

United States Court
Southern District of Texas
FILED

JUN 17 2005

Michael N. Milby, Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS

RICHARD DARQUEA, On Behalf of Himself
and All Others Similarly Situated,

Plaintiff,

vs.

CYBERONICS INC., ROBERT P.
CUMMINS, RICHARD L. RUDOLPH, ALAN
TOTAH AND PAMELA B. WESTBROOK,

Defendants.

Civil Action No.

H 05 - 2121

JURY TRIAL DEMANDED

**CLASS ACTION COMPLAINT FOR VIOLATIONS
OF FEDERAL SECURITIES LAWS**

CR# 2232

Plaintiff, individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based on, inter alia, the investigation conducted by and through his attorneys, which included, amongst other things, a review of the defendants' press releases, Securities and Exchange Commission ("SEC") filings by Cyberonics, Inc. ("Cyberonics" or the "Company"), communications to the Company from the US Food and Drug Administration ("FDA") and media reports about the Company. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CASE

1. This is a securities class action on behalf of plaintiff and all other persons or entities, except for defendants, who purchased or otherwise acquired Cyberonics securities ("the "Class") during the period June 15, 2004 and through October 1, 2004, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "1934 Act").

JURISDICTION AND VENUE

2. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise under §§10(b) and 20(a) of the 1934 Act and Rule 10b-5.

3. Venue is proper in this District pursuant to §27 of the 1934 Act. The corporate headquarters of Cyberonics are located in this District.

4. In connection with the acts and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and the facilities of the national securities exchanges.

PARTIES

5. Plaintiff, as set forth in the accompanying certification purchased shares of Cyberonics stock at artificially inflated prices during the Class Period as described in the attached certification and was damaged thereby.

6. Defendant Cyberonics designs, develops, manufactures and markets medical devices, including the Cyberonics Implanted Vagus Nerve Stimulation (VNS) System, submitted under a premarket approval application supplement (“Implanted Vagus Nerve Stimulation System, PMA P970003/S50,” “PMA-S”) to FDA as a therapy for depression. Cyberonics maintains its corporate and administrative offices, where the Company’s day-to-day business activities are conducted at 100 Cyberonics Blvd., Houston Texas 77058

7. Defendant Robert P. Cummins (“Cummins”) was Chairman and CEO of Cyberonics.

8. Defendant Richard L. Rudolph (“Rudolph”) was Vice President of Clinical and Medical Affairs and Chief Medical Officer (“CMO”) of Cyberonics. During the Class Period, defendant Rudolph sold approximately \$1.91 million worth of his Cyberonics stock.

9. Defendant Alan Totah (“Totah”) was Vice President of Regulatory Affairs of Cyberonics. During the Class Period, defendant Totah sold approximately \$76,000 worth of his Cyberonics stock.

10. Defendant Pamela B. Westbrook (“Westbrook”) was Vice President of Finance and Administration and CFO of Cyberonics.

11. The individuals named as defendants in ¶¶7-10 are referred to herein as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Cyberonics quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was

provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein as those statements were the result of the collective actions of the Individual Defendants.

SCIENTER

12. In addition to the above-described involvement, each Individual Defendant had knowledge of Cyberonics' problems. Each defendant was motivated to conceal such problems. Defendant Westbrook, serving as CFO, provided for financial reporting and communications with the market. Communications with the market, including conference calls, as well as internal reports showing Cyberonics' forecasted and actual growth were prepared under her direction. Defendant Cummins, serving as Chairman and CEO also provided for communications with the market, including conference calls, as well as reports on Company operations, financing and press releases issued by the Company. Defendants Rudolph, as Chief Medical Officer, and Totah, as Vice President for Regulatory Affairs, had joint responsibility for communications with the US Food and Drug Administration ("FDA"), regarding regulatory matters, the PMA-S for the VNS device for the depression indication and communications before the Neurological Devices Panel of the FDA Medical Devices Advisory Committee. Each Individual Defendant sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. Each individual defendant also owed a duty to the Company and its shareholders not to trade on inside information.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

13. Each defendant is liable for (a) making false statements, *or* (b) failing to disclose adverse facts known to him about Cyberonics. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Cyberonics publicly traded securities was a success, as it: (a) deceived the investing public regarding Cyberonics's prospects and business; (b) artificially inflated the prices of Cyberonics's publicly traded securities; (c) allowed defendants to sell approximately \$1.98 million dollars of their own shares at inflated prices; and (d) caused plaintiff and other members of the Class to purchase Cyberonics's publicly traded securities at inflated prices.

OVERVIEW OF THE CASE

14. The Cyberonics Vagus Nerve Stimulation (VNS) Therapy System is implantable medical device for the treatment of epilepsy and other debilitating chronic disorders. The device is already approved by the Food and Drug Administration (FDA) as an adjunctive therapy for reducing the frequency of seizures in patients over 12 years of age with partial onset seizures that are refractory or resistant to drugs. The Company claims that they are engaged in clinical investigation of the VNS device for various other indications, including depression, anxiety disorders.

