manufacturing operations, the issuance of a number of Form-483 inspectional observations, Cyberonics' submission of written responses, and a meeting with the Dallas District Office. The Warning Letter cited a number of observations in the areas of MDR Reporting, device design validation procedures, complaint handling, quality systems and quality corrective and preventive actions. On January 21, 2005 we submitted a response to the FDA Warning Letter regarding nonconformities with CGMP requirements of the QSR for medical devices.

On February 2, 2005, FDA deemed the VNS Therapy System approvable as an adjunctive treatment for treatment-resistant depression. The approvable letter indicated that final approval was conditional on satisfying the following four conditions: final labeling, final protocols for a post-approval dosing optimization study and patient registry, satisfactory compliance with QSR and satisfactory resolution of any outstanding bioresearch monitoring issues.

In February 2005, FDA notified us that the bioresearch monitoring condition of approval was satisfied. On April 6, 2005, FDA's Dallas District Office notified us that our response to FDA's Warning Letter dated December 22, 2004 was found to be complete and adequate.

On June 2, 2005, we received an FMD 145 letter from FDA's Dallas District Office notifying us that the inspection and Warning Letter dated December 22, 2004 were officially closed under 21 C.F.R. 20.64(d)(3). We also were informed that FDA's Center for Devices and Radiological Health (CDRH) that CDRH was nearing completion of its final review of the conditions of TRD approval and that CDRH had requested the Dallas District Office conduct a follow-up facility inspection at our headquarters to confirm the QSR corrective and preventative actions implemented in response to the Warning Letter observations. That follow-up inspection was concluded on June 10, 2005 with no observations.

On July 15, 2005, FDA approved VNS Therapy as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression in a major depressive episode and have not responded to at least four adequate antidepressant treatments.

We will be required to obtain FDA approval of a new premarket application or premarket application supplement before making any change to the VNS Therapy System affecting the safety or effectiveness of the device including, but not limited to, new indications for use of the device, changes in the device's performance or design specifications and device modifications and future generation products. New premarket applications and premarket application supplements generally require submission of information needed to support the proposed change and may require additional clinical data. If clinical data are required for a new indication, FDA can additionally require review of the results of a clinical study by one of their advisory panels. If the clinical testing required to obtain the information necessary to support the change places research subjects at

risk, we could be required to obtain FDA's approval of an investigational device exemption, or IDE, before beginning such testing. We intend to sponsor additional clinical trials of the VNS Therapy System in the U.S. for non-epilepsy central nervous system disorders. We believe that we will be required to conduct these additional clinical trials under one or more FDA-approved IDEs and under the auspices of one or more independent institutional review boards, also referred to as IRBs, established pursuant to FDA regulations. We may be unable to obtain any required FDA or IRB approvals for such clinical trials or to complete the studies in a timely manner. Further, the information obtained may not be sufficient to support the filing or approval of a new premarket application or premarket application supplement for the proposed changes. Any of these events would prevent us from obtaining approvals to market our product for the indications, which could harm our business.

We are required to register, and have registered, as a medical device manufacturer with FDA and state agencies and to list our products with FDA. Our facilities are subject to inspection on a routine basis by FDA for compliance with FDA's QSR and other applicable regulations. The QSR imposes procedural and documentation requirements upon us with respect to product designs, manufacturing, testing, control, process validation and similar activities.

Regulations governing post-market surveillance also apply to the VNS Therapy System. FDA also actively enforces regulations prohibiting marketing of products for non-indicated uses. The advertising of most FDA-regulated products, including the VNS Therapy System, is also subject to Federal Trade Commission jurisdiction and we are also subject to the Occupational Safety and Health Administration and other governmental entities.

Healthcare regulations implementing the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (the "HIPAA Privacy Rule") became effective in April 2003. Under the HIPAA privacy rule, the privacy of all medical records, billing records and other health information must be protected. Our proprietary patient identification and pull-through sales and marketing model relies on direct contact with patients to verify their insurance and provide education on VNS Therapy. Although we conduct our business as a HIPAA "covered entity" affording maximum protection to patients' protected health information, some institutions and physicians may choose to limit direct access to patient information and their patients, which could negatively impact awareness and acceptance of VNS Therapy among patients and physicians.

Clinical testing, manufacturing and sale of our products outside of the U.S. are subject to regulatory approval by other jurisdictions which may be more or less rigorous than in the U.S., and which vary from country to country. In order to market and sell our product in the European community, we must comply with the medical device directives. We are audited on a voluntary basis for compliance with these directives. We have obtained several foreign governmental approvals, including the approval to use the European Union CE Mark for epilepsy and depression, and have applied for additional approvals. However, we may not be granted the necessary approvals, including approval of new premarket applications or supplements to existing premarket applications for the VNS Therapy System, on a timely basis or at all. Delays in receipt of or failure to receive these approvals, or the withdrawal of previously received approvals, could harm our international operations and our business.

Changes in existing requirements or the adoption of new requirements could significantly harm our ability to comply with regulatory requirements. Failure to comply with applicable regulatory requirements can result in, among other things, fines, suspensions or withdrawal of approvals, confiscations or recalls of products, operating restrictions and criminal prosecutions.

Product Liability and Insurance

The manufacture and sale of our products subjects us to the risk of product liability claims. We are currently named as a defendant in several product liability lawsuits alleging claims of negligence, strict liability, breach of warranty, negligent misrepresentation, failure to warn, wrongful death and other claims. We do not believe that the VNS Therapy System is defective or otherwise caused injury to the patients involved in these lawsuits, and we are vigorously defending these lawsuits; however, the outcome of litigation is inherently

unpredictable and could result in an adverse judgment and an award of substantial and material damages against us. The Company's product liability insurer has acknowledged coverage without reservation in all ongoing lawsuits. The Company establishes a liability reserve on its balance sheet in an amount within the unpaid deductible for all matters that the Company believes are probable of payment. The Company does not expect that the amount of any judgment that may be rendered in any pending lawsuit will exceed the limits of the Company's product liability insurance coverage. Although we maintain product liability insurance in amounts that we believe to be reasonable, coverage limits may not prove to be adequate in all circumstances. Product liability insurance is expensive and in the future may be available only at significantly higher premiums or not be available on acceptable terms, if at all. A successful claim brought against us in excess of our insurance coverage could severely harm our business and consolidated results of operations and financial condition.

Employees

As of May 20, 2005, we had approximately 660 full-time employees. We believe that the success of our business depends, in part, on our ability to attract and retain qualified personnel. We believe our relationship with our employees is good. However, we cannot assure you that we will be successful in hiring or retaining qualified personnel. The loss of key personnel, or the inability to hire or retain qualified personnel, could significantly harm our business.

Financial Information

Our financial information is described in the consolidated financial statements and footnotes attached hereto beginning on page F-1.

Executive Officers of Cyberonics

Robert P. Cummins, age 51, became a director of Cyberonics in June 1988. He was appointed President and Chief Executive Officer of Cyberonics in September 1995. He was appointed Chairman of the Board of Cyberonics in June 2001. Until September 1995, Mr. Cummins was also a general partner of Vista Partners, L.P., a venture capital partnership which he joined in 1984, a general partner of Vista III Partners, L.P., a venture capital firm formed in 1986 and Vice President of Vista Ventures Inc., a venture capital advisory firm. Until July 1998, Mr. Cummins was also a director of Sigma Circuits Inc., a manufacturer of electronic interconnect products.

Pamela B. Westbrook, age 47, joined Cyberonics as Vice President, Finance and Administration and Chief Financial Officer in October 1998. Ms. Westbrook has over 20 years in financial management experience and over 18 years in medical device industry experience. From April 1998 to October 1998, she served as Chief Financial Officer for Physicians Resource Group, an ophthalmic physician practice management company. Prior to that, from November 1986 to March 1998, Ms. Westbrook was employed by Sulzer Medica, a leading manufacturer of implantable medical devices including pacemakers, heart valves and orthopedic implants. During her employment with Sulzer Medica, Ms. Westbrook was Vice President, Finance for Sulzer Medica, and Vice President, Controller for Sulzer Cardiovascular Prosthesis Division.

Michael A. Cheney, age 51, joined Cyberonics in July 2001 as Vice President of Marketing and Managing Director of the Depression Business Unit. Mr. Cheney has more than 18 years of pharmaceutical marketing and product launch experience. Prior to joining Cyberonics, Mr. Cheney was Senior Director, Obesity Business Unit at Knoll Pharmaceutical Company (recently acquired by Abbott Laboratories) from 1997 to 2001, where he was responsible for the launch of Meridia® (sibutramine hydrochloride), a leading anti-obesity drug. Prior to that, Mr. Cheney was Group Director, Central Nervous System Therapeutics Marketing at Wyeth-Ayerst Laboratories, a subsidiary of American Home Products, where he was responsible for the marketing of Effexor® (venlafaxine hydrochloride) and the launch of Effexor® XR, a leading brand of medication for the treatment of depression.

W. Steven Jennings, age 53, joined Cyberonics in May 2003 as Vice President, Sales. Mr. Jennings has more than 25 years of pharmaceutical sales and marketing experience, including over 15 years of sales

management experience at Solvay Pharmaceuticals from 1993 to 2003, CIBA GEIGY and Reed & Carnrick Pharmaceuticals. Prior to joining Cyberonics, Mr. Jennings was Global Vice President, Gastrointestinal and Women's Health at Solvay where he was responsible for worldwide sales and marketing for the two largest of Solvay's four pharmaceutical divisions. During his 10-year career at Solvay, he held positions in product management, regional and U.S. national sales management and Business Director for Solvay's Mental Health and Cardiovascular business.

Shawn P. Lunney, age 41, joined Cyberonics in April 1991 and served in various sales, marketing and reimbursement planning positions until May 1996, when he became Vice President, Marketing. He is currently serving as Vice President of Market Development and Engineering. Prior to joining Cyberonics, Mr. Lunney held the position of Sales and Marketing Manager with Perceptive Systems, Inc., a hospital laboratory medical instrument manufacturer from December 1985 to April 1991.

George Parker, age 42, joined Cyberonics in July 2003 as Vice President of Human Resources. Prior to joining Cyberonics, he was Vice President, Human Resources at PerkinElmer Instruments from 1999 to 2002. Mr. Parker has 20 years of human resource management and consulting experience and has worked in a number of industries including medical equipment and pharmaceuticals with experience in building and developing people and organizations to support rapidly growing products and markets in both the U.S. and Europe.

Richard L. Rudolph, M.D., age 56, joined Cyberonics in August 2001 as Vice President, Clinical and Medical Affairs and Chief Medical Officer. He has 20 years of pharmaceutical and medical device research and management experience in the neuroscience area. He has authored and co-authored numerous publications. Prior to joining Cyberonics, Dr. Rudolph was Senior Director, Clinical Research and Development at Wyeth-Ayerst Research. During his 16-year career at Wyeth-Ayerst, Dr. Rudolph was responsible for numerous clinical studies and research on Effexor® (venlafaxine hydrochloride) and Effexor® XR, a leading brand of medication for the treatment of patients with depression and generalized anxiety disorder.

Randal L. Simpson, age 45, joined Cyberonics in 1998 and has served in various manufacturing management positions until October 2003 when he became Vice President, Operations. Prior to that, he served in the positions of Director, Manufacturing, Director, Materials and Sr. Director of Operations for Cyberonics. Prior to his joining Cyberonics, Mr. Simpson was employed by Intermedics, as Manager of Manufacturing. Mr. Simpson has over 20 years of manufacturing experience with over 14 years of experience in the medical device industry.

Alan D. Totah, age 61, joined Cyberonics as Vice President, Regulatory Affairs in February 2001. Mr. Totah was certified as a Regulatory Affairs Professional in October 1991 and has over 31 years of medical industry regulatory affairs, quality control and quality assurance management experience including 20 years in cardiac rhythm management and regulatory affairs management at Medtronic and Sulzer Intermedics. Prior to joining Cyberonics, Mr. Totah was Senior Regulatory Manager, Heart Failure and Low Power Leads at Medtronic, Inc. from 1999 to 2001. Prior to that, he spent 18 years at Sulzer Intermedics, most recently as Director, Regulatory Affairs.

David S. Wise, age 50, joined Cyberonics in September 2003, as Vice President and General Counsel. He was appointed Secretary of Cyberonics in November 2003. He has over 20 years of experience in intellectual property, business development and legal affairs in private practice and in corporate practice in the medical device industry. Prior to joining Cyberonics, he was Group Vice President and General Counsel at Centerpulse USA, Inc. (formerly Sulzer Medica), a medical technology company specializing in orthopedic products recently acquired by Zimmer Holdings, Inc. from 1994 to 2003. Prior to Centerpulse, he spent 12 years in private practice focused on intellectual property and commercial litigation.

Internet Website and Availability of Public Filings

Our internet address is *www.cyberonics.com*. We make available free of charge on or through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange

Act of 1934 as soon as reasonably practicable after electronically filing such material with, or furnishing it to the Securities and Exchange Commission (SEC). Also available on our website are our corporate governance guidelines, corporate code of business conduct and ethics, financial code of ethics, and charters for each standing committee of our Board of Directors.

Item 2. ***Properties***

We have agreed to lease approximately 130,455 square feet of office and manufacturing space in Houston, Texas through December 2009. We have also agreed to lease approximately 10,835 square feet in a sales office in Brussels, Belgium through April 2010. Both leased properties have been expanded to accommodate expected growth in our domestic and international business.

Item 3. ***Legal Proceedings***

We are named as a defendant in lawsuits from time to time arising in the ordinary course of business. While the outcome of such lawsuits or other proceedings against us cannot be predicted with certainty, management does not expect the outcome of these matters to have a material adverse effect on our consolidated financial position or results of operations.

We received a letter from the Senate Finance Committee (SFC) advising us that it is examining FDA's handling of our PMA-Supplement for the use of VNS Therapy to address treatment-resistant depression. The SFC's letter requested that we provide the SFC with certain documents and information. Responding to this request and any further requests by the SFC could divert the efforts and attention of our management team. We are unable to provide assurance as to the time it will take for the SFC to complete its review or of such review's ultimate consequence, if any.

On June 17, 2005, a putative class action lawsuit was filed against the Company and certain of its current officers in the United States District Court for the Southern District of Texas. The lawsuit is styled *Richard Darquea v. Cyberonics Inc., et al.*, Civil Action No. H:05-cv-02121. A second lawsuit with similar allegations, styled *Stanley Sved v. Cyberonics, Inc., et al.*, Civil Action No. H:05-cv-2414 was filed on July 12, 2005. The complaints generally allege, among other things, that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements relating to the Company's Vagus Nerve Stimulation Therapy System device (the "VNS Device"). Specifically, the plaintiffs allege that the defendants failed to disclose that the U.S. Food and Drug Administration (the "FDA") had "safety and efficacy concerns" about the use of the VNS Device for the treatment of depression and that the defendants failed to disclose the existence of certain "manufacturing and quality practices," as detailed in the FDA's December 22, 2004 Warning Letter, that negatively impacted the Company's prospects for obtaining FDA approval to use the VNS Device to treat depression. Plaintiffs seek to represent a class of all persons and entities, except those named as defendants, who purchased or otherwise acquired Company securities during the period June 15, 2004 through October 1, 2004. The complainants seek unspecified monetary damages and equitable or injunctive relief, if available. We intend to vigorously defend against these lawsuits and any related lawsuits that may be filed; however, an adverse result in these lawsuits, or related lawsuits, could have a material adverse effect on us, our financial condition, results of operations and cash flows.