15. The Neurological Devices Panel of the Medical Devices Advisory Committee for the US Food and Drug Administration ("FDA") met with the Company on June 15, 2004, to consider the use of the VNS device to treat depression disorders. Representatives of the FDA detailed serious safety and efficacy concerns and the committee provided, at best, recommended to FDA a path for a "conditional approval," for the use of the device for the depression indication.

16. The Class Period begins on this same day -- June 15, 2004 -- as the Company aggressively promoted and misled investors in its press release and

communications, indicating that the advisory committee had presented defendants with an outright victory, even though Company officials participating in the advisory committee meeting understood the conditional nature of the committee's decision, particularly in the context of ongoing disagreements with FDA regarding study plans and safety issues facing the PMA-S for the device.

17. Moreover, unbeknownst to investors and advisory committee members, defendants were engaged in serious violative manufacturing and quality practices that would have a serious negative impact on prospects for product approval. These violations involved poorly managed handling of product complaints, including cases of device reimplantation, unauthorized pediatric use, death reports and poorly investigated occurrences of manufacturing defects.

18. Well aware of true nature of the serious issues facing FDA approval of the PMA-S for the depression indication, Company insiders sold over \$1.98 million of Company stock during the Class Period.

19. On August 12, 2004, the Company announced the receipt of the FDA nonapprovable ("rejection") letter for the use of the depression device. Faced with the worst possible outcome for approval of the VNS device, the Company's shares plummeted -- to \$9.59 -- losing 40% percent of their value and closing at \$14.36 on volume of over 27 million shares.

BACKGROUND AND DEFENDANTS'
PRE-CLASS STATEMENTS

20. On April 11, 2001, the Company issued a press release entitled, "Cyberonics Inc. (CYBX) Acknowledges Receipt Of FDA Warning Letter Regarding Medical Device Reporting." The press release referred to the posting of an FDA "Warning Letter" detailing serious violations of medical device reporting procedures as required by the Medical Device Reporting Regulation (MDR). The letter stated in part:

March 23, 2001
Ref: 2001 -DAL-WL-I 3
WARNING LETTER
CERTIFIED MAIL
RETURNED RECEIPT REQUESTED
Mr. Robert (Skip) P. Cummins
President and Chief Executive Officer
Cyberonics, Inc.
16511 Space Center Blvd., Suite 600
Houston, Texas 77058

Dear Mr. Cummins:

During an inspection of your firm located in Houston, Texas, on January 22 to 25, 30 and February 1, 2001, our investigator determined that your firm manufactures the NeuroCybernetic Prosthesis (NCP®) System, a vagus nerve stimulator indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with medically intractable partial seizures. The NCP® System includes a pulse generator, programming wand, programming software, bipolar leads, tunneling tool, and accessory pack. These products are medical devices as defined by Section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act in that medical device reporting procedures were not implemented and maintained and information was not submitted to FDA as required by the Medical Device Reporting Regulation (MDR), as specified in Title 21, Code of Federal Regulations (CFR), Part 803. Specifically:

1. Failure to submit reports within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any sources, that reasonably suggests a device marketed by your firm may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1). For example, approximately 60 events, received by your firm between 3/15/99 and 12/20/00, that suggest your device may have caused or contributed to a death and 102 infection events received between 1/98 and 12/00 were not reported to FDA until 2/22/01 after completion of the inspection.

Our inspection revealed that your MDR event files either were incomplete or do not contain sufficient records of investigations to change the alleged association between the devices and the deaths or to support your decision making process that these death events were or were not reportable within the 30-day reporting time frame [see FDA-item 1 and 2]. Your firm can not postpone its decision to report the event while it

continues to deliberate or collect additional information. Therefore, your firm must submit a report for each event within the 30-day time frame. If subsequent information or evaluation alters your firm's decision, then a supplemental report should be submitted to update the status of the MDR report.

Regarding the infection events, your firm indicated to our investigator that adverse events in which the NCP® Systems were explanted due to the occurrence of infections were known events that are addressed in the device labeling; thus, no MDR reports had been submitted prior to the inspection. We have concluded that these infection events meet the reporting threshold and therefore should have been submitted to FDA because the explanation the NCP® System amounts to medical or surgical intervention to preclude impairment of a body function or permanent damage to a body structure.

Events described in medical device labeling are not exempt by statute or the MDR regulation from the reporting requirements set forth in 21 CFR 803.

2. Failure to establish and maintain MDR event files [21 CFR 803.18(b)(1)(i)] and failure to investigate and evaluate the cause of MDR reportable events [21 CFR 803.50(b)(2)]. For example, records of investigation for MDR reportable events were not complete to show that reasonable efforts were made to obtain missing information, evaluate returned devices, and determine the relationship of the devices to the reported incidents [FDA-483 Item 1 and 2].

3. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100]. For example:

(a) Field reports of death events were not classified as complaints and lacked adequate treatment data (e.g., missing programming history, incomplete patient follow-up forms, no follow-up on product returns) to allow for effective data analysis [FDA-item 3].

(b) The firm's CAPA procedures do not address how results from trending analysis are to be used to initiate corrective action for lead anomalies (i.e., lead breaks, high impedance) [FDA-483 Item 4].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or

assessing civil money penalties. Also, until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when awarding government contracts.

We acknowledge the receipt of your firm's response, dated February 22, 2001, provided to us at the district meeting on February 23, 2001, and additional responses faxed on March 1 and 12, 2001, responding to the inspectional observations (FDA-483, copy attached) issued to Ms. Annette Zinn, Director and Senior Counsel, Regulatory Affairs, at the completion of the inspection. As part of your firm's corrective action plan to address the system-level issues, your firm has now submitted all death (83) and infection (116) events to FDA, made some organizational changes, hired additional senior management staff, revised and added procedures, provided updated employee training to address the shortcomings in the areas of complaint handling and CAPA activities, and plan to utilize a third party auditor to facilitate improvement in your quality systems. We consider your responses to be adequate and will verify the effectiveness of your corrective action at the next scheduled inspection.

Further responses should be sent to Mr. Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions regarding this letter, please contact Mr. Ta at (214) 655-5310.

Sincerely yours,

/s/

Michael A. Chappell
Dallas District Director
Enclosure(s)
cc: Mr. Alan D. Totah
Vice President of Regulatory Affairs and Quality Assurance
Cyberonics, Inc.
16511 Space Center Blvd., Suite 600
Houston, Texas 77058
Ms. Annette M. Zinn
Director and Senior Counsel, Regulatory Affairs
Cyberonics, Inc.
16511 Space Center Blvd., Suite 600
Houston, Texas 77058

21. On January 22, 2002, the Company issued a press release entitled "CYBERONICS ANNOUNCES ACUTE DEPRESSION PIVOTAL STUDY RESULTS - Conference Call Scheduled for 10:00 AM EST on Tuesday, January 22, 2002." The press release stated in part:

HOUSTON, Texas, January 22, 2002 -- Cyberonics, Inc. (NASDAQ:CYBX) today announced acute results in the pivotal depression study (D-02) assessing the efficacy of Vagus Nerve Stimulation Therapy (VNS Therapy™) in 235 people with chronic or recurrent depression. There were no statistically significant differences found when 12-week acute treatment and placebo group response and remission rates were compared. A thorough review of all acute data and long-term data is underway. Preliminary review of the treatment group stimulation parameters suggests that over 50% of the patients in the treatment group received insufficient stimulation to derive benefit from VNS Therapy.

“Cyberonics was initially surprised by these acute depression pivotal study results considering the encouraging acute and long-term data from the 60-patient pilot study and the depression mechanism of action findings,” commented Robert P. Cummins, Cyberonics’ Chairman and Chief Executive Officer. “Our preliminary detailed review of the acute and long-term data from the study suggests that response and remission rates improve over time similar to what was seen in the pilot study, but that inconsistent with our previous epilepsy and depression studies, over 50% of the patients in the treatment group may have been under-stimulated and did not receive efficacious doses of VNS Therapy during the entire 10-week acute treatment period. Our clinical development team led by Richard L. Rudolph, M.D., Vice President of Clinical and Medical Affairs & Chief Medical Officer, is rapidly completing their review of the pivotal study results. At this point, it appears as though we will: 1) request an amendment to the D-02 protocol to require adequate doses of VNS Therapy during the long-term follow-up phase of the study, and 2) request approval to convert our conditionally-approved 550-patient Phase IIIB D-08 protocol into a 300-patient 6-month randomized, double-blind, placebo-controlled confirmatory pivotal study to prove that VNS Therapy is an effective and tolerable long-term maintenance therapy for patients with chronic or recurrent depression.”

Dr. Rudolph added, “Although we are disappointed in the acute study results, it is noteworthy that approximately 50% of clinical trials submitted in recent antidepressant New Drug Applications were failed trials. Our preliminary review suggests that the lack of a significant difference between treatment and placebo groups represents a failed study, not a failure of the therapy. We remain confident in the unique value of VNS Therapy as a treatment for depression. Although our depression PMA-S submission may be delayed for two or three years, when it is submitted, it will be supported by compelling long-term clinical evidence that VNS Therapy is an effective and tolerable long-term maintenance therapy which could benefit up to 4 million people with chronic or recurrent depression. The need is still there and the VNS Therapy investigators and patients are still enthusiastic. We expect that we will have FDA approval for our new protocol by June 2002.”