Item 4. ***Submission of Matters to a Vote of Security Holders***

In a special shareholders meeting on May 19, 2005, Cyberonics' shareholders approved a stock option plan to provide up to one million shares for issuance of restricted stock or options to purchase common stock to qualified employees and board members at fair market value on the date of grant or issuance. The table below sets out the number of votes cast for, against or withheld, as well as the number of abstentions and broken non-votes.

Number of votes for	12,508,898
Number of votes against	4,337,221
Number of votes abstaining	16,508

16,862,627 proxies were tabulated representing 68% of outstanding shares.

PART II

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

Our common stock is quoted on the NASDAQ National Market under the symbol "CYBX." The high and low sale prices for our common stock during fiscal years 2004 and 2005 are set forth below. Price data reflect actual transactions, but do not reflect mark-ups, mark-downs or commissions.

	High	Low
Fiscal Year Ended April 30, 2004		
First Quarter	$28.35	$18.57
Second Quarter	34.97	26.00
Third Quarter	38.74	26.19
Fourth Quarter	34.10	20.65
Fiscal Year Ended April 29, 2005		
First Quarter	$40.07	$16.78
Second Quarter	28.69	12.78
Third Quarter	26.24	18.10
Fourth Quarter	46.71	24.20

The stock market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Like the stock prices of other medical device companies, the market price of our common stock has in the past been, and may in the future be, subject to significant volatility. Factors such as reports on the clinical efficacy and safety of the VNS Therapy System for existing and new indications, fluctuations in our sales and operating results, product and component supply issues, government approval status, announcements of technological innovations or new products by our competitors, changes in estimates of our performance by securities analysts, failure to meet securities analysts' expectations, developments with respect to patents or proprietary rights, public concern as to the safety of products developed by us or others may have a significant effect on the market price of the common stock. In addition, the price of our stock could be affected by stock price volatility in the medical device industry or the capital markets in general without regard to our operating performance.

As of May 20, 2005, according to data provided by our transfer agent, there were 349 stockholders of record.

We currently intend to retain future earnings to fund the development and growth of our business and, therefore, do not anticipate paying cash dividends within the foreseeable future. Any future payment of dividends will be determined by our Board of Directors and will depend on our consolidated financial condition and results of operations and other factors deemed relevant by our Board of Directors.

Please refer to Item 12 of this Annual Report concerning securities authorized under our Equity Compensation Plans.

Item 6. *Selected Financial Data*

The following table summarizes certain selected financial data and is qualified by reference to, and should be read in conjunction with the Consolidated Financial Statements and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere herein. The selected financial data for the 52 weeks ended April 25, 2003, the 53 weeks ended April 30, 2004 and the 52 weeks ended April 29, 2005 is derived from consolidated financial statements that are included elsewhere herein. The selected financial data for the 52 weeks ended April 25, 2003, for the 53 weeks ended April 30, 2004, and for the 52 weeks ended April 29, 2005 has been audited by KPMG LLP, an independent registered public accounting firm. The selected financial data for the 52 weeks ended April 27, 2001 was not audited due to a change in our fiscal year in April 2001, and is presented here for comparison purposes only. The selected financial data for the 10 months ended April 27, 2001 and the year ended April 26, 2002 are derived from audited consolidated financial statements not included herein.

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended			10 Months Ended April 27, 2001
			April 25, 2003	April 26, 2002	April 27, 2001 (Unaudited)	
Consolidated Statement of Operations Data:						
Net sales	$ 103,442,570	$ 110,721,499	$ 104,466,998	$ 70,111,293	$ 53,567,994	$ 43,418,736
Cost of sales	15,575,741	16,295,562	16,066,229	13,616,374	14,338,769	11,806,353
Gross profit	87,866,829	94,425,937	88,400,769	56,494,919	39,229,225	31,612,383
Operating expenses:						
Selling, general and administrative	81,430,943	70,597,149	65,842,238	59,190,554	39,826,652	33,571,072
Research and development	19,341,075	17,133,709	17,874,909	24,516,547	19,414,819	17,201,179
Non-recurring charges	—	—	—	—	6,467,415	6,467,415
Total operating expenses	100,772,018	87,730,858	83,717,147	83,707,101	65,708,886	57,239,666
Earnings (loss) from operations	(12,905,189)	6,695,079	4,683,622	(27,212,182)	(26,479,661)	(25,627,283)
Interest income	1,072,488	469,924	471,213	1,264,853	1,428,845	1,141,939
Interest expense	(444,270)	(565,702)	(413,192)	(266,270)	(68,868)	(65,331)
Other income (expense), net	84,736	390,997	572,851	93,694	(37,544)	(147,058)
Earnings (loss) before income taxes	(12,192,235)	6,990,298	5,314,494	(26,119,905)	(25,157,228)	(24,697,733)
Income tax expense	26,113	230,789	129,563	—	—	—
Net earnings (loss)	$ (12,218,348)	$ 6,759,509	$ 5,184,931	$ (26,119,905)	$ (25,157,228)	$ (24,697,733)
Basic earnings (loss) per share	$ (0.51)	$ 0.29	$ 0.24	$ (1.21)	$ (1.31)	$ (1.27)
Diluted earnings (loss) per share	$ (0.51)	$ 0.26	$ 0.22	$ (1.21)	$ (1.31)	$ (1.27)
Shares used in computing basic earnings (loss) per share	24,036,736	22,921,031	22,034,651	21,655,009	19,247,253	19,382,460
Shares used in computing diluted earnings (loss) per share	24,036,736	26,053,330	23,173,324	21,655,009	19,247,253	19,382,460
Consolidated Balance Sheet Data (as of Year End):						
Cash, cash equivalents and marketable securities	$ 61,475,892	$ 58,363,731	$ 43,576,305	$ 38,195,962	$ 57,250,907	$ 57,250,907
Total assets	98,855,397	94,296,524	75,115,312	64,451,679	78,452,639	78,452,639
Line of credit	3,000,000	10,031,000	8,370,000	6,500,000	—	—
Long-term obligations	209,928	—	141,066	274,969	396,964	396,964
Accumulated deficit	(130,024,056)	(117,805,708)	(124,565,217)	(129,750,148)	(103,630,243)	(103,630,243)
Common stockholders' equity	75,595,841	68,980,479	48,512,003	36,613,813	59,647,084	59,647,084

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

You should read the following discussion and analysis together with "Selected Financial Data" and our Consolidated Financial Statements and the related Notes as of April 29, 2005, April 30, 2004 and April 25, 2003 which are contained elsewhere in the Annual Report on Form 10-K. This discussion contains forward-looking statements based on our current expectations, assumptions, estimates and projections about our industry and us. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, as more fully described under the heading "Factors Affecting Future Operating Results" and in the "Business" section and elsewhere in this Annual Report on Form 10-K. We undertake no obligation to update publicly any forward-looking statements, even if new information becomes available or other events occur in the future.

Management's Discussion and Analysis provides material historical and prospective disclosures enabling investors and other users to assess our financial condition and results of operations. The Consolidated Financial Statements, excluding the related notes, include the statements of consolidated operations, consolidated balance sheets, statements of consolidated shareholders' equity and comprehensive income (loss) and statements of consolidated cash flows. The notes are an integral part of the Consolidated Financial Statements and provide additional information required to fully understand the nature of amounts included in the consolidated financial statements.

Business Overview

We are a neuromodulation company founded to design, develop and bring to market medical devices which provide a unique therapy, VNS, for the treatment of epilepsy, treatment-resistant depression and other debilitating neurological, psychiatric diseases and other disorders. VNS Therapy is currently approved for use as an adjunctive therapy in reducing the frequency of seizures in patients with partial onset seizures that are refractory or resistant to antiepileptic drugs and as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression in a major depressive episode that has not responded to at least four adequate antidepressant treatments. Product sales to date have been primarily from sales in the epilepsy market.

On July 15, 2005 FDA approved VNS Therapy as a long-term adjunctive treatment for patients 18 years of age or older with chronic or recurrent treatment-resistant depression. Since February 2005, we have been preparing our organization for approval and launch in depression and we have recently expanded our organization from approximately 500 to 660 personnel, primarily in the areas of sales, case management, clinical engineering and surgical support staff, to create the organizational capacity necessary to support anticipated market demand for VNS Therapy in the epilepsy and depression markets. While we anticipate significant increases in revenues in fiscal 2006 related to sales of VNS Therapy in the U.S. for TRD, and we believe that we have created adequate organizational capacity to support our expanded business requirements, the scale-up of our organization is substantial. We expect quarterly operating expenses to increase significantly and in advance of anticipated increases in quarterly revenues. Furthermore, our expectations for market acceptance in a completely new device market for TRD will likely change as we complete our product launch in TRD and promote awareness and acceptance of VNS Therapy among new psychiatric prescribers. Accordingly, while we expect to achieve revenue growth as a result of this approval, we can provide no assurance as to the size or timing of such growth, particularly, because FDA's approval was so recently received.

Since inception, we have incurred substantial expenses, primarily for research and development activities that include product and process development and clinical trials and related regulatory activities, sales and marketing activities, manufacturing start-up costs and systems infrastructure. We have also made significant investments in recent periods in connection with sales and marketing activities in the U.S. and clinical research costs associated with new indications development, most notably depression. For the period from inception through April 29, 2005, we incurred a cumulative net deficit of approximately $130 million. We anticipate significant investments in sales and marketing expenses associated with a planned product launch and start-up in depression as well as increasing investments in post-approval and pre-approval clinical studies

in epilepsy, depression and other new indications. Excluding epilepsy and depression studies, clinical studies are for investigational therapies subject to FDA approval.

The primary exchange rate movements that impact our consolidated net sales growth include the U.S. dollar as compared to the Euro. The weakening of the U.S. dollar in fiscal 2005 generally has a favorable impact on our sales for the year. The impact of foreign currency fluctuations on net sales is not indicative of the impact on net earnings due to the offsetting foreign currency impact on operating costs and expenses.

Critical Accounting Policies

We have adopted various accounting policies to prepare the Consolidated Financial Statements in accordance with accounting principles generally accepted in the United States of America (U.S.). Our most significant accounting policies are disclosed in Note 1 to the Consolidated Financial Statements.

The preparation of the Consolidated Financial Statements, in conformity with accounting principles generally accepted in the U.S., requires us to make estimates and assumptions that affect the amounts reported in the Consolidated Financial Statements and accompanying notes. Our estimates and assumptions are updated as appropriate, which in most cases is at least quarterly. We base our estimates on historical experience or various assumptions that are believed to be reasonable under the circumstances, and the results form the basis for making judgments about the reported values of assets, liabilities, revenues and expenses. Actual results may materially differ from these estimates.

We consider the following accounting policies as the most critical because, in management's view, they are most important to the portrayal of our consolidated financial condition and results and most demanding in terms of requiring estimates and other exercises of judgment.

Accounts Receivable. We provide an allowance for doubtful accounts based upon specific customer risks and a general provision based upon historical trends. An increase in losses beyond that expected by management or that historically have been experienced by us would reduce earnings when they become known.

Inventories. We state our inventories at the lower of cost, first-in, first-out (FIFO) method, or market. Cost includes the acquisition cost of raw materials and components, direct labor and overhead. Management considers potential obsolescence at each balance sheet date. An acceleration of obsolescence could occur if consumer demand should differ from expectations.

Property and Equipment. Property and equipment are carried at cost, less accumulated depreciation. Maintenance, repairs and minor replacements are charged to expense as incurred; significant renewals, improvements and expansions are capitalized. For financial reporting purposes, we compute depreciation using the straight-line method over useful lives ranging from two to nine years. An unanticipated change in the utilization or expected useful life of property and equipment could result in acceleration in the timing of the expenses.

Revenue Recognition. We sell our products through a combination of a direct sales force in the U.S. and certain European countries and through distributors elsewhere. Cyberonics recognizes revenue when title to the goods and risk of loss transfer to customers, providing there are no remaining performance obligations required of Cyberonics or any matters requiring customer acceptance. We record estimated sales returns and discounts as a reduction of net sales in the same period revenue is recognized. Our revenues are dependent upon sales to new and existing customers pursuant to our current policies. Changes in these policies or sales terms could impact the amount and timing of revenue recognized.

Research and Development. All research and development costs are expensed as incurred. We have entered into contractual obligations for the conduct of clinical studies. Costs are incurred primarily at the time of enrollment and paid under the terms of the contracts. Research and development expenses could vary significantly with changes in the timing of clinical activity.

Stock Options. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standard Board (SFAS) No. 123, *"Accounting for Stock-Based Compensation"* and SFAS No. 148,

"Accounting for Stock-Based Compensation — Transition and Disclosure," which disclosures are presented in Note 1, *"Summary of Significant Accounting Policies and Related Data — Stock Options."* Because of this election, we continue to account for our employee stock-based compensation plans under Accounting Principles Board (APB) Opinion No. 25 and the related interpretations. We are required to comply with SFAS No. 123 (revised 2004) starting on the first day of our fiscal year 2007 or April 29, 2006. We are currently evaluating the effect that the adoption of SFAS No. 123 (revised 2004) will have on Cyberonics' consolidated operating results and financial condition. No stock-based compensation cost is currently reflected in net income for employee option grants as most options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. There is only one exception further disclosed under Note 6 of our Consolidated Financial Statements, whereby deferred compensation is recorded for certain stock-based compensation grants based on the excess of the market value of the common stock on the measurement date over the exercise price. The deferred compensation is amortized over the vesting period of each unit of stock-based compensation.

Income Taxes. We account for income taxes under the asset and liability method. Under this method, deferred income taxes reflect the impact of temporary differences between financial accounting and tax bases of assets and liabilities. Such differences relate primarily to the deductibility of certain accruals and reserves and the effect of tax loss and tax credit carryforwards not yet utilized. Deferred tax assets are evaluated for realization based on a more-likely-than-not criterion in determining if a valuation allowance should be provided.

Results of Operations

Net Sales

U.S. net sales decreased by 10% in fiscal year 2005 compared to fiscal year 2004, primarily due to a 16% volume decrease caused by reductions in both replacement and new patient sales, partially offset by an increase of 7% in average selling price due to new product introductions and changes in product mix. International net sales increased by 25% in fiscal year 2005 due to increases in unit sales of 16% and increases in average selling prices of 8%. The increases in international average selling prices are primarily due to the favorable impact of foreign currency exchange and changes in product and country mix.

U.S. net sales increased by 5% in fiscal year 2004 compared to fiscal year 2003, primarily due to an increase of 5% in average system price resulting from new product introductions and changes in product mix. International net sales increased by 21% in fiscal year 2004 due to increases in sales volume and average system price. Sales volume increased by approximately 6% due to increasing demand in Europe. Average system price increased 16% primarily due to the favorable impact of foreign currency and changes in product and country mix.

Gross Profit

Gross profit decreased by 7% in fiscal 2005 compared to fiscal year 2004, primarily due to lower sales volumes. Gross profit margin decreased by 34 basis points to 84.9% due to operational inefficiencies relating to ramp up activities conducted during the first quarter of the fiscal year that negatively impacted gross profit margin by approximately 210 basis points which were offset by improvements in average selling prices and favorable manufacturing variances throughout the remainder of the year which had a favorable impact of approximately 176 basis points.