22. On January 7, 2004, the Company issued a press release entitled "CYBERONICS ACCELERATES DEPRESSION PLAN AND REVISES FISCAL 2004 GUIDANCE." The press release stated in part:

Cyberonics, Inc. (NASDAQ:CYBX) today announced acceleration of its U.S. depression plan and revised guidance for the third and fourth quarters of its fiscal year ending April 30, 2004.

"We are accelerating all aspects of our current U.S. depression plan by four months," commented Robert P. ("Skip") Cummins, Cyberonics' Chairman and Chief Executive Officer. "That acceleration is based on recent communications with FDA and on the proposed CDRH Neurological Devices Panel meeting dates published on FDA's website (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/search.cfm>). While we have yet to receive any notice from FDA confirming the Panel date for the review of our proposed depression indication, we were notified in the letter from FDA formally accepting the PMA-S for filing that "a meeting of the Neurological Devices Panel will be held at which your PMA-S will be reviewed." Furthermore, the proposed Neurological Devices Panel meeting dates for 2004 are April 1 and 2, August 5 and 6 and October 28 and 29. Considering that there is currently no FDA-approved treatment for the 4.4 million Americans who today suffer from treatment resistant depression, and given the Expedited Review status and FDA's apparent progress with their interactive review of Cyberonics' depression PMA-S, we believe it prudent to accelerate planned fiscal 2005 depression investments into fiscal 2004 and base our revised business plan and the scale-up of our organization on an April Panel date."

HISTORY OF VNS THERAPY DEPRESSION STUDIES

Cyberonics' comprehensive VNS Therapy depression study program began with the first pilot study implant in July 1998. The depression study program includes the following studies: a 60-patient acute and long-term pilot study (D-01); a 235-patient double blind, randomized, placebo controlled 8-week fixed dose acute pivotal study with a long-term extension (D-02); a 127-patient long-term observational study of patients with chronic or recurrent treatment resistant depression treated only with treatment as usual (D-04); neuroimaging, neurochemical and sleep mechanism of action studies; and several healthcare utilization and cost effectiveness studies. The patients in these studies were suffering from chronic or recurrent treatment resistant depression. In the D-02 and D-04 studies, the average lifetime illness exceeded 25 years and the average duration of the current depressive episode exceeded 48 months.

Highly statistically and clinically significant acute and long-term response and remission rates were observed in the D-01 pilot study. The first implant in the D-02 pivotal study occurred in August 2000. In January 2002, Cyberonics announced that although clinically meaningful,

the difference in the D-02 treatment and placebo group HRSD-24 response rates at the end of the eight-week fixed dose acute study was not statistically significant. In September 2002, after determining the likely contributors to the lack of statistical significance, Cyberonics submitted a revised, prospective long-term pivotal study analysis plan to FDA. That plan is designed to determine the statistical and clinical significance of the long-term improvements from baseline in all D-02 study patients treated over a one-year period with VNS Therapy and treatment as usual and to determine the causal relationship between those outcomes and VNS Therapy by comparing those D-02 outcomes with the outcomes of the D-04 patients treated only with treatment as usual.

In January 2003, Cyberonics announced that the one-year data from its D-02 depression pivotal study, analyzed pursuant to the D-02 analysis plan submitted to the FDA in September 2002, showed statistically and clinically significant improvements compared to baseline. Statistical significance was determined using a repeated measures linear regression technique to analyze improvements from pre-treatment baseline in the 24-item Hamilton Rating Scale (HRSD-24) during one year of VNS Therapy. The HRSD-24 improvements observed over the first year were highly significant with a p-value < 0.001. The secondary measures of statistical significance showed similarly positive results. Clinical significance was determined by analyzing the percent of patients who showed a sustained HRSD-24 response between nine and 12 months of treatment with VNS Therapy. In the absence of published literature that defines a long-term success criterion, Cyberonics' psychiatric clinical advisors suggested that a sustained response rate of approximately 30% would be significant. Approximately 30% of the patients from the original acute treatment group and 25% of all patients in the analysis showed a sustained response between months nine and 12.

In July 2003, Cyberonics announced that the preliminary one-year results from its D-02 VNS Therapy™ depression pivotal study and D-04 companion study of chronic and recurrent treatment resistant depression, analyzed pursuant to the D-02 analysis plan submitted to the U.S. Food and Drug Administration (FDA) in September 2002, showed a highly statistically significant causal relationship (p-value < 0.001) between VNS Therapy and the depression improvements from baseline observed in the D-02 VNS Therapy study. The causal relationship between VNS Therapy and the D-02 patients' one-year outcomes was determined using a repeated measures linear regression analysis to compare depression improvements as measured by the Inventory of Depressive Symptomatology-Self Report (IDS-SR) over one year in 205 D-02 patients receiving VNS Therapy and treatment as usual with the IDS-SR outcomes of 124 patients in a companion study, D-04, receiving only treatment as usual. In D-04, patients with chronic or recurrent treatment resistant depression who met the critical D-02 inclusion criteria were treated with standard medical management at 13 total study sites including 12 of the 21 D-02 study sites. Statistically and clinically significant differences in the physician and patient reported D-02 and D-04 patients' one-year response and remission rates were also observed. One-year response rates, defined as at least a 50% improvement in depression symptoms as measured by the IDS-SR and HRSD-24 (24 item clinician rated Hamilton Rating Scale for Depression) were 21% and 30%,

respectively in D-02 and 12% and 13%, respectively in D-04. One-year remission rates, defined as the percentage of patients free of depressive symptoms after one year of treatment, were 16% and 17%, respectively in D-02 and 5% and 7%, respectively in D-04.

In October 2003 Cyberonics submitted an 87-volume PMA-Supplement (PMA-S) to the U.S. Food and Drug Administration (FDA) seeking approval to market the VNS Therapy System in the United States as "as an adjunctive long-term treatment of chronic or recurrent depression for patients who are experiencing a major depressive episode that has not had an adequate response to two or more antidepressant treatments." That PMA-S included acute and one-year data and analyses on 335 patients treated with VNS plus treatment as usual and 125 patients treated only with treatment as usual. FDA accepted the depression PMA-S for filing on December 9, 2003. The official filing date for regulatory timeline purposes is October 27, 2003. Cyberonics expects to receive FDA's decision regarding approvability of the depression PMA-S by July 2004.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS
MADE DURING THE CLASS PERIOD

23. On June 15, 2004, the Company issued a press release entitled, "FDA ADVISORY PANEL RECOMMENDS APPROVAL OF CYBERONICS' DEPRESSION DEVICE - Conference Call Scheduled for June 16, 2004 at 4:00 PM EDT." The press release stated in part:

HOUSTON, Texas, June 15, 2004 -- Cyberonics, Inc. (NASDAQ:CYBX) announced that the Neurological Devices Panel of FDA's Medical Devices Advisory Committee today 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 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." Regarding conditions, 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. FDA's Division of General and Restorative Neurological Devices will consider the deliberations, vote and recommendation of the Advisory Panel and make the final decision on approval of the VNS Therapy System for the proposed indication for use.

"The Panel's recommendation represents a major step forward toward U.S. availability of the first FDA-approved, safe, tolerable and effective long-term treatment for patients with treatment-resistant

depression,” commented Robert P. (“Skip”) Cummins, Cyberonics’ Chairman of the Board and Chief Executive Officer. “Millions of Americans today suffer from treatment-resistant depression (TRD), a devastating, lifelong and life-threatening illness. According to published studies, 15% of previously hospitalized patients commit suicide and annual depression treatment costs in the United States exceed \$30 billion including \$13.7 billion for drugs alone. Today’s Panel vote suggests that not only was there agreement on the significant unmet need, but also that the comprehensive one-year data and analyses on 460 patients included in Cyberonics’ PMA-Supplement demonstrated the safety and effectiveness of VNS Therapy as an adjunctive long-term treatment for chronic or recurrent treatment-resistant depression.

“Cyberonics is looking forward to working with FDA to finalize labeling that will ensure informed use of VNS Therapy, implement the Panel’s recommendations and obtain a timely approvability decision,” continued Mr. Cummins. “The Panel’s recommended conditions are consistent with Cyberonics’ depression plans and epilepsy history, including the proposed depression patient registry, which will be similar to our existing epilepsy registry. The Panel’s vote is a tribute to the patients, families, psychiatrists and other clinicians whose courage, determination and pioneering spirit made the last six years of depression clinical studies possible. Special thanks go to (1) the six VNS patients, Drs. John Rush and Harold Sackeim, the American Psychiatric Association and the Depression and Bipolar Society of America for speaking at today’s meeting, (2) the Advisory Panel and FDA for their timely reviews of our PMA-Supplement and all supporting information and (3) last but not least to the dedicated men and women on Cyberonics’ depression team led by Dr. Richard Rudolph, Vice President of Clinical and Medical Affairs and Chief Medical Officer and Alan Totah, Vice President of Regulatory Affairs and Quality for their unwavering commitment to the 4 million Americans and their families suffering with TRD.

“Cyberonics’ mission is to improve the lives of people touched by epilepsy, depression and other chronic illnesses that prove to be treatable with our patented therapy, VNS,” concluded Mr. Cummins. “The plan to accomplish our mission in epilepsy in fiscal 2005 has been implemented and the plan to properly scale our organization to accomplish our mission in depression will be implemented as soon as we are confident of depression approval.”

24. The press release of June 15, 2004, was false and misleading because defendants knew that a number of safety-related issues for the VNS device remained unresolved.