Gross profit increased by 6.8% in fiscal 2004 compared to fiscal year 2003, due to improved sales volumes. Gross profit margin increased by 70 basis points to 85.3% as a result of sales growth and increases in average selling price which had a favorable impact of 150 basis points and was offset by manufacturing inefficiencies relating to ramp up activities conducted during the last quarter of the fiscal year 2004 that negatively impacted gross profit margin by approximately 80 basis points.

Cost of sales consists primarily of direct labor, allocated manufacturing overhead, third-party contractor costs, royalties and the acquisition cost of raw materials and components. Gross margins can be expected to

fluctuate in future periods based upon the mix between U.S. and international sales, direct and distributor sales, the VNS Therapy System selling price, applicable royalty rates and the levels of production volume.

Operating Expenses

Selling, General and Administrative (SG&A) Expenses. SG&A expenses are comprised of sales, marketing, development, general and administrative activities. SG&A expenses increased by 15% in fiscal year 2005 compared to fiscal year 2004 due to additional expenses associated with preparing the organization for a potential U.S. approval and launch in depression. SG&A expenses increased by 7% in fiscal year 2004 compared to fiscal year 2003 due to increased expenses associated with market shaping initiatives supporting depression development activities, international operations and expanded corporate administrative functions.

Research and Development (R&D) Expenses. R&D expenses are comprised of expenses related to our product and process development, product design efforts, clinical trials programs and regulatory activities. R&D expenses increased by 13% in fiscal year 2005 compared to fiscal year 2004 due to additional product development programs and expanded regulatory activities. R&D expenses decreased by 4.1% in fiscal year 2004 due to reduced spending in new indications development, primarily in the depression pivotal study costs which were lower in fiscal year 2004, as clinical program costs progressed into the long-term, lower-cost phase of the D-02 study.

Interest Income

Interest income of $1,072,000 during fiscal year 2005 increased by 128% as compared to interest income of $470,000 for fiscal year 2004, due to higher level of investments and higher interest rates. Interest income for fiscal year 2004 was comparable to fiscal year 2003 despite greater cash balances in fiscal year 2004 as a result of lower interest rates.

Interest Expense

Interest expense of $444,000 for fiscal year 2005 decreased primarily due to lower borrowings against the line of credit facility, lower interest rates negotiated during the renewal of the line of credit during the fiscal year. Interest expense of $566,000 in fiscal 2004 increased primarily due to the expanded use of the line of credit. The credit facility was increased from $10 million to $25 million in April 2003, and decreased to $20 million in August of 2004. The original line of credit facility earned interest at the designated bank rate plus 1.5% on the greater of $3 million or the average of net balance owed by us at the close of each day during the month. Under the latest amendment, borrowings against the line of credit facility earn the Chase Bank rate on the greater of $3 million or the average of the net balance owed by us at the close of each day during the month.

Other Income, Net

Other income, net, primarily includes transaction gains and losses associated with the impact of changes in foreign currency exchange rates.

Income Taxes

At April 29, 2005, we had net operating loss carryforwards for federal income tax purposes of approximately $154.0 million. The following is a reconciliation of statutory federal income tax rates to our effective income tax rate expressed as a percentage of income from operations before income taxes:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Provision for Income Taxes	$26,113	$230,789	$129,563
U.S. statutory rate	(34.0)%	34.0%	34.0%
Change in deferred tax valuation allowance	31.8	(34.0)	(29.5)
Foreign taxes	0.2	0.3	0.0
State & local tax provision	0.0	2.3	1.7
Other, net	2.2	0.7	(3.7)
	0.2%	3.3%	2.5%

Liquidity and Capital Resources

Key performance indicators used by management to assess our liquidity are as follows:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Cash, Cash Equivalents and Short-Term Marketable Securities	$61,475,892	$58,363,731	$43,576,305
Line of Credit	3,000,000	10,031,000	8,370,000
Net Cash Provided by (Used in) Operating Activities	(3,969,672)	3,595,349	1,275,666
Net Cash Provided by Financing Activities	10,851,738	14,496,645	8,220,710

During fiscal year 2005, cash, cash equivalents and short-term marketable securities increased by $3,112,000 to $61,476,000. Cash generated from stock option and employee stock purchase plans continues to provide a major source of funds and was the primary driver of the increase in cash for the year. We received approximately $18,024,000 in connection with the issuance of shares pursuant to these plans in fiscal year 2005. Borrowings against the line of credit were reduced by approximately $7,000,000 to $3,000,000. Net cash used in operating activities in fiscal 2005 was $3,970,000 as compared to net cash provided by operating activities of $3,595,000 in fiscal 2004. Operational cash flow decreased by approximately $7,565,000 due to net loss in fiscal 2005 of approximately $12,218,000.

During fiscal year 2004, cash, cash equivalents and short-term marketable securities increased by $14,787,000 to $58,364,000. Cash generated from stock option and employee stock purchase plans provided a major source of funds and was the primary driver of the increase in cash for the year. We received approximately $12,968,000 in connection with the issuance of shares pursuant to these plans in fiscal year 2004. Borrowings against the line of credit were increased by $1,661,000 to $10,031,000. Net cash provided by operating activities in fiscal 2004 was $3,595,000, as compared to net cash provided by operating activities in fiscal 2003 of $1,276,000, as operational cash flow increased by $2,320,000 largely due to net income in fiscal 2004 of approximately $6,760,000.

During fiscal year 2003, cash on hand increased by $5,380,000 to $43,576,000. Cash generated from stock option and employee stock purchase plans provided approximately $6,476,000 in connection with the issuance of shares pursuant to these plans in fiscal year 2003 and was a primary source of funds. Borrowings against the line of credit were increased by approximately $1,870,000 to $8,370,000. Net cash provided by operating

activities in fiscal 2003 was approximately $1,276,000. Cash proceeds during the period were primarily used to fund working capital and capital expenditures.

We are party to a number of contracts pursuant to which we are paying for clinical studies for current operating obligations payable totaling $1.1 million as of April 29, 2005. Although we have no firm commitments, we expect to make capital expenditures of approximately $11.7 million during fiscal year 2006, primarily to expand organizational capacity and to enhance business infrastructure and facilities.

The chart below reflects our current obligations under our material contractual obligations.

	Line of Credit	Operating Leases	Other	Total Contractual Obligations
Contractual obligations:				
Less Than One Year	$3,000,000	$ 2,799,448	$550,730	$ 6,350,178
1-3 Years	—	5,599,739	—	5,599,739
3-5 Years	—	4,497,734	—	4,497,734
Over 5 Years	—	366	—	366
Total Contractual Obligations	$3,000,000	$12,897,287	$550,730	$16,448,017

We believe our current financial and capital resources will be adequate to fund anticipated business activities throughout fiscal 2006, although there can be no assurance of this as this estimate is based upon a number of assumptions, which may not hold true. Our current projections of the future TRD market for VNS Therapy are not yet proven and will be significantly impacted by the timing of FDA's decision for VNS treatment in TRD and our planned depression launch activities in fiscal 2006. Unanticipated delays in FDA's approval decision may materially change our current revenue and expense projections and negatively impact our liquidity. We would consider additional financing which would provide funding for expanded market development programs and new clinical development studies to advance existing and new indications for VNS Therapy as well as leverage our core competencies to exploit non-VNS neuromodulation opportunities through strategic partnerships. Furthermore, our liquidity could be adversely affected by the "Factors Affecting Future Operating Results" discussed below.

Factors Affecting Future Operating Results and Common Stock Price

In addition to the factors described above in this section and in the section of this Annual Report on Form 10-K entitled "Business," the following additional factors could affect our future results and, as a result, our common stock price.

Our common stock price constantly changes. Our common stock is traded on the NASDAQ National Market under the ticker symbol "CYBX." The price of stock on that trading market fluctuates, and we expect that the market price of common stock will continue to fluctuate. For instance, during the fiscal year ended April 29, 2005, our stock has traded from a high of $46.71 to a low of $12.78 per share. The fluctuation in our stock price is caused by a number of factors, some of which are beyond our control, including:

- quarterly variations in our sales and operating results;
- regulatory activities and announcements;
- results of studies regarding the efficacy of our VNS Therapy treatment for other indications including depression, Alzheimer's Disease, anxiety and other disorders;
- announcements of significant contracts, acquisitions, or capital commitments;
- changes in financial estimates by securities analysts;
- changes in market valuations of medical device companies;
- additions or departures of key personnel;

- sales or purchases of common stock by us, our officers and members of our Board of Directors; and
- changes in the general conditions of the economy.

In addition, the stock market in recent years has experienced broad price and volume fluctuations that have often been unrelated to the operating performance of companies. These broad market fluctuations have also adversely affected, and may continue to adversely affect, the market price of our common stock.

Our quarterly operating results may fluctuate in the future, which may cause our stock price to decline. Our consolidated results of operations may fluctuate significantly from quarter to quarter and may be below the expectations of security analysts. If so, the market price of our shares may decline. Our quarterly revenues, expenses and operating results may vary significantly from quarter to quarter for several reasons, including the extent to which the VNS Therapy System gains market acceptance, the timing of obtaining marketing approvals for the VNS Therapy System for other indications, the timing of any approvals for reimbursement by third-party payers, the rate and size of expenditures incurred as we expand our clinical, manufacturing, sales and marketing efforts, our ability to retain qualified sales personnel and the availability of key components, materials and contract services, which may depend on our ability to forecast sales.

We rely solely on sales of VNS Therapy Systems for our revenues and if sales of these Systems are not achieved, our operating results will be severely harmed. Our product portfolio is limited to VNS Therapy Systems for two indications: as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures that are refractory to antiepileptic drugs and as a long-term adjunctive treatment of chronic or recurrent depression for patients 18 years or older who are experiencing a major depressive episode and have not had an adequate response to four or more antidepressant treatments. Moreover, we cannot assure you that sales of the VNS Therapy System for the treatment of epilepsy will increase. We do not yet have the approvals for reimbursement of the VNS Therapy System for the treatment of depression in the U.S. We cannot assure you that we will receive such reimbursement approvals or otherwise be successful in commercializing the VNS Therapy System for the treatment of depression. The same uncertainty surrounds our efforts in anxiety disorders, Alzheimer's Disease applications and other indications for which we currently do not have FDA approvals. Our inability to successfully commercialize the VNS Therapy System for depression and other indications will severely harm our future growth.

We may experience difficulties and delays inherent in the development, manufacturing, marketing and sale of our VNS Therapy System for the treatment of depression. We are subject to extensive and rigorous ongoing regulation of the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our product. Our failure to comply with these requirements or the identification of manufacturing or safety problems during commercial marketing could lead to the need for product marketing restrictions, product withdrawal or recall or other voluntary or regulatory action, which could delay further marketing until the product is brought into compliance. Our failure to comply with these requirements may also subject us to stringent penalties.

We may need significant additional capital. Our capital requirements may be substantial and will depend on many factors, including market acceptance of our product and clinical and strategic development opportunities. A large portion of our expenses is currently fixed, including expenses related to our facilities, equipment and personnel, and we expect to spend significant amounts to market our product for the treatment of depression. As a result, we expect that our operating expenses will continue to increase and will exceed revenues in the first full year after U.S. approval. Consequently, we will need to generate significant additional revenues to achieve profitability in the future. Even if we do achieve profitability, we may not be able to increase profitability on a quarterly or annual basis. Furthermore, if additional capital is required, we may not be able to access sufficient sources or to access capital on terms which are acceptable to us.

We may not be successful in our efforts to develop VNS Therapy for the treatment of bulimia, Alzheimer's Disease, anxiety or any other indications. We are in the process of conducting studies to help us evaluate, and potentially obtain FDA approval, for the use of VNS Therapy as a treatment for bulimia, Alzheimer's Disease, anxiety and other neurological disorders. We cannot assure you that our study results

will be positive or that we will receive FDA approval for the use of our product for the treatment of any other indication. Even if we receive FDA approval for another indication, we can provide no assurances with respect to market acceptance. If our study results are not as we anticipate or if we receive no additional FDA approvals or if alternative indications do not prove to be commercially viable, our revenues may not experience the growth that we would anticipate with the successful development of any of these indications.

We may not be able to expand or maintain market acceptance of the use of the VNS Therapy System to treat epilepsy or depression, which could cause our sales to be lower than expectations. Market acceptance of the VNS Therapy System will depend on our ability to convince the medical community of the clinical efficacy and safety of vagus nerve stimulation and the VNS Therapy System. While the VNS Therapy System has been implanted in approximately 32,000 patients, many physicians are still unfamiliar with this form of therapy. We believe that existing pharmacological therapies and surgery are the only other approved and currently available therapies competitive with the VNS Therapy System. These therapies may be more attractive to patients or their physicians than the VNS Therapy System in terms of efficacy, cost or reimbursement availability. Furthermore, we have not funded significant post-market clinical research that will change physicians' opinions or use of our product. We cannot assure you that sales will increase. We cannot assure you that the VNS Therapy System will achieve expanded market acceptance for the treatment of epilepsy, depression or for any other indication. Failure of the VNS Therapy System to gain additional market acceptance would severely harm our business, financial condition and results of operations.

We may not be successful in our marketing and sales efforts, which could severely harm our business. Since February 2005, we have intensified the preparation of our organization for approval and launch in depression and we have recently significantly expanded our sales and case management organization to support anticipated sales demand in both epilepsy and depression markets. While the recent approval of VNS Therapy in TRD will likely result in significant revenue growth in fiscal 2006, other factors affecting market acceptance, may significantly affect the size and structure of our sales organization and the effectiveness of our sales and marketing efforts. Accordingly, improvements in sales force productivity are not expected in fiscal 2006, as we are planning to support product launch activities in depression throughout fiscal 2006. Furthermore, our expectations for potential sales demand in a completely new device market for TRD will likely change as we complete our physician targeting programs and promote awareness and acceptance of VNS Therapy among new psychiatric prescribers. The time necessary for our expanded sales organization to establish new territories and relationships of trust with new physicians may take longer than projected, which could substantially delay improvements in U.S. sales performance or jeopardize attainment of quarterly revenue goals. Our inability to achieve annual or quarterly revenue targets could substantially harm our consolidated results of operations and financial condition.

Patient confidentiality and federal and state privacy laws and regulations may adversely impact our patient pull-through selling model. The HIPAA Privacy Rule became effective in April 2003 and the HIPAA security rule became effective in April 2005. In addition, virtually every state has enacted one or more laws to safeguard privacy, and these laws vary significantly from state to state and change frequently. The HIPAA Privacy Rule preempts a state privacy law only if the state privacy law is narrower in scope than the HIPAA Privacy Rule. Consequently, the applicable privacy rules can vary state by state, and the determination of the privacy rules applicable in any one state can be very difficult. The operation of our business involves the collection and use of substantial amounts of "protected health information," including patient information provided by physicians to assist in the treatment of patients, information provided by patients themselves to assist them in scheduling surgery and confirming their eligibility for third-party reimbursement, patient information provided by hospitals in connection with their efforts to obtain third-party reimbursement, patient information collected by our Product Performance Department in the investigation of product complaints and the tracking of implanted devices. We endeavor to conduct our business as a "covered entity" under the HIPAA Privacy Rule and consistent with the Texas privacy laws, obtaining HIPAA-compliant patient authorizations where required to support the collection and use of patient information, including in connection with our Patient Identification and Qualification (PIQ) pull-through selling model. We also sometimes act as a "business associate" for a covered entity. For example, we sometimes provide assistance to hospitals (covered entities) in connection with their claims for third-party reimbursement of VNS Therapy Systems

and procedures. Even if our business model is compliant with the HIPAA Privacy Rule and the Texas privacy laws, it may not be compliant with the privacy laws of all states. In addition, despite extensive efforts to conduct our business as a covered entity under the HIPAA Privacy Rule and the Texas privacy laws, the Office of the Inspector General of the Department of Health and Human Services or another government enforcement agency may determine that we are obligated to comply with the HIPAA Privacy Rule or another law and that our business model or operations are not in compliance, which could subject us to penalties and could severely limit our ability to market and sell VNS Therapy under our existing business model and could harm our business growth and financial condition.

We may be unable to obtain and maintain adequate third-party reimbursement on our product. Our ability to commercialize the VNS Therapy System successfully depends in part on whether third-party payers, including private healthcare insurers, managed care plans, the U.S. government's Medicare and Medicaid programs and others, agree both to cover the VNS Therapy System and associated procedures and services and to reimburse at adequate levels for the costs of the VNS Therapy System and the related services in the U.S. or internationally. If we fail to maintain or expand favorable coverage decisions for the VNS Therapy System in a timely manner, patients and their physicians could be deterred from using the VNS Therapy System, which could reduce our sales and severely harm our business.

Our current and future expense estimates are based, in large part, on estimates of future sales, which are difficult to predict. We may be unable to, or may elect not to, adjust spending quickly enough to offset any unexpected sales shortfall. If increased expenses are not accompanied by increased sales, our consolidated results of operations and financial condition for any particular quarter could be harmed.

If our suppliers and manufacturers are unable to meet our demand for materials, components and contract services, we may be forced to qualify new vendors or change our product design which would impair our ability to deliver products to our customers on a timely basis. We rely upon sole source suppliers for certain of the key components, materials and contract services used in manufacturing the VNS Therapy System. We periodically experience discontinuation or unavailability of components, materials and contract services which may require us to qualify alternative sources or, if no such alternative sources are identified, change our product design. We believe that pursuing and qualifying alternative sources and/or redesigning specific components of the VNS Therapy System, if or when necessary, could consume significant resources. In addition, such changes generally require regulatory submissions and approvals. Any extended delays in or an inability to secure alternative sources for these or other components, materials and contract services could result in product supply and manufacturing interruptions, which could significantly harm our business.

Our products may be found to have defects that result in product recalls. The VNS Therapy System includes an electronic pulse generator and lead designed to be implanted in the human body. Component failures, manufacturing or shipping problems or design defects could result in the product not delivering the therapy for which it is indicated. The occurrence of such problems or other adverse clinical reactions could result in a recall of our products, possibly requiring explantation and potential reimplantation of the VNS Therapy System, which may increase risk to the patient. Any product recall could severely harm our business and our consolidated financial condition and results of operations.

We may not be able to protect our technology from unauthorized use, which could diminish the value of our products and impair our ability to compete. Our success depends upon our ability to obtain and maintain patent and other intellectual property protection for the VNS Therapy System and its improvements, and for vagus nerve stimulation therapy. To that end, we have acquired licenses under certain patents and have patented and intend to continue to seek patents on our own inventions used in our products and treatment methods. The process of seeking patent protection can be expensive and time consuming, and we cannot assure you that patents will be issued from our currently pending or future applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection of our technology or any commercial advantage to us. Further, the protection offered by the licensed international patents is not as strong as that offered by the licensed U.S. patents due to differences in patent laws. In particular, the European Patent Convention prohibits patents covering methods for treatment of the human body by surgery or therapy.

We may engage in litigation to protect our proprietary rights, or defend against infringement claims by third parties, causing us to suffer significant expenses or prevent us from selling our products. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which could result in substantial cost to and diversion of effort by us, may be necessary to enforce patents issued or licensed to us, to protect trade secrets or know-how owned by us or to defend ourselves against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the VNS Therapy System, any of which could severely harm our business.

Intense competition and rapid technological changes could reduce our ability to market our products and achieve sales. We believe that existing and future pharmaceutical therapies will continue to be the primary competition for the VNS Therapy System. We may also face competition from other medical device companies that have the technology, experience and capital resources to develop alternative devices for the treatment of epilepsy and depression. Medtronic, Inc., for example, continues to assess clinically an implantable signal generator used with an invasive deep brain probe, or thalamic stimulator, for the treatment of neurological disorders and has received FDA approval for the device for the treatment of essential tremor, including that associated with Parkinson's Disease. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do and have obtained third-party reimbursement approvals for their therapies. In addition, the healthcare industry is characterized by extensive research efforts and rapid technological progress. Our competitors may develop technologies and obtain regulatory approval for products that are more effective in treating epilepsy and depression than our current or future products. In addition, advancements in surgical techniques may make surgery a more attractive therapy for epilepsy and depression. The development by others of new treatment methods with novel drugs, medical devices or surgical techniques for epilepsy and depression could render the VNS Therapy System non-competitive or obsolete. We may not be able to compete successfully against current and future competitors, including new products and technology, which could severely harm our business and our consolidated financial condition and results of operations.

We are subject to claims of product liability and we may not have the resources or insurance to cover the cost for losses under these claims. As an implantable medical device, the manufacture and sale of the VNS Therapy System entails the risk of product liability claims, which we have received from time to time in the ordinary course of business. We may be responsible for large deductibles for each claim, and our product liability coverage may not be adequate to cover judgments that may result from these claims. Product liability insurance is expensive and in the future may only be available at significantly higher premiums or not be available on acceptable terms, if at all. A successful claim brought against us in excess of our insurance coverage could significantly harm our business and financial condition.

If we do not continue to comply with changing government laws and regulations, we could lose our ability to market and sell our product or be subject to substantial fines or other penalties. The preclinical and clinical testing, manufacturing, labeling, sale, distribution and promotion of the VNS Therapy System are subject to extensive and rigorous federal and state laws and regulations, including regulations from the Department of Health and Human Services (related to Medicare, HIPAA and FDA) and from comparable state agencies. In the future, it will be necessary for us to obtain additional government approvals for other applications of the VNS Therapy System and for modified or future-generation products. It will also be necessary for us to ensure that our marketing and sales practices comply with all laws and regulations. Commercial distribution in certain foreign countries is also subject to regulatory approvals from the appropriate authorities in such countries. The process of obtaining FDA and other required regulatory approvals is lengthy, expensive and uncertain. Moreover, regulatory approvals may include regulatory restrictions on the indicated uses for which a product may be marketed. Failure to comply with applicable regulatory requirements can result in, among other things, fines, suspension or withdrawal of approvals, confiscations or recalls of products, operating restrictions and criminal prosecution. Furthermore, changes in existing regulations or adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. We may not be able to obtain additional future regulatory approvals on a timely

basis or at all. Delays in receipt of or failure to receive such future approvals, suspension or withdrawal of previously received approvals or recalls of the VNS Therapy System could severely harm our ability to market and sell our current and future products and improvements.

We are subject to federal and state laws governing our sales and marketing practices, and failure to adhere to these laws could result in substantial fines and other penalties. We are subject to certain laws and regulations, including the federal Anti-Kickback Statute and the HIPAA Privacy Rule, that govern the sales and marketing practices of healthcare companies. In 2004, we adopted a healthcare law compliance program, including our Business Practice Standards, which is a set of policies that embody the AdvaMed Code of Ethics for Interactions with Health Care Professionals. We endeavor to conduct our business in compliance with our Business Practice Standards and to ensure continued compliance through regular education of the Company's employees and regular audits of employee activities. Although we believe that these efforts have been successful and that we are in compliance with our policies and the healthcare laws, given the complexity of our patient pull-through business model, including extensive interactions with patients and healthcare professionals, and the large number of field personnel employed by the Company, violations of our policy and the law could occur. We could be subject to investigation by the Office of the Inspector General of the Department of Health and Human Services or the Department of Justice. If investigated, we could be forced to incur substantial expense responding to the investigation and defending our actions. If unsuccessful in our defense, we could be found to be in violation of the healthcare laws and be subject to substantial fines and penalties, including exclusion of our products from Medicare and Medicaid reimbursement.

Our international operations are subject to risks not generally associated with commercialization efforts in the U.S. We may not be successful in increasing our international market sales or in obtaining reimbursement or any regulatory approvals required in foreign countries. The anticipated international nature of our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or where the VNS Therapy System is sold. The regulation of medical devices in a number of such jurisdictions, particularly in the European Union, continues to develop and new laws or regulations may impair our ability to market and sell our products in those jurisdictions.

If we fail to manage our growth effectively, our ability to maintain our costs or capture new business could suffer. In connection with the commercialization of the VNS Therapy System in the U.S. for TRD, we have begun and intend to continue to expand significantly the scope of our operations. Such activities have placed, and may continue to place a significant strain on our resources and operations. Our ability to manage such growth effectively will depend upon our ability to attract, hire and retain highly qualified employees and management personnel. We compete for such personnel with other companies, academic institutions, government entities and other organizations and we may not be successful in hiring or retaining qualified personnel. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational, management information and financial control systems. If we fail to manage our growth effectively, our business will suffer.

We received a letter from the Senate Finance Committee (SFC) advising us that it is examining FDA's handling of our PMA-Supplement for the use of VNS Therapy to address treatment-resistant depression. The SFC's letter requested that we provide the SFC with certain documents and information. Responding to this request and any further requests by the SFC could divert the efforts and attention of our management team. We are unable to provide assurance as to the time it will take for the SFC to complete its review or of such review's ultimate consequence, if any.

We have been named in a putative class action shareholder lawsuit. The Company and certain of its officers have been named as defendants in a putative class action lawsuit. A discussion of this lawsuit is contained in "Item 3. Legal Proceedings." Although it is not possible at this early stage to predict the likely outcome of this lawsuit, an adverse result could have a material adverse affect on us, our consolidated financial condition, results of operations and cash flows.

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

We are exposed to limited market risk on interest rates and foreign currency exchange rates.

Our exposure to market risk for changes in interest rates relates primarily to our short-term investments in commercial paper, auction rate securities and our line of credit. We do not hedge interest rate exposure or invest in derivative securities. Based upon the average outstanding balances in cash, cash equivalents and our line of credit, a 100-basis point change in interest rates would not have a material impact on our consolidated financial results.

Due to the global reach of our business, we are also exposed to market risk from changes in foreign currency exchange rates, particularly with the U.S. dollar over the Euro. Our wholly owned foreign subsidiary is consolidated into our financial results and is subject to risks typical of an international business including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions and foreign exchange rate volatility. Accordingly, our future results could be materially impacted by changes in these or other factors. At this time, we have not deemed it to be cost effective to engage in a program of hedging the effect of foreign currency fluctuations on our operating results using derivative financial instruments. A sensitivity analysis indicates that, if the U.S. dollar uniformly weakened 10% against the Euro, the effect upon net income would be favorable by approximately $240,000 or 1.8%. Conversely, if the U.S. dollar uniformly strengthened 10% against the Euro, the impact on net income would decrease by approximately $196,000 or 1.5%.

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

The information required by this Item is incorporated by reference to the Consolidated Financial Statements beginning on page F-1.

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

None.

Item 9A. ***Controls and Procedures***

Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities and Exchange Act of 1934) designed to ensure that we are able to record, process, summarize and report, within the applicable time periods, the information required in our annual and quarterly reports under the Securities Exchange Act of 1934.

As of the end of the period covered by this report, an evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective. In addition, there have been no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during our last fiscal year that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Management's Report On Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. The internal control system was designed to provide reasonable assurance to management and the Board of Directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management assessed the effectiveness of internal control over financial reporting as of April 29, 2005. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework. Based on this assessment, management concluded, that, as of April 29, 2005, the Company's internal control over financial reporting is effective at a reasonable assurance level based on those criteria.

KPMG LLP, an independent registered public accounting firm, has issued an audit report on management's assessment of internal control over financial reporting. This report in which they expressed an unqualified opinion is included herein.

Audit Committee Oversight

The adequacy of our internal accounting controls, the accounting principles employed in our financial reporting and the scope of independent audits are reviewed by the Audit Committee of the Board of Directors, consisting solely of outside directors. The independent auditors meet with, and have confidential access to, the Audit Committee to discuss the results of their audit work.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Cyberonics, Inc.:

We have audited management's assessment, included in the accompanying *Management's Report on Internal Controls Over Financial Reporting*, that Cyberonics, Inc. maintained effective internal control over financial reporting as of April 29, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cyberonics, 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. Our responsibility is to express an opinion on management's assessment and 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Cyberonics, Inc. maintained effective internal control over financial reporting as of April 29, 2005, is fairly stated, in all material respects, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Cyberonics, Inc. maintained, in all material respects, effective internal control over financial reporting as of April 29, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cyberonics, Inc. and subsidiary as of April 29, 2005 and April 30, 2004, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for the 52 weeks ended April 29, 2005 and April 25, 2003 and the 53 weeks ended April 30, 2004, and our report dated June 21, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Houston, Texas
June 21, 2005

PART III

Item 10. *Directors and Executive Officers of the Registrant*

The information required by this Item as to our directors and executive officers is hereby incorporated by reference from the information appearing under the captions "Election of Directors — Director Nominees," "Election of Directors — Code of Ethics" and "Election of Directors — Compliance with Section 16(a) of the Exchange Act" in our definitive proxy statement which involves the election of directors and is to be filed with the SEC pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on April 29, 2005.

Item 11. *Executive Compensation*

The information required by this Item as to our management is hereby incorporated by reference from the information appearing under the captions "Election of Directors — Executive Compensation" and "Election of Directors — Director Compensation" in our definitive proxy statement which involves the election of directors and is to be filed with the SEC pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on April 29, 2005. Notwithstanding the foregoing, in accordance with the instructions to Item 402 of Regulation S-K, the information contained in our proxy statement under the sub-heading "Fiscal 2005 Report of the Compensation Committee" and "Performance Graph" shall not be deemed to be filed as part of or incorporated by reference into this Annual Report on Form 10-K.

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

The information required by this Item as to the ownership by management and others of our securities is hereby incorporated by reference from the information appearing under the captions "Election of Directors — Security Ownership of Certain Beneficial Owners and Management" and "Election of Directors — Equity Compensation Plan Information" in our definitive proxy statement which involves the election of directors and is to be filed with the SEC pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on April 29, 2005.

Item 13. *Certain Relationships and Related Transactions*

The information required by this Item as to certain business relationships and transactions with our management and other related parties is hereby incorporated by reference to such information appearing under the captions "Election of Directors — Certain Relationships and Related Transactions" and "Election of Directors — Compensation Committee Interlocks and Insider Participation" in our definitive proxy statement which involves the election of directors and is to be filed with the SEC pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on April 29, 2005.

Item 14. *Principal Accounting Fees and Services*

The information required by this Item as to the fees we pay our principal accountant is hereby incorporated by reference from the information appearing under the caption "Ratify Appointment of Independent Registered Public Accounting Firm — Audit and Other Fees" in our definitive proxy statement which involves the election of directors and is to be filed with the SEC pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on April 29, 2005.