25. On June 18, 2004, defendant Richard L. Rudolph, CMO of Cyberonics, sold 2,905 shares of the Company’s stock, for proceeds of \$107,485.

26. On June 25, 2004, defendant Richard L. Rudolph, CMO of Cyberonics, sold 50,000 shares of the Company's stock, for proceeds of \$1,803,000.

27. On June 28, 2004, defendant Alan D. Totah, Vice President of Regulatory Affairs of Cyberonics, sold 1,410 shares of the Company's stock, for proceeds of \$51,042.

28. On August 11, 2004, the Company issued a press release entitled, "CYBERONICS REPORTS Q1 RESULTS - Conference call scheduled for 4:30 PM EDT." The press release stated in part:

HOUSTON, Texas, August 11, 2004 -- Cyberonics, Inc. (NASDAQ:CYBX) today announced financial results for the first quarter ended July 30, 2004 of its fiscal year ending April 29, 2005. Net sales were \$25.1 million, compared to net sales of \$26.7 million for the quarter ended July 25, 2003. U.S. net sales for the first quarter were \$22.5 million compared to U.S. net sales of \$25.0 million for the first quarter last year. International sales for the first quarter were \$2.6 million, compared to \$1.7 million for the first quarter last year.

Robert P. ("Skip") Cummins, Cyberonics' Chairman of the Board and Chief Executive Officer commented, "Cyberonics' goals for fiscal 2005 are to maintain our epilepsy business while at the same time obtaining regulatory approval and successfully launching VNS Therapy™ as a treatment for chronic or recurrent treatment-resistant depression. We made good progress towards those objectives in the first quarter. In Q1, Cyberonics not only obtained a favorable FDA Advisory Panel depression recommendation, but we also prudently managed our depression investments to report a better than planned net loss and positive cash flow."

"Depression investments are both direct and indirect," continued Mr. Cummins. "In Q1, direct new indications expenses were essentially on plan at \$3.4 million. Indirect depression investments increased in Q1 and were made primarily by Cyberonics' U.S. sales and operations departments. A successful depression launch will require approximately six months to adequately scale Cyberonics' sales and operations organizations and processes to accomplish our mission both in epilepsy and depression. A delicate balance between the regulatory approval process and a successful launch must be maintained with investments triggered by regulatory milestones. One such milestone was the favorable Advisory Panel recommendation that triggered (1) an investment of U.S. epilepsy sales resources in depression pre-launch activities and (2) the commencement of the recruiting process to identify and qualify the additional sales personnel necessary to support depression. Those two

investments are reflected in a sequential increase in administration expenses and a sequential decrease in U.S. sales. The other Q1 indirect depression investment was made in operations. In Q1 a planned one-time doubling of production to evaluate the scalability of Cyberonics' manufacturing personnel, equipment and processes highlighted several opportunities for improvements that were made in Q1 with a one-quarter impact on gross margin."

"We continue to work with FDA to obtain a favorable depression decision," concluded Mr. Cummins. "Regulations and precedents would suggest that FDA should make its decision by October. We are optimistic that FDA's decision will be favorable considering that (1) all PMA-Supplements with Expedited Review status and a favorable Panel recommendation in the last seven years have been approved by FDA, (2) 4.4 million Americans suffering with treatment-resistant depression today have no FDA-approved, safe and effective long-term treatment, (3) VNS Therapy is the only anti-depressant to have Expedited Review status, (4) FDA's Advisory Panel including four deputized psychiatrists voted in favor of approval with straightforward conditions, (5) the one-year data from the VNS studies shows remarkable safety and efficacy in a group of patients with extreme, previously unstudied levels of treatment-resistant depression, and (6) widespread support for approval has been expressed by psychiatric thought leaders, patients and payers."

"Our guidance for the second quarter reflects planned progress in depression and an increase in depression spending," commented Pamela B. Westbrook, Vice President, Finance and Administration and Chief Financial Officer. "We expect that direct new indications expenses will increase to at least \$6 million and that indirect investments to properly scale and train our U.S. sales organization will also increase. As a result, we expect sales for the second quarter to be essentially flat versus Q1 at \$25 million and that gross margin will be 84%. Although we are not planning to hire the majority of the sales personnel to support a depression launch until we receive a formal communication from FDA, we expect that the net loss for the quarter will be approximately \$9 million or \$0.38 per fully diluted share reflecting an increase in direct and indirect depression spending. With our strong balance sheet, including \$62 million in cash, Cyberonics has more than adequate capital to internally fund its growth and development going forward."

29. The press release of August 11, 2004 was false and misleading due to strong FDA concerns regarding the safety assessment during the clinical trials.