PART IV

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

1. *Exhibits*

INDEX TO EXHIBITS

Exhibit Number	Description
3.1(1)	— Amended and Restated Certificate of Incorporation of Cyberonics.
3.2(2)	— Bylaws of Cyberonics.
3.3(3)	— Amendment No. 1 to the Bylaws of Cyberonics.
4.1(2)	— Second Amended and Restated Preferred Shares Rights Agreement, dated as of August 21, 2000 between Cyberonics and BankBoston, N.A. (formerly known as The First National Bank of Boston), including the Form of First Amended Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock, Form of Rights Certificate and Stockholder Rights Plan attached thereto as Exhibits A, B and C, respectively.
4.2(4)	— Amendment No. 1 to Second Amended and Restated Preferred Share Rights Agreement dated April 26, 2001.
4.3(27)	— Amendment No. 2 to Second Amended and Restated Preferred Share Rights Agreement dated October 31, 2001.
4.4(5)	— Amendment No. 3 to Second Amended and Restated Preferred Share Rights Agreement dated December 9, 2003.
4.5(6)	— Amendment No. 4 to Second Amended and Restated Preferred Share Rights Agreement dated January 9, 2004.
10.1(7)	— 1991 Employee Stock Purchase Plan.
10.2(8)	— Amended 1991 Employee Stock Purchase Plan dated April 8, 1998.
10.3(9)	— Second Amendment to the 1991 Employee Stock Purchase Plan dated November 29, 2001.
10.4(7)	— License Agreement dated March 15, 1988 between Cyberonics and Dr. Jacob Zabara.
10.5(7)	— Patent License Agreement effective as of July 28, 1989 between Cyberonics and Huntington Medical Research Institute.
10.6(10)	— Lease Agreement dated November 3, 1994 together with amendments dated April 18, 1996 and April 30, 1997, respectively, between Cyberonics and Salitex II, Ltd.
10.7(7)	— Form of Indemnification Agreement.
10.8(7)	— Amended and Restated Stockholders Agreement dated October 16, 1992.
10.9(11)	— Registration Rights Agreement dated March 28, 1997.
10.10(12)	— Amended and Restated 1996 Stock Option Plan.
10.11(13)	— First Amendment to the Amended and Restated 1996 Stock Option Plan dated October 2, 2000.
10.12(27)	— Second Amendment to the Amended and Restated 1996 Stock Option Plan dated March 21, 2001.
10.13(14)	— Third Amendment to the Amended and Restated 1996 Stock Option Plan dated July 27, 2001.
10.14(14)	— Fourth Amendment to the Amended and Restated 1996 Stock Option Plan dated January 2002.
10.15(15)	— Fifth Amendment to the Amended and Restated 1996 Stock Option Plan dated July 19, 2002.
10.16(10)	— Stockholders' Agreement dated April 8, 1996 between Cyberonics and St. Jude Medical, Inc.
10.17(10)	— Letter Agreement dated March 28, 1997 between The Clark Estates, Inc. and Cyberonics.
10.18(16)	— Lease Agreement dated August 19, 1997 between Cyberonics and Space Assets II, Inc.
10.19(17)	— Amended and Restated 1997 Stock Plan.
10.20(18)	— First Amendment to the Amended and Restated 1997 Stock Plan dated March 21, 2001.
10.21(19)	— Second Amendment to the Amended and Restated 1997 Stock Plan dated November 21, 2002.

Exhibit Number	Description
10.22(20)	— 1998 Stock Option Plan.
10.23(27)	— First Amendment to the 1998 Stock Option Plan dated March 21, 2001.
10.24(21)	— Employment Agreement effective as of June 1, 2003 between Cyberonics and Robert P. Cummins.
10.25(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and Pamela B. Westbrook.
10.26(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and Shawn P. Lunney.
10.27(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and Alan D. Totah.
10.28(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and Michael A. Cheney.
10.29(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and Richard L. Rudolph, M.D.
10.30(21)	— Employment Agreement effective as of June 2, 2003 between Cyberonics and William Steven Jennings.
10.31(22)	— Employment Agreement effective as of July 14, 2003 between Cyberonics and George E. Parker.
10.32(22)	— Employment Agreement effective as of September 17, 2003 between Cyberonics and David S. Wise.
10.33(23)	— Employment Agreement effective as of October 27, 2003 between Cyberonics and Randal L. Simpson.
10.34(21)	— Severance Agreement effective as of June 1, 2003 between Cyberonics and William Steven Jennings.
10.35(24)	— Severance Agreement effective as of May 1, 2001 between Cyberonics and Shawn P. Lunney.
10.36(24)	— Severance Agreement effective as of May 1, 2001 between Cyberonics and Alan D. Totah.
10.37(24)	— Severance Agreement effective as of May 1, 2001 between Cyberonics and Pamela B. Westbrook.
10.38(25)	— Severance Agreement effective as of January 1, 2002 between Cyberonics and Michael A. Cheney.
10.39(25)	— Severance Agreement effective as of January 1, 2002 between Cyberonics and Richard L. Rudolph, M.D.
10.40(27)	— Severance Agreement effective as of July 14, 2003 between Cyberonics and George E. Parker.
10.41(27)	— Severance Agreement effective as of October 27, 2003 between Cyberonics and Randal L. Simpson.
10.42(27)	— Severance Agreement effective as of September 17, 2003 between Cyberonics and David S. Wise.
10.43(7)	— 1988 Incentive Stock Plan.
10.44(13)	— First Amendment to the 1988 Incentive Stock Plan dated October 2, 2000.
10.45(27)	— Second Amendment to the 1988 Incentive Stock Plan dated March 21, 2001.
10.46(26)	— New Employee Equity Inducement Plan.
10.47(28)	— Third Amendment to Financing Agreement effective as of August 30, 2004 between Cyberonics, Inc. and the CIT Group/Business Credit, Inc.
10.48(29)	— 2005 Stock Plan.
21.1(10)	— List of Subsidiaries of Cyberonics.
23.1*	— Consent of Independent Registered Public Accounting Firm.
24.1	— Powers of Attorney (included on the Signature Page to this Annual Report Form 10-K).
31.1*	— Certification of the Chief Executive Officer of Cyberonics pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Description
31.2*	— Certification of the Chief Financial Officer of Cyberonics pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	— Certification of the Chief Executive Officer and Chief Financial Officer of Cyberonics pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

(1) Incorporated by reference to Cyberonics' Registration Statement on Form S-3 (Reg. No. 333-56022) filed on February 21, 2001.

(2) Incorporated by reference to Cyberonics' Report on Form 8-K filed on September 12, 2000.

(3) Incorporated by reference to Cyberonics' Report on Form 8-K filed on March 30, 2001.

(4) Incorporated by reference to Cyberonics' Annual Report and Transition Report on Form 10-K for the fiscal period ended April 27, 2001 and the transition period from July 1, 2000 to April 27, 2001, respectively.

(5) Incorporated by reference to Cyberonics' Report on Form 8-K filed on December 12, 2003.

(6) Incorporated by reference to Cyberonics' Report on Form 8-K filed on January 13, 2004.

(7) Incorporated by reference to the Cyberonics' Registration Statement on Form S-1 (Reg. No. 33-45118) declared effective February 10, 1993.

(8) Incorporated by reference to the Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-66689) filed on November 3, 1998.

(9) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-74948) filed on December 12, 2001.

(10) Incorporated by reference to Cyberonics' Annual Report on Form 10-K for the fiscal period ended June 30, 1997.

(11) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.

(12) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-77361) filed on April 29, 1999.

(13) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.

(14) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-81158) filed on January 22, 2002.

(15) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-97095) filed on July 25, 2002.

(16) Incorporated by reference to the Cyberonics' Annual Report on Form 10-K/A for the fiscal period ended June 30, 1997.

(17) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-56694) filed on March 8, 2001.

(18) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended July 26, 2002.

(19) Incorporated by reference to Annex B of Cyberonics' Proxy Statement for the Annual Meeting of Stockholders filed on October 15, 2002.

(20) Incorporated by reference to the Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-66691) filed on November 3, 1998.

(21) Incorporated by reference to Cyberonics' Annual Report on Form 10-K for the fiscal period ended April 25, 2003.

(22) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended October 24, 2003.

(23) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended January 23, 2004.

(24) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended July 27, 2001.

(25) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended January 25, 2002.

(26) Incorporated by reference to Cyberonics' Registration Statement on Form S-8 (Reg. No. 333-108281) filed on August 27, 2003.

(27) Incorporated by reference to Cyberonics' Annual Report on Form 10-K for the fiscal period ended April 30, 2004.

(28) Incorporated by reference to Cyberonics' Quarterly Report on Form 10-Q for the quarter ended October 29, 2004.

(29) Incorporated by reference to Annex A of Cyberonics' Proxy Statement for the Special Meeting of Stockholders filed on April 14, 2005.

2. *Financial Statements.* The Consolidated Financial Statements of Cyberonics, Inc. and its subsidiary, and the Report of Independent Registered Public Accounting Firm are included in this Annual Report on Form 10-K beginning on page F-1:

SIGNATURES

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

CYBERONICS, INC.

By: /s/ PAMELA B. WESTBROOK
Pamela B. Westbrook
Vice President, Finance and Administration and Chief Financial Officer (Principal Financial and Accounting Officer)

Date: July 18, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert P. Cummins and Pamela B. Westbrook, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and conforming all that each of said attorneys-in-fact, or his substitute or substitutes, any do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ ROBERT P. CUMMINS Robert P. Cummins	Chairman of the Board, Chief Executive Officer and President (Principal Executive Officer)	July 18, 2005
/s/ PAMELA B. WESTBROOK Pamela B. Westbrook	Vice President, Finance and Administration and Chief Financial Officer (Principal Financial and Accounting Officer)	July 18, 2005
/s/ STANLEY H. APPEL Stanley H. Appel, M.D.	Director	July 18, 2005
/s/ TONY COELHO Tony Coelho	Director	July 18, 2005
/s/ GUY C. JACKSON Guy C. Jackson	Director	July 18, 2005
/s/ RONALD A. MATRICARIA Ronald A. Matricaria	Director	July 18, 2005

Signature	Title	Date
/s/ KEVIN S. MOORE Kevin S. Moore	Director	July 18, 2005
/s/ ALAN J. OLSEN Alan J. Olsen	Director	July 18, 2005
/s/ MICHAEL J. STRAUSS, M.D. Michael J. Strauss, M.D.	Director	July 18, 2005
/s/ REESE S. TERRY, JR. Reese S. Terry, Jr.	Director	July 18, 2005

CONSOLIDATED FINANCIAL STATEMENTS

As of April 29, 2005 and April 30, 2004

TOGETHER WITH INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S REPORT

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Cyberonics, Inc.:

We have audited the accompanying consolidated balance sheets of Cyberonics, Inc. (a Delaware corporation) and subsidiary as of April 29, 2005 and April 30, 2004, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for the 52 weeks ended April 29, 2005 and April 25, 2003 and the 53 weeks ended April 30, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the Standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cyberonics, Inc. and subsidiary as of April 29, 2005 and April 30, 2004, and the results of their operations and their cash flows for the 52 weeks ended April 29, 2005 and April 25, 2003 and the 53 weeks ended April 30, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cyberonics, Inc.'s internal control over financial reporting as of April 29, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 21, 2005, expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Houston, Texas
June 21, 2005

CYBERONICS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	April 29, 2005	April 30, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 38,675,892	$ 43,463,267
Short-term marketable securities	22,800,000	14,900,464
Accounts receivable, net	16,476,084	16,951,176
Inventories	8,545,385	7,793,856
Other current assets	3,355,778	2,663,299
Total Current Assets	89,853,139	85,772,062
Property and equipment, net	8,854,063	8,348,595
Other assets	148,195	175,867
	$ 98,855,397	$ 94,296,524
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Line of credit	$ 3,000,000	$ 10,031,000
Accounts payable	6,620,464	4,439,407
Accrued liabilities	13,375,565	10,704,572
Other	53,599	141,066
Total Current Liabilities	23,049,628	25,316,045
Long Term Liabilities — Other	209,928	—
Total Liabilities	23,259,556	25,316,045
Commitments and Contingencies		
Stockholders' Equity:		
Preferred Stock, $.01 par value per share; 2,500,000 shares authorized; no shares issued and outstanding	—	—
Common Stock, $.01 par value per share; 50,000,000 shares authorized; 24,781,456 and 23,457,397 shares issued and outstanding at April 29, 2005 and April 30, 2004, respectively	247,815	234,574
Additional paid-in capital	205,999,521	187,995,580
Deferred compensation	(78,750)	(797,219)
Accumulated other comprehensive loss	(548,689)	(646,748)
Accumulated deficit	(130,024,056)	(117,805,708)
Total Stockholders' Equity	75,595,841	68,980,479
	$ 98,855,397	$ 94,296,524

CYBERONICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Net sales	$103,442,570	$110,721,499	$104,466,998
Cost of sales	15,575,741	16,295,562	16,066,229
Gross Profit	87,866,829	94,425,937	88,400,769
Operating Expenses:			
Selling, general and administrative	81,430,943	70,597,149	65,842,238
Research and development	19,341,075	17,133,709	17,874,909
Total Operating Expenses	100,772,018	87,730,858	83,717,147
Earnings (Loss) From Operations	(12,905,189)	6,695,079	4,683,622
Interest income	1,072,488	469,924	471,213
Interest expense	(444,270)	(565,702)	(413,192)
Other income, net	84,736	390,997	572,851
Earnings (loss) before income taxes	(12,192,235)	6,990,298	5,314,494
Income tax expense	26,113	230,789	129,563
Net Earnings (Loss)	$(12,218,348)	$ 6,759,509	$ 5,184,931
Basic earnings (loss) per share	$ (0.51)	$ 0.29	$ 0.24
Diluted earnings (loss) per share	$ (0.51)	$ 0.26	$ 0.22
Shares used in computing basic earnings (loss) per share	24,036,736	22,921,031	22,034,651
Shares used in computing diluted earnings (loss) per share	24,036,736	26,053,330	23,173,324

CYBERONICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)

	Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at April 26, 2002	21,751,261	$217,513	$167,855,437	$(1,496,250)	$(212,739)	$(129,750,148)	$ 36,613,813
Stock options exercised	566,339	5,663	5,587,370	—	—	—	5,593,033
Issuance of common stock under Employee Stock Purchase Plan	68,136	681	882,532	—	—	—	883,213
Amortization of deferred compensation	—	—	—	472,500	—	—	472,500
Net Earnings	—	—	—	—	—	5,184,931	5,184,931
Translation adjustment	—	—	—	—	(235,487)	—	(235,487)
Comprehensive income	—	—	—	—	—	—	4,949,444
Balance at April 25, 2003	22,385,736	223,857	174,325,339	(1,023,750)	(448,226)	(124,565,217)	48,512,003
Stock options exercised	974,837	9,749	11,947,259	—	—	—	11,957,008
Issuance of common stock under Employee Stock Purchase Plan	65,980	660	1,010,110	—	—	—	1,010,770
Issuance of restricted stock	30,844	308	712,872	(713,180)	—	—	—
Amortization of deferred compensation	—	—	—	939,711	—	—	939,711
Net Earnings	—	—	—	—	—	6,759,509	6,759,509
Translation adjustment	—	—	—	—	(198,522)	—	(198,522)
Comprehensive income	—	—	—	—	—	—	6,560,987
Balance at April 30, 2004	23,457,397	234,574	187,995,580	(797,219)	(646,748)	(117,805,708)	68,980,479
Stock options exercised	1,241,889	12,419	16,674,877	—	—	—	16,687,296
Issuance of common stock under Employee Stock Purchase Plan	82,420	824	1,335,684	—	—	—	1,336,508
Cancellation of restricted stock	(250)	(2)	(6,620)	6,622	—	—	—
Amortization of deferred compensation	—	—	—	711,847	—	—	711,847
Net Loss	—	—	—	—	—	(12,218,348)	(12,218,348)
Translation adjustment	—	—	—	—	98,059	—	98,059
Comprehensive loss	—	—	—	—	—	—	(12,120,289)
Balance at April 29, 2005	24,781,456	$247,815	$205,999,521	$ (78,750)	$(548,689)	$(130,024,056)	$ 75,595,841

CYBERONICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Cash Flows From Operating Activities:			
Net earnings (loss)	$(12,218,348)	$ 6,759,509	$ 5,184,931
Non-cash items included in net earnings (loss):			
Depreciation	3,274,843	3,978,340	4,648,061
Gain on disposal of assets	(50,066)	(114,947)	(182,028)
Unrealized (gain) loss in foreign currency transactions	15,757	439,684	(566,834)
Amortization of deferred compensation	711,847	939,711	472,500
Changes in operating assets and liabilities:			
Accounts receivable, net	747,906	(2,566,387)	(3,490,665)
Inventories	(758,512)	(1,648,759)	(1,545,600)
Other current assets	(668,745)	(1,304,933)	(15,364)
Other assets, net	33,435	62,062	(50,042)
Accounts payable and accrued liabilities	4,678,684	(2,948,931)	(3,179,293)
Other	263,527	—	—
Net Cash Provided By (Used In) Operating Activities	(3,969,672)	3,595,349	1,275,666
Cash Flows From Investing Activities:			
Purchase of short-term marketable securities	(10,400,229)	(16,300,464)	—
Proceeds from sale of short-term marketable securities	2,500,693	1,400,000	—
Purchases of property and equipment	(3,713,637)	(2,600,592)	(4,206,728)
Net Cash Used In Investing Activities	(11,613,173)	(17,501,056)	(4,206,728)
Cash Flows From Financing Activities:			
Increase (decrease) in borrowing against line of credit	(7,031,000)	1,661,000	1,870,000
Payments on capital lease obligations	(141,066)	(132,133)	(125,535)
Proceeds from issuance of Common Stock	18,023,804	12,967,778	6,476,245
Net Cash Provided By Financing Activities	10,851,738	14,496,645	8,220,710
Effect of exchange rate changes on cash and cash equivalents	(56,268)	(703,976)	90,695
Net Increase (Decrease) in Cash and Cash Equivalents	(4,787,375)	(113,038)	5,380,343
Cash and cash equivalents at beginning of period	43,463,267	43,576,305	38,195,962
Cash and cash equivalents at end of period	$ 38,675,892	$ 43,463,267	$43,576,305
Supplementary Disclosures of Cash Flow Information:			
Cash paid for interest	$ 416,986	$ 418,042	$ 368,082
Cash paid for income taxes	$ 53,312	$ 348,558	$ 78,483
Supplemental Disclosure of Non-cash Activity:			
Cancellation (Issuance) of Restricted Stock to selected employees	$ 6,622	$ (713,180)	$ —

CYBERONICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies and Related Data

Nature of Operations. Cyberonics, Inc. (Cyberonics) is headquartered in Houston, Texas and designs, develops, manufactures and markets the VNS Therapy System, an implantable medical device which delivers a unique therapy, Vagus Nerve Stimulation, for the treatment of refractory epilepsy, treatment-resistant depression and other debilitating neurological disorders. Cyberonics has regulatory approval to market and sell the VNS Therapy System for refractory epilepsy in the United States, Canada, Europe, Australia and other markets. In 2001, Cyberonics obtained regulatory approval for commercial distribution of the VNS Therapy System for the treatment of depression in the European market and in Canada. On July 15, 2005, FDA approved the VNS Therapy System as an adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.

We operate our business as a single segment with similar economic characteristics, technology, manufacturing processes, customers, distribution and marketing strategies, regulatory environments and shared infrastructures. We are a neurostimulation business focused on creating new markets, developing other indications for VNS Therapy covered by our method patents and expanding our business into other neuromodulation opportunities.

Consolidation. The accompanying consolidated financial statements include Cyberonics and its wholly-owned subsidiary, Cyberonics Europe, S.A. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates. The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Critical estimates that require management's judgment relate to the allowance for doubtful accounts, estimates of any obsolete inventory, useful lives for property and equipment, impairment of any long-lived assets, sales returns and allowances, product warranties and income tax valuation reserves.

Foreign Currency Translation. The assets and liabilities of Cyberonics Europe, S.A. are generally translated into U.S. dollars at exchange rates in effect on reporting dates, while capital accounts and certain obligations of a long-term nature payable to the parent company are translated at historical rates. Income statement items are translated at average exchange rates in effect during the financial statement period. The gains and losses that result from this process are shown in the accumulated other comprehensive income (loss) section of stockholders' equity and comprehensive income (loss), and are not included in the determination of the results of operations. Gains and losses resulting from foreign currency transactions denominated in currency other than the functional currency are included in other income and expense.

Cash Equivalents. Cyberonics considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents.

Investments in Short-Term Marketable Securities. Included in short-term investments are auction rate securities classified as available-for-sale securities. Cyberonics' investment in these securities are recorded at cost, which approximates fair market value due to their variable interest rates, which typically reset every 7 to 35 days, and, despite the long-term nature of their stated contractual maturities, Cyberonics has the ability to quickly liquidate these securities. As a result, Cyberonics had no cumulative gross unrealized holding gains (losses) or gross realized gains (losses) from these current investments.

In connection with the preparation of the 2005 annual report on Form 10-K, Cyberonics concluded that it was appropriate to classify its auction rate securities as short-term investments. Previously, such securities had been classified as cash and cash equivalents due to their liquidity and pricing reset feature. Accordingly,

Cyberonics has revised the classification to report these securities within short-term investments on its Consolidated Balance Sheet as of April 30, 2004 to conform to the current year presentation. Cyberonics has also made corresponding adjustments to its Consolidated Statement of Cash Flows for the period ended April 30, 2004 to reflect the gross purchases and sales of these securities as investing activities rather than as a component of cash and cash equivalents. No reclassifications were necessary in the Consolidated Statement of Cash Flows for the period ended April 25, 2003. There was no impact on net earnings or cash flows from operations as a result of the reclassification.

Fair Value of Financial Instruments. The carrying amounts reported in the consolidated balance sheets for cash equivalents, short-term marketable securities, accounts receivable, accounts payable and line of credit approximate their fair values due to the short-term maturity of these financial instruments.

Accounts Receivable. Activity in Cyberonics' allowance for doubtful accounts consists of the following:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004
Balance at beginning of period	$279,699	$292,176
Increase in allowance	75,374	—
Reductions in allowance	—	(9,137)
Reductions for write-offs	(79,616)	(3,340)
Balance at end of period	$275,457	$279,699

Inventories. Cyberonics states its inventories at the lower of cost, first-in, first-out (FIFO) method or market. Cost includes the acquisition cost of raw materials and components, direct labor and overhead net of obsolescence provisions.

Property and Equipment. Property and equipment are carried at cost, less accumulated depreciation. Maintenance, repairs and minor replacements are charged to expense as incurred; significant renewals and betterments are capitalized. Cyberonics computes depreciation using the straight-line method over useful lives ranging from two to nine years. Property and equipment under capital leases are stated at the lower of the present value of minimum lease payments at the beginning of the lease term or fair value at the inception of the lease. Property and equipment under capital leases are depreciated using the straight-line method over the shorter of the lease term or the estimated useful life of the property.

Leases. Statement of Financial Accounting Standards (SFAS) No. 13 *"Accounting for Leases,"* establishes standards of financial accounting and reporting for leases by lessees and lessors. Cyberonics is a party to the contract of leased facilities and other lease obligations recorded in compliance with SFAS No. 13.

Long-Lived Assets. SFAS No. 144, *"Accounting for the Impairment or Disposals of Long-Lived Assets,"* provides a single accounting model for long-lived assets to be disposed of. SFAS No. 144 also establishes the criteria for classifying an asset as held for sale and sets the scope of business to be disposed of that qualify for reporting as discontinued operations as well as changes the timing of recognizing losses on such operations.

Stock Options. Cyberonics has adopted the disclosure-only provisions of SFAS No. 123, *"Accounting for Stock-Based Compensation"* and SFAS No. 148, *"Accounting for Stock-Based Compensation — Transition and Disclosure,"* which disclosures are presented in Note 7, *"Stock Incentive and Purchase Plans."* Because of this election, Cyberonics continues to account for its employee stock-based compensation plans under Accounting Principles Board (APB) Opinion No. 25 and the related interpretations. We are required to comply with SFAS No. 123 (revised 2004) starting on the first day of our fiscal year 2007, or April 29, 2006. We are currently evaluating the effect that the adoption of SFAS No. 123 (revised 2004) will have on Cyberonics' consolidated operating results and financial condition. No stock-based compensation cost is

reflected in net income for employee option grants, as most options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. There is only one exception further disclosed under Note 6, whereby deferred compensation is recorded for certain stock-based compensation grants based on the excess of the market value of the common stock on the measurement date over the exercise price. The deferred compensation is amortized over the vesting period of each unit of stock-based compensation.

The following table illustrates the effect on net income and earnings per share if Cyberonics had applied the fair value recognition provision of SFAS No. 123, *"Accounting for Stock-Based Compensation"* and SFAS No. 148 *"Accounting for Stock-Based Compensation — Transition and Disclosure,"* to stock-based employee compensation.

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Net earnings (loss) as reported	$(12,218,348)	$ 6,759,509	$ 5,184,931
Add: Stock-based employee compensation expense included in reported net earnings (loss), net of related tax effects	711,847	939,711	472,500
Deduct: Total stock-based employee compensation expense determined under the fair value method for all awards, net of related tax effects, if applicable	(20,746,938)	(18,365,471)	(18,060,760)
Pro forma net loss	$(32,253,439)	$(10,666,251)	$(12,403,329)
Earnings (loss) per share:			
Basic — as reported	$ (0.51)	$ 0.29	$ 0.24
Basic — pro forma	$ (1.34)	$ (0.47)	$ (0.56)
Diluted — as reported	$ (0.51)	$ 0.26	$ 0.22
Diluted — pro forma	$ (1.34)	$ (0.47)	$ (0.56)

Revenue Recognition. We sell our products through a combination of a direct sales force in the United States and certain European countries and through distributors elsewhere. Cyberonics recognizes revenue when title to the goods and risk of loss transfer to customers, providing there are no remaining performance obligations required of Cyberonics or any matters requiring customer acceptance. We record estimated sales returns and discounts as a reduction of net sales in the same period revenue is recognized. Our revenues are dependent upon sales to new and existing customers pursuant to our current policies. Changes in these policies or sales terms could impact the amount and timing of revenue recognized.

Research and Development. All research and development costs are expensed as incurred.

Product Warranty. Cyberonics offers warranties on its leads and generators for one to two years from the date of implant, depending on the product in question. Cyberonics provides at the time of shipment for costs estimated to be incurred under its product warranties. Provisions for warranty expenses are made based upon projected product warranty claims.

Changes in Cyberonics' liability for product warranties during the 52 weeks ended April 29, 2005, the 53 weeks ended April 30, 2004 and the 52 weeks ended April 25, 2003 are as follows:

Year	Balance at the Beginning of the Year	Warranty Expense Recognized	Warranties Settled	Balance at the End of the Year
2005	$ 50,935	$ 29,077	$(33,021)	$ 46,991
2004	160,581	(66,536)	(43,110)	50,935
2003	128,803	45,000	(13,222)	160,581

License Agreements. Cyberonics has executed licensing agreements under which it has secured the rights provided under certain patents. Royalties, payable under the terms of these agreements, are expensed as incurred.

Income Taxes. Cyberonics accounts for income taxes under the asset and liability method. Under this method, deferred income taxes reflect the impact of temporary differences between financial accounting and tax basis of assets and liabilities. Such differences relate primarily to the deductibility of certain accruals and reserves and the effect of tax loss and tax credit carryforwards not yet utilized. Deferred tax assets are evaluated for realization based on a more-likely-than-not criterion in determining if a valuation allowance should be provided.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change of tax rates is recognized in income in the period that includes the enactment date.

Net Earnings (Loss) Per Share. SFAS No. 128, *"Earnings Per Share"* requires dual presentation of earnings per share (EPS): basic EPS and diluted EPS. Basic EPS is computed by dividing net earnings or loss applicable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted EPS includes dilutive stock options and unvested restricted stock that are considered common stock equivalents using the treasury stock method.

The following table sets forth the computation of basic and diluted net earnings (loss) per share of common stock:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Numerator:			
Net earnings (loss)	$(12,218,348)	$ 6,759,509	$ 5,184,931
Denominator:			
Basic weighted average shares outstanding	24,036,736	22,921,031	22,034,651
Effect of dilutive stock options and unvested restricted stock	—	3,132,299	1,138,673
Diluted weighted average shares outstanding	24,036,736	26,053,330	23,173,324
Basic earnings (loss) per share	$ (0.51)	$ 0.29	$ 0.24
Diluted earnings (loss) per share	$ (0.51)	$ 0.26	$ 0.22

Excluded from the computation of diluted EPS for the 52 weeks ended April 29, 2005 were outstanding options to purchase approximately 6,927,000 common shares, because to include them would have been antidilutive due to the net loss. Excluded from the computation of diluted EPS for the 53 weeks ended April 30, 2004 and the 52 weeks ended April 25, 2003 were outstanding options to purchase approximately

409,100 and 1,677,400 common shares, respectively, because to include them would have been antidilutive, meaning the exercise price exceeded fair market value.

Comprehensive Income (Loss). Comprehensive income (loss) is the total of net earnings (loss) and all other non-owner changes in equity.

Reclassifications. Certain reclassifications have been made to prior period consolidated financial statements to conform with the April 29, 2005 presentation.

Note 2. Inventories

Inventories consist of the following:

	April 29, 2005	April 30, 2004
Raw materials	$4,543,744	$3,723,791
Finished goods	2,693,390	2,598,779
Work-in-process	1,308,251	1,471,286
	$8,545,385	$7,793,856

Note 3. Property and Equipment

Property and equipment consist of the following:

	April 29, 2005	April 30, 2004
Computer equipment	$ 7,644,161	$ 6,200,780
Manufacturing equipment	6,643,037	6,130,770
Furniture and fixtures	3,218,068	2,653,143
Offsite programming equipment	3,197,432	3,233,259
Leasehold improvements	3,308,585	2,809,408
Construction in progress	1,755,377	1,129,174
Office equipment	967,320	917,145
	26,733,980	23,073,679
Accumulated depreciation	(17,879,917)	(14,725,084)
	$ 8,854,063	$ 8,348,595

Note 4. Line of Credit

Cyberonics has a revolving credit facility of $20,000,000 with a one-year term ending in September 2005. The credit facility is collateralized by accounts receivable, inventory, equipment, documents of title, general intangibles, subsidiary stock and other collateral. The amount available to borrow under the facility is limited to 80% of eligible accounts receivable and a portion of eligible inventory. As of April 29, 2005, the eligible balance of our accounts receivable was approximately $13,493,000. We had borrowings of $3,000,000 outstanding under the credit facility and an available borrowing capacity of approximately $7,794,000. Interest is payable in the amount of the Chase bank rate of 5.75% on the greater of $3,000,000 or the average of the net balance owed by Cyberonics at the close of each day during the period. Under the terms of the revolving credit facility, we agree to maintain liquidity (being the aggregate of availability under the credit facility and Cyberonics' cash on hand) equal to or greater than $10,000,000. An unused line of credit fee is payable at the rate of 0.5%.