30. On August 12, 2004, the Company issued a press release entitled "FDA IGNORES PANEL RECOMMENDATION AND DETERMINES CYBERONICS' EXPEDITED REVIEW DEPRESSION PMA-SUPPLEMENT NOT APPROVABLE - 4.4 Million Americans with treatment-resistant depression left with no long-term treatment option." The press release stated in part:

HOUSTON, Texas, August 12, 2004 -- Cyberonics, Inc. (NASDAQ:CYBX) today announced that late yesterday it was notified by FDA in writing that "notwithstanding their (the Neurological Devices Panel's) recommendation, we regret to inform you that (your) PMA-Supplement, absent additional information, must be considered not approvable." FDA's stated reasons included worsening depression, potential biases stemming from a non-randomized control and an inability to distinguish one-year VNS effects from placebo and concomitant treatment effects.

"We are shocked and bewildered by FDA's decision to ignore its expert Advisory Panel's recommendation," commented Robert P. ("Skip") Cummins, Cyberonics' Chairman of the Board and Chief Executive Officer. "FDA's Center for Neurological and Restorative Devices had no prior depression experience before the VNS submission and as a result, FDA deputized four of the seven voting members of its expert Advisory Panel. All four of these deputized members were psychiatrists, including three who also serve on the antidepressant drug Advisory Panel. All of the reasons cited in yesterday's not-approvable letter were addressed at the Panel meeting on June 15 prior to the Panel's vote recommending approval. FDA has now chosen inexplicably to ignore not only the recommendation of its panel of experts, but also the strong recommendations of numerous psychiatric thought leaders and the compelling testimony and needs of people with treatment-resistant depression who today have no long-term treatment for their lifelong and life-threatening illness."

"Depression is the leading cause of disability for women in the U.S., and every month an estimated 2,500 Americans with treatment-resistant depression commit suicide," continued Mr. Cummins. "The VNS studies targeted patients with extreme treatment-resistant depression that are excluded from other antidepressant studies, including studies of electro-convulsive therapy (ECT). Despite the extreme treatment resistance of the VNS patients, after one year of treatment, one out of six were depression free and 56% had realized a meaningful benefit. Most importantly, approximately 70% of the VNS responders sustained their response out to two years. By comparison, an active control group of similarly resistant patients treated for one year with currently available treatments (no VNS) predictably showed minimal response and no sustained response. Once again, FDA's specially chosen Advisory Panel of experts considered this one-year data to be compelling and sufficient to recommend approval."

"This is the first Expedited Review PMA-Supplement in history with a favorable Panel recommendation that has been determined by FDA to be not approvable," concluded Mr. Cummins. "In its letter, FDA seems to be rationalizing its unprecedented decision based on FDA's seemingly arbitrary preference for a randomized controlled study that is neither required by the regulations nor the norm in the majority of device approval precedents reported by FDA in a recent CDRH Staff College Report. Apparently, FDA believes that the absence of a randomized control is adequate justification to leave 4.4 million Americans at significant suicide

risk without a treatment option. FDA's expert Advisory Panel, people living with treatment-resistant depression, psychiatric thought leaders, payers and all of us at Cyberonics strongly disagree."

"We are in the process of arranging a meeting with senior FDA management to discuss their letter," commented David S. Wise, Cyberonics' Vice President and General Counsel. "We are actively considering all regulatory and legal options, including those successfully employed by other device companies to reverse inexplicable decisions and obtain PMA approvals."

31. The press release of August 12, 2004, was false and misleading because defendant Cummings actively misrepresented the FDA action as unfair, arbitrary and unprecedented, on the basis of issues related to clinical studies design.

32. On August 20, 2004, defendants issued a press release entitled, "CYBERONICS ACKNOWLEDGES ANSI PURCHASE OF 3.5 MILLION SHARES AND EXPRESSES NO INTEREST IN ANY MERGER OR COMBINATION." The press release stated in part:

HOUSTON, Texas, August 20, 2004 -- Cyberonics, Inc. (NASDAQ:CYBX) today announced that it was notified by the President and Chief Executive Officer of Advanced Neuromodulation Systems Inc. (NASDAQ:ANSI) that ANSI had purchased approximately 3.5 million shares or 14.8% of Cyberonics' common stock on the open market.

"ANSI's actions are evidence that yet another knowledgeable device market leader, in this case with highly relevant FDA experience, has recognized the value of Cyberonics' VNS Therapy™ franchise, intellectual property, demand creation organization and model, profitable epilepsy business, and depression and other new indications opportunities," commented Robert P. ("Skip") Cummins, Cyberonics' Chairman and Chief Executive Officer. "Cyberonics is not interested in any combination or merger and remains focused on growing its epilepsy business and gaining clarity and certainty in a revised depression regulatory timeline. In the few days since learning of FDA's decision, we are making good progress towards those objectives. We will provide more information on that progress on the conference call scheduled for Wednesday August 25, 2004."