Note 5. Accrued Liabilities

Accrued liabilities consist of the following:

	April 29, 2005	April 30, 2004
Payroll and other compensation	$ 7,021,246	$ 5,480,401
Clinical costs	1,109,097	1,105,095
Professional services	870,843	617,298
Royalties	789,530	1,034,722
Other	3,584,849	2,467,056
	$13,375,565	$10,704,572

Note 6. Stockholders' Equity

Preferred Stock. Cyberonics has 2,500,000 shares of undesignated Preferred Stock authorized and available for future issuance, of which none have been issued through April 29, 2005. With respect to the shares authorized, Cyberonics' Board of Directors, at its sole discretion, may determine, fix and alter dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any such series and may determine the designation, terms and conditions of the issuance of any such shares.

Deferred Compensation. In June 2000, the Board of Directors granted 450,000 options at $18.00 per share to purchase shares of common stock under a proposed modification to the 1997 Stock Option Plan that was subject to shareholder approval. On December 29, 2000, the shareholders approved the modifications to the plan and Cyberonics recorded approximately $2.4 million in deferred compensation relating to the options. The charge reflects the difference between the exercise price and the fair market value of the stock on the date shareholder approval was received. The deferred compensation is being amortized to expense over the five-year vesting period of the options. Approximately $473,000 of compensation expense has been recognized for the vested portion of this option grant during each of the fiscal years 2003, 2004 and 2005, respectively.

In fiscal year 2004, the Board of Directors granted 30,844 shares of restricted stock at market rates that vest in one year and recorded approximately $713,000 in deferred compensation. Approximately $239,000 and $467,000 of compensation expense was recognized for the vested portion of these option grants during fiscal year 2005 and 2004, respectively.

Preferred Share Purchase Rights. In January 1997, Cyberonics' Board of Directors declared a dividend of one Preferred Share Purchase Right (Right) on each outstanding share of Cyberonics' Common Stock to stockholders of record on March 10, 1997. Cyberonics amended and restated the Preferred Share Rights (Plan) on August 21, 2000. The Rights will become exercisable following the tenth day after a person or group of affiliated persons (an Acquiring Person), acquires beneficial ownership of 15 percent or more of Cyberonics' Common Stock or announces commencement of a tender offer, the consummation of which would result in such person or group of persons becoming an Acquiring Person (a Triggering Event). Each Right entitles the holder thereof to buy 1/1000 of a share of Cyberonics' Series A Participating Preferred Stock at an exercise price of $150 (the Exercise Price). Cyberonics will be entitled to redeem the Rights at $.01 per Right at any time prior to a Triggering Event. If, prior to redemption of the Rights, a person becomes an Acquiring Person, each Right (except for Rights owned by the Acquiring Person, which will thereafter be void) will entitle the holder thereof to purchase, at the Right's then current exchange price, that number of shares of Common Stock of Cyberonics (or, in certain circumstances as determined by the Board, cash, other property or other securities) having a market value at that time of twice the Right's exercise price. In the event a person becomes an Acquiring Person and Cyberonics sells more than 50% of its assets or earning power or is acquired

in a merger or other business combination, proper provision must be made so that a holder of a Right which has not theretofore been exercised (except for Rights owned by the Acquiring Person, which will thereafter be void), will thereafter have the right to receive, upon exercise of a Right, shares of common stock of the acquiring company having a value equal to two times the then current Exercise Price. At any time after a Triggering Event and prior to acquisition by such Acquiring Person of 50% or more of the outstanding Common Stock, the Board of Directors of Cyberonics may exchange the Rights (other than Rights owned by the Acquiring Person or its affiliates) for the Common Stock of Cyberonics at an exchange ratio of one share of common stock per Right. In April 2001, Cyberonics amended the Plan to designate the State of Wisconsin Investment Board (SWIB) as an Exempt Person under the terms of the Plan as long as SWIB is the Beneficial Owner of less than 20%. In December 2003, Cyberonics amended the Plan to designate Boston Scientific Corporation (BSX) as an Exempt Person under the terms of the Plan as long as BSX is the Beneficial Owner of less than 20% of Cyberonics' common stock, or such percentage that is less than 20% as shall be held by BSX as of the close of business on January 15, 2004. In January 2004, Cyberonics amended the Plan to designate BSX as an Exempt Person under the terms of the Plan as long as BSX is the Beneficial Owner of less than 20% of Cyberonics' common stock, or such percentage that is less than 20% as shall be held by BSX on the tenth business day following the earlier of the expiration or termination of the Hart Scott Rodino Act waiting period, but in no event later than February 28, 2004.

Note 7. Stock Incentive and Purchase Plans

Stock Options. Cyberonics has reserved an aggregate of 13,850,000 shares of its Common Stock through April 29, 2005, for issuance pursuant to its Amended 1988 Incentive Stock Option Plan, its 1996 Stock Option Plan, its 1997 Stock Option Plan and its 1998 Stock Option Plan (the Stock Option Plans). Options granted under the Stock Option Plans generally vest ratably over four or five years following their date of grant. The vesting of certain options occurs up to 7 years from the grant date. Options granted under the Stock Option Plans have maximum terms of 10 years. The Amended 1988 Incentive Stock Option and the 1997 Stock Option Plans allow issuance of either nonstatutory or incentive stock options, while the 1996 and the 1998 Stock Option Plans provide for issuance of nonstatutory stock options exclusively. The 1997 Stock Option Plan also allows for the issuance of restricted stock.

The following is a summary of Cyberonics' stock option and restricted stock activity for the 52 weeks ended April 29, 2005, the 53 weeks ended April 30, 2004 and the 52 weeks ended April 25, 2003, respectively.

		Outstanding		Exercisable	
	Shares Reserved	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Balance at April 26, 2002	984,239	7,130,369	$13.60	2,739,384	$11.57
Shares reserved	2,000,000	—	—	—	—
Granted	(1,303,275)	1,303,275	15.10	—	—
Options becoming exercisable	—	—	—	1,190,798	—
Exercised	—	(566,339)	9.96	(566,339)	—
Canceled or forfeited	854,621	(854,621)	15.29	—	—
Balance at April 25, 2003	2,535,585	7,012,684	13.97	3,363,843	12.76
Shares reserved	750,000	—	—	—	—
Granted	(1,519,844)	1,519,844	23.58	—	—
Options becoming exercisable	—	—	—	1,250,625	—
Exercised	—	(974,837)	12.25	(974,837)	—
Canceled or forfeited	627,540	(627,540)	16.27	—	—
Balance at April 30, 2004	2,393,281	6,930,151	16.11	3,639,631	13.99
Shares canceled	(154,999)	—	—	—	—
Granted	(1,456,781)	1,456,781	22.62	—	—
Options becoming exercisable	—	—	—	1,259,445	—
Exercised	—	(1,241,889)	13.67	(1,241,889)	—
Canceled or forfeited	217,567	(217,567)	19.01	—	—
Balance at April 29, 2005	999,068	6,927,476	$17.87	3,657,187	$15.41

Had the compensation cost for these plans been determined pursuant to the alternative method under SFAS No. 123 and SFAS No. 148, Cyberonics' pro forma net loss and loss per share would have been as follows:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Net earnings (loss) as reported	$(12,218,348)	$ 6,759,509	$ 5,184,931
Add: Stock-based employee compensation expense included in reported net earnings (loss), net of related tax effects	711,847	939,711	472,500
Deduct: Total stock-based employee compensation expense determined under the fair value method for all awards, net of related tax effects, if applicable	(20,746,938)	(18,365,471)	(18,060,760)
Pro forma net loss	$(32,253,439)	$(10,666,251)	$(12,403,329)
Earnings (loss) per share:			
Basic — as reported	$ (0.51)	$ 0.29	$ 0.24
Basic — pro forma	$ (1.34)	$ (0.47)	$ (0.56)
Diluted — as reported	$ (0.51)	$ 0.26	$ 0.22
Diluted — pro forma	$ (1.34)	$ (0.47)	$ (0.56)

The weighted average fair value of options granted at prices equal to Cyberonics' market value in fiscal periods 2005, 2004 and 2003 was $14.99, $14.95 and $10.08, respectively.

For SFAS No. 123 and SFAS No. 148 purposes, the fair values of each option grant are estimated using the Black-Scholes option pricing model with the following weighted average assumptions used for grants: risk-free interest rates of 3.7%, 3.7%, and 3.4% for fiscal years 2005, 2004 and 2003, respectively, expected life of 5.9, 5.7, and 5.7 years for options and restricted stock in fiscal years 2005, 2004 and 2003, respectively, expected volatility of 87.3%, 84.6%, and 90.2% for fiscal years 2005, 2004 and 2003, respectively, and no expected dividend yields.

Because the SFAS Nos. 123 and 148 method of accounting has not been applied to options granted prior to July 1, 1995, the resulting pro forma compensation cost may not be representative of that to be expected in future years. Additionally, the pro forma amounts include $235,854, $178,371 and $155,861 related to the purchase discount offered under Cyberonics' Employee Stock Purchase Plan during fiscal years 2005, 2004 and 2003, respectively. The weighted average fair values of shares granted to employees were $14.99, $14.93 and $15.25 during fiscal years 2005, 2004 and 2003, respectively.

Cyberonics' outstanding options are segregated into the following ten categories in accordance with SFAS No. 123:

Options Outstanding and Exercisable by Price Range
As of April 29, 2005

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Outstanding as of April 29, 2005	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Exercisable as of April 29, 2005	Weighted-Average Exercise Price
$0.0000000 - $4.501000	131,770	1.5	$ 3.0554	131,770	$ 3.0554
$4.5011000 - $9.002000	376,167	3.2	$ 6.3945	349,792	$ 6.4007
$9.0021000 - $13.50300	875,324	6.3	$12.0810	569,395	$12.1419
$13.503100 - $18.00400	2,880,701	6.4	$15.6228	1,839,170	$16.0290
$18.004100 - $22.50500	1,424,071	8.2	$19.6491	466,107	$19.8538
$22.505100 - $27.06000	547,352	8.1	$25.1636	173,656	$24.7293
$27.061000 - $31.50700	305,975	8.2	$28.5243	102,867	$28.6744
$31.507100 - $36.00800	87,116	8.7	$33.5366	21,864	$33.5212
$36.008100 - $40.50900	143,500	9.9	$37.2856	2,566	$37.3020
$40.509100 - $45.01000	155,500	9.9	$42.5499	0	$ 0.0000
	6,927,476	6.9	$17.8650	3,657,187	$15.4113

During fiscal year 2004, the Board of Directors approved grants outside of the existing stock option plans. The grants, which totaled 450,000 were approved for new officers as inducements essential to their entering into employment with Cyberonics. No such grants were approved for 2005 or 2003.

Stock Purchase Plan. Under the Cyberonics, Inc. Employee Stock Purchase Plan (Stock Purchase Plan), 950,000 shares of Cyberonics' Common Stock have been reserved for issuance. Subject to certain limits, the Stock Purchase Plan allows eligible employees to purchase shares of Cyberonics' Common Stock through payroll deductions of up to 15 percent of their respective current compensation at a price equaling the lesser of 85 percent of the fair market value of Cyberonics' Common Stock on (a) the first business day of the purchase period or (b) the last business day of the purchase period. Purchase periods, under provisions of the Stock Purchase Plan, are six months in length and begin on the first business days of June and December. At April 29, 2005, 509,239 shares remain available for future issuances under the Stock Purchase Plan.

Stock Recognition Program. In May 1992, Cyberonics' Board of Directors established the Cyberonics Employee Stock Recognition Program. Since its inception, a total of 8,200 shares of Cyberonics' Common Stock have been reserved for issuance as special recognition grants. The shares are granted to employees for special performances and/or contributions at the discretion of Cyberonics' President, based on nominations made by fellow employees. At April 29, 2005, 2,230 shares remain available for future issuances under the program.

Note 8. New Accounting Pronouncements

In November 2004, the Financial Accounting Standard Board (FASB) issued SFAS No. 151, *"Inventory Costs — an Amendment to ARB No. 43, Chapter 4."* This statement amends the guidance in Accounting Research Bulletin (ARB) No. 43, Chapter 4, *"Inventory Pricing,"* to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "*... under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require*

treatment as current period charges. . . ." This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of *"so abnormal."* In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 will not have a material impact on Cyberonics' consolidated operating results or financial condition.

In December 2004, the FASB issued SFAS No. 153, *"Exchange of non-monetary assets"*, an amendment to Opinion APB No. 29. The guidance in APB Opinion No. 29, *"Accounting for non-monetary Transactions,"* is based on the principle that exchanges of non-monetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This statement amends Opinion 29 to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 will not have a material impact on Cyberonics' consolidated operating results or financial condition.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *"Share-Based Payment."* This statement is a revision of FASB Statement No. 123, *"Accounting for Stock-Based Compensation."* This statement supersedes APB Opinion No. 25, *"Accounting for Stock Issued to Employees,"* and its related implementation guidance. This statement establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. This statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This statement does not change the accounting guidance for share-based payment transactions with parties other than employees provided in Statement No. 123 as originally issued and Emerging Issues Task Force (EITF) Issue No. 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."* This statement does not address the accounting for employee share ownership plans, which are subject to American Institute of Certified Public Accountants (AICPA) Statement of Position 93-6, *"Employers' Accounting for Employee Stock Ownership Plans."* We are required to comply with this statement at the beginning of our fiscal year 2007. This statement applies to all awards granted after the required effective date and to awards modified, repurchased or cancelled after that date. The cumulative effect of initially applying this statement, if any, is recognized as of the required effective date. Cyberonics is currently evaluating the effect that the adoption of SFAS No. 123 (revised 2004) will have on Cyberonics' consolidated operating results or financial condition.

Note 9. Income Taxes

The U.S. and foreign components of earnings (loss) before income taxes and the provision for income taxes are presented in this table:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
Earnings (loss) before income taxes:			
Domestic	$(11,638,574)	$7,419,794	$5,964,872
Foreign	(553,661)	(429,496)	(650,378)
	$(12,192,235)	$6,990,298	$5,314,494
Provision for current income tax expense:			
Federal	$ —	$ 52,224	$ 40,505
State and local	—	160,315	89,058
Foreign	26,113	18,250	—
	$ 26,113	$ 230,789	$ 129,563

The following is a reconciliation of the statutory federal income tax rate to Cyberonics' effective income tax rate expressed as a percentage of earnings (loss) before income taxes:

	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
U.S. statutory rate	(34.0)%	34.0%	34.0%
Change in deferred tax valuation allowance	31.8	(34.0)	(29.5)
Foreign taxes	0.2	0.3	0.0
State and local tax provision	0.0	2.3	1.7
Other, net	2.2	0.7	(3.7)
	0.2%	3.3%	2.5%

Significant components of Cyberonics' deferred tax assets and liabilities are as follows:

	April 29, 2005	April 30, 2004
Deferred tax assets:		
Federal net operating loss carryforwards	$ 51,666,992	$ 39,257,321
Foreign net operating loss carryforwards	5,921,787	5,507,602
Federal tax credit carryforwards	4,511,029	4,511,312
State net operating loss carryforwards and other	4,100,938	2,652,233
Deferred compensation expense	763,284	732,379
Accrued expenses	335,588	335,490
Reserves	401,503	442,276
Property and equipment	349,102	290,205
Inventory costs capitalized	277,335	248,408
Total deferred tax assets	68,327,558	53,977,226
Deferred tax valuation allowance	(68,327,558)	(53,977,226)
Net deferred tax assets and liabilities	$ —	$ —

At April 29, 2005, Cyberonics has net operating loss carryforwards of approximately $154 million for federal income tax purposes, which expire during the years 2006 through 2024, and tax credit carryforwards of approximately $4.5 million for federal income tax purposes, which expire during the years 2005 through 2021. At April 29, 2005, Cyberonics has net operating loss carryforwards of approximately $58.2 million for state and local income tax purposes, which expire at various dates beginning in 2005. In August 2004, Cyberonics experienced an ownership change as defined in Section 382 of the Internal Revenue Code (IRC). Cyberonics' ability to utilize credit carryforwards to offset future tax liabilities and utilize certain net operating losses to offset future taxable income may be limited pursuant to IRC Section 382. Cyberonics is subject to examination by the Internal Revenue Service as well as state and local tax authorities.

A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax assets will not be realized. Cyberonics has historically experienced significant operating losses and operates in an industry subject to rapid technological changes. Cyberonics believes there is sufficient uncertainty regarding future taxable income and realizability of deferred tax assets such that a valuation allowance is required to fully offset deferred tax assets for the 52 weeks ended April 29, 2005. Cyberonics continually reviews the adequacy and necessity of the valuation allowance in accordance with the provision of SFAS No. 109. Of the total valuation allowance at April 29, 2005, approximately $21.7 million relates to stock option compensation deductions. The tax benefit associated with stock option compensation deductions will be credited to equity when realized. The valuation allowance increased approximately $14.4 million for the 52 weeks ended April 29, 2005 compared to the 53 weeks ended April 30, 2004 due primarily to an increase in the federal net operating loss carryforwards for tax year 2004.

Note 10. Employee Retirement Savings Plan

Cyberonics sponsors an employee retirement savings plan (the Plan) which qualifies under Section 401(k) of the IRC. The Plan is designed to provide eligible employees with an opportunity to make regular contributions into a long-term investment and savings program. Substantially all U.S. employees are eligible to participate in the Plan beginning with the first quarterly open enrollment date following start of employment. In July 2004, Cyberonics started matching 50% of employees' contributions up to 6% of eligible earnings.

Note 11. Commitments

Post-market Clinical Surveillance. Pursuant to the post-market surveillance conditions specified as part of Cyberonics' FDA marketing approval, Cyberonics is required to conduct clinical follow-up on a limited number of patients from its most recent epilepsy study in order to monitor the safety and tolerability of the VNS Therapy System on an extended basis. Cyberonics expenses the costs related to these long-term follow-up activities as they are incurred and establishes accruals for such costs incurred but not paid as of the respective balance sheet dates.

License Agreements. Cyberonics has executed a license agreement which provides Cyberonics with worldwide exclusive rights under five U.S. patents (and their international counterparts) covering the method and devices of the VNS Therapy System for vagus nerve and other cranial nerve stimulation for the control of epilepsy and other movement disorders, as well as a number of other conditions and disorders. The license agreement provides that Cyberonics will pay a royalty equal to the greater of $36,000 per year or at the rate of three percent of net sales of licensed products during fiscal year 2004 through 2011, after which the royalty rate will decline to one percent for the remaining term of the licensed patents. These patents expire between 2011 and 2022. The license agreement runs for successive three-year terms, renewable at Cyberonics' election. The license agreement, and its periods of extension, may not be terminated by the licensor without cause. Cyberonics' royalty payments pursuant to this agreement are expensed as incurred.

Cyberonics has an agreement with an inventor on two patents co-owned by Cyberonics pursuant to which Cyberonics is obligated to pay 1.0% of the first $10 million of net obesity sales covered by one of the patents and 0.5% of net obesity sales thereafter. The agreement also obligates Cyberonics to pay minimum royalties of $25,000 per year for five years commencing January 1, 2000 and up to $325,000 in additional advanced royalties based on achievement of certain milestones.

Royalty expenses for the 52 weeks ended April 29, 2005, the 53 weeks ended April 30, 2004 and the 52 weeks ended April 25, 2003 were $3,106,000, $4,034,000 and $4,099,000, respectively.

Lease Agreements. Cyberonics leases facilities at its headquarter office and manufacturing facility in Houston, Texas and office space in Zaventem, Belgium under noncancelable operating leases, as well as transportation and office equipment under operating leases. The lease terms provide for tenant improvement allowances which are recorded as deferred rent and amortized, straight-line, as reductions to rent expense over the term of the lease. At April 29, 2005 and April 30, 2004, Cyberonics had approximately $264,000 and $0 of deferred rent, respectively. Scheduled rent increases and rent holidays are recognized on a straight-line basis over the term of the lease.

Future minimum payments relating to these agreements at April 29, 2005 are as follows:

52/53 Weeks Ending on the last Friday of April:	
2006	$2,799,448
2007	2,825,830
2008	2,773,909
2009	2,683,217
2010	1,814,517
Thereafter	366

Cyberonics leased certain manufacturing equipment under long-term capital leases with a 6.56% interest rate that matured in April 2005. Capitalized costs of $646,959 are included in manufacturing equipment at April 29, 2005 and April 30, 2004. Accumulated depreciation amounted to $614,611 and $485,220 at April 29, 2005 and April 30, 2004, respectively.

Cyberonics' rental expense for the 52 weeks ended April 29, 2005, the 53 weeks ended April 30, 2004 and the 52 weeks ended April 25, 2003 amounted to about $2,850,000, $2,174,000 and $1,720,000, respectively.

Other Commitments. At April 29, 2005, Cyberonics had approximately $551,000 in noncancelable commitments related to domestic marketing programs planned for Cyberonics' VNS Therapy System during fiscal year 2006.

Litigation. Cyberonics is involved in legal actions arising in the ordinary course of business. Management does not believe the outcome of such legal actions will have a material adverse effect on Cyberonics' consolidated financial position or results of operations.

Note 12. Concentrations

Cyberonics' cash equivalents, marketable securities and trade accounts receivable represent potential concentrations of credit risk.

Cyberonics minimizes potential concentrations of credit risk in cash equivalents and marketable securities by placing investments in high quality financial instruments and, as required by its corporate investment policy, limiting the amount of investment in any one issuing party. At April 29, 2005, management believes that Cyberonics has no significant concentrations of credit risk related to these assets and has incurred no material impairments in the carrying values of its cash equivalents and marketable securities.

Concentrations of credit risk with respect to trade accounts receivable are limited due to the large number of customers and their dispersion across a number of geographic areas. However, essentially all trade receivables are concentrated in the hospital and healthcare sectors in the U.S. and several other countries and, accordingly, are exposed to their respective business, economic and country-specific variables. Although Cyberonics does not currently foresee a concentrated credit risk associated with these receivables, repayment is dependent upon the financial stability of these industry sectors and the respective countries' national economies and healthcare systems.

We rely upon sole source suppliers for certain of the key components, materials and contract services used in manufacturing the VNS Therapy System. We periodically experience discontinuation or unavailability of components, materials and contract services which may require us to qualify alternative sources or, if no such alternative sources are identified, change our product design. We believe that pursuing and qualifying alternative sources and/or redesigning specific components of the VNS Therapy System, if or when necessary, could consume significant resources. In addition, such changes generally require regulatory submissions and approvals. Any extended delays in or an inability to secure alternative sources for these or other components, materials and contract services could result in product supply and manufacturing interruptions, which could significantly harm our business.

We rely upon favorable reimbursement, coverage and coding for VNS Therapy. Essentially all patients implanted with VNS Therapy are covered by private payers, Medicare or Medicaid. VNS Therapy has specifically approved codes for physicians, surgeons and hospitals. Since reimbursement policies and payment methodologies change on a regular basis, vigilant and ongoing work is necessary to ensure continued access and acceptable reimbursement for patients, physicians and hospitals. Any changes in reimbursement policies or payment methodologies could result in reduced reimbursement, which could significantly harm our business.

Note 13. Geographic Information

Geographic Information:

	Net Sales		
	52 Weeks Ended April 29, 2005	53 Weeks Ended April 30, 2004	52 Weeks Ended April 25, 2003
United States	$ 90,281,978	$100,224,277	$ 95,761,687
International	13,160,592	10,497,222	8,705,311
Total	$103,442,570	$110,721,499	$104,466,998

	Long-Lived Assets	
	April 29, 2005	April 30, 2004
United States	$8,659,804	$8,244,588
International	342,454	279,874
Total	$9,002,258	$8,524,462

Sales are classified according to the country of destination, regardless of the shipping point.

All assets located outside of the U.S. are classified as "International."

Note 14. Quarterly Financial Information — Unaudited

The following table sets forth certain unaudited condensed quarterly financial data for the 52 weeks ended April 25, 2005 and for the 53 weeks ended April 30, 2004. This information has been prepared on the same basis as the consolidated financial statements and all necessary adjustments have been included in the amounts below to present fairly the selected quarterly information when read in conjunction with the consolidated financial statements and notes thereto. Historical quarterly financial results and trends may not be indicative of future results.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Totals(1)
52 Weeks Ended April 29, 2005					
Net Sales	$25,149,322	$25,420,794	$26,212,509	$26,659,945	$103,442,570
Gross Profit	20,366,190	21,699,342	22,458,886	23,342,411	87,866,829
Net loss	(2,908,732)	(2,026,248)	(817,287)	(6,466,081)	(12,218,348)
Diluted loss, per share(1)	(0.12)	(0.08)	(0.03)	(0.26)	(0.51)
53 Weeks Ended April 30, 2004					
Net Sales	$26,682,274	$29,296,746	$28,434,662	$26,307,817	$110,721,499
Gross Profit	22,688,321	24,939,257	24,080,327	22,718,032	94,425,937
Net earnings (loss)	2,561,990	3,848,003	1,595,046	(1,245,530)	6,759,509
Diluted earnings (loss) per share(1)	0.10	0.15	0.06	(0.05)	0.26

(1) EPS in each quarter is computed using the weighted-average number of shares outstanding during that quarter while EPS for the full year is computed using the weighted-average number of shares outstanding during the year. Thus, the sum for the four quarters' EPS does not necessarily equal the full year EPS.

Investor Information

INVESTOR RELATIONS CONTACT
Shareholders, securities analysts, and prospective investors are welcome to call, write, or telefax Cyberonics with questions or requests for additional information. Inquiries should be directed to:

Cyberonics, Inc.
Investor Relations
Cyberonics, Inc.
100 Cyberonics Blvd.
Houston, Texas 77058
Tel 800.332.1375
Fax 281.218.9332
In addition, Cyberonics encourages interested investors to visit the Company's web site at **www.cyberonics.com** for direct access to company news and investment information.

TRANSFER AGENT AND REGISTRAR
Communications concerning stock holdings, lost certificates, transfers of shares, duplicate mailings, or changes of address should be directed to:

Cyberonics, Inc.
Investor Relations
100 Cyberonics Blvd.
Houston, TX 77058
Tel 800.332.1375
Fax 281.218.9332

FINANCIAL RESULTS AND QUARTERLY REPORTS
Quarterly results are generally released in August, November, February and May (year-end). The Company's Quarterly Reports on Form 10-Q are mailed to all shareholders who have requested to be included on our mailing list in September, December and March. Results are released and posted on Company's web site: www.cyberonics.com.

CASH DIVIDENDS
Cyberonics has never paid a cash dividend on its common stock and does not anticipate a change in this policy in the foreseeable future. The Company currently intends to retain any future earnings to fund the development and growth of its business.

STOCK PRICES AND TRADING DATA
The Company's common stock trades on the National Association of Securities Dealers Automated Quotation (NASDAQ) National Market System under the symbol "CYBX." Stock price quotations are printed daily in major newspapers including *The Wall Street Journal.*

As of May 20, 2005, there were 24,781,665 shares of common stock outstanding, of which approximately 13.1% were owned by the Company's officers and directors.

The ranges of high and low prices per share for the Company's common stock for Fiscal 2005 and 2004 are set forth below. Price data reflect actual transactions. In all cases, prices shown are inter-dealer and do not reflect mark-ups, markdowns, or commissions.

STOCK PRICE RANGE
2004-2005

Fiscal Year Ended April 30, 2004

	HIGH	LOW
First Quarter	$ 28.35	$ 18.57
Second Quarter	34.97	26.00
Third Quarter	38.74	26.19
Fourth Quarter	34.10	20.65

Fiscal Year Ended April 29, 2005

	HIGH	LOW
First Quarter	$ 40.07	$ 16.78
Second Quarter	28.69	12.78
Third Quarter	26.24	18.10
Fourth Quarter	46.71	24.20

This annual report contains statements concerning our strategy to become a dominant neuromodulation industry leader by developing the U.S. TRD market, rejuvenating growth and penetration in the U.S. epilepsy market, increasing our investment in rest-of-world markets, developing new VNS indications, and exploiting non-VNS neuromodulation opportunities. While these statements reflect our current plans, we cannot assure you that they will prove correct. For a discussion of the challenges and risks we face in achieving these plans, please see the enclosed Annual Report on Form 10-K, including the discussion appearing under the header "Forward Looking Statements."

Corporate Information

BOARD OF DIRECTORS

Robert P. Cummins
Chairman of the Board of Directors
Chief Executive Officer and President
Cyberonics, Inc.

Stanley H. Appel, M.D.[1,3]
Professor and Chairman
Department of Neurology
Methodist Neurological Institute
Chairman of Cyberonics
Scientific Advisory Board

Tony Coelho[1,3,4]
Business Consultant
Former Majority Whip
U.S. House of Representatives

Guy C. Jackson[2]
Business Consultant
Former Partner for Ernst & Young, LLP.

Kevin S. Moore[1,3,4]
President, The Clark Estates, Inc.

Alan J. Olsen[2]
Founder
Robomedica, Inc.

Michael J. Strauss, M.D.[2]
Business Consultant

Reese S. Terry, Jr.[1,3]
Business Consultant
Cyberonics Founder

[1] Denotes member of the Compensation Committee
[2] Denotes member of the Audit Committee
[3] Denotes member of the Nominating/ Coporate Governance Committee
[4] Denotes member of the Strategic Advisory Committee

OFFICERS

Robert P. Cummins
Chairman of the Board of Directors
Chief Executive Officer and President

Pamela B. Westbrook
Vice President, Finance and Administration
Chief Financial Officer and Treasurer

Michael A. Cheney
Vice President, Marketing

W. Steven Jennings
Vice President, Sales

Shawn P. Lunney
Vice President, Market Development and Engineering

George E. Parker
Vice President, Human Resources

Richard L. Rudolph, M.D.
Vice President, Clinical and Medical Affairs
Chief Medical Officer

Randal L. Simpson
Vice President, Operations

Alan D. Totah
Vice President, Regulatory Affairs and Quality

David S. Wise
Vice President, General Counsel and Secretary

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Equal Opportunity Employer
Cyberonics is an equal opportunity employer.

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