AUGUST 25, 2004 CONFERENCE CALL AND WEBCAST ACCESS INFORMATION

To listen to the August 25, 2004 conference call live by telephone dial 877-451-8943 (if dialing from within the U.S.) or 706-679-3062 (if dialing from outside the U.S.). The conference ID is 9510401; the leader is Pam Westbrook.

33. The press release of August 20, 2004, was false and misleading because defendant Cummings knew that the FDA inspection of Cyberonics facilities, in connection with its manufacture of the VNS device was ongoing.

34. On September 15, 2004, defendants issued a press release entitled, "CYBERONICS REITERATES NO INTEREST IN ANY MERGER OR COMBINATION WITH ADVANCED NEUROMODULATION SYSTEMS - Conference call at 4:30 PM EDT today, September 15." The press release stated in part:

HOUSTON, Texas, September 15, 2004 -- Cyberonics, Inc. (NASDAQ:CYBX) today announced that its Board of Directors, after consulting with its financial advisor, Merrill Lynch & Co., has unanimously rejected Advanced Neuromodulation Systems Inc.'s (NASDAQ:ANSI) invitation to "meet to discuss a business combination." The Company reconfirms its previously stated position in its press release dated August 20, 2004, that it is not interested in any combination or merger and remains focused on strengthening its epilepsy business and gaining clarity and certainty in a revised depression regulatory plan and timeline.

CONFERENCE CALL ACCESS INFORMATION

A conference call to discuss this press release will be held at 4:30 PM EDT today, Wednesday, September 15, 2004. To listen to the conference call live by telephone dial 877-451-8943 (if dialing from within the U.S.) or 706-679-3062 (if dialing from outside the U.S.). The conference ID is 210644; the leader is Pam Westbrook.

35. The press release of September 15, 2004, provided for the repetition of false and misleading statements already made on August 20, 2004, affording defendants yet another opportunity to artificially inflate the value of the stock.

36. On September 16, 2004, defendant Totah, Vice President of Regulatory Affairs for Cyberonics, sold 2,000 shares of Cyberonics stock for proceeds of \$25,518.

37. Although the repetition of these false and misleading statements caused Cyberonics stock to again rise on September 15, 2004, the gain was short-lived as investors received an astute interpretation of Company information that cut through the

false and misleading pronouncements of relevant issues and progress by defendants to the true prospects for PMA-S approval from one of the Company's largest shareholders. On October 1, 2004, ANSI formally withdrew its bid for a business combination. Following the news, Chris Chavez, President and Chief Executive Officer of ANSI, explained the decision:

"Since we made our proposal, however, Cyberonics has publicly stated that it intends to 'gain clarity and certainty in a revised depression regulatory plan and timetable,' and has taken steps to try to persuade the FDA to reverse its decision in its 'non-approvable letter' by submitting additional data through a PMA-S Amendment. Cyberonics has said that it could take 120-180 days or more to obtain an FDA decision on the Amendment. Given the amount of time that could transpire before Cyberonics attains the clarity and certainty it seeks, its Board's decision not to discuss a combination, and our judgment that it does not make good business sense to try to force the issue, we have decided to withdraw our proposal at this time."

38. Thus, Chavez reminded investors of the true uncertainties defendants eagerly sought to dismiss, in spite of defendants' attempts to spin facts and mislead investors. On the news, the stock fell once more, losing 7.9% of its value to \$18.85 for a loss of \$1.61 on volume of 3.6 million shares.

POST-CLASS PERIOD REVELATIONS

39. As if to underscore the ANSI rationale for walking away from its bid for the Company and the false and misleading nature of defendant Cummin's insistence that defendants were making "good progress" with FDA on the PMA-S rejection, FDA delivered the Company another "black eye." The Company revealed, on January 3, 2005, that it was in receipt of an FDA "Warning Letter," dated December 22, 2004. This letter, nearly three times the length of the Warning Letter the Company received in 2001, provided confirmation of shocking nature of defendants' Class Period knowledge of the unsafe, defective, deficient and substantially flawed nature of its manufacturing process

and quality systems -- issues that contributed to FDA's decision regarding marketing approval for the VNS device, stating in part:

Department of Health and Human Services Public Health Service
Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 22, 2004

Ref: 2005-DAL-WL-7

WARNING LETTER
CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Robert (Skip) P. Cummins, President and CEO
Cyberonics, Inc.
100 Cyberonics Blvd.
Houston, Texas 77058 - 2017

Dear Mr. Cummins:

During an inspection of your firm's manufacturing operations located in Houston, Texas, on July 12 through September 15, 2004, United States Food and Drug Administration (FDA) Investigator, Ellen J. Tave, determined that your firm manufactures the Vagus Nerve Stimulator (VNS), an implanted generator that is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with medically intractable partial seizures. The VNS system includes a pulse generator, programming wand, programming software, electrode leads, tunneling tool, and accessory pack. This product is a device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR). Part 820.

Quality System Regulation

At the close of the inspection, your firm was issued a list of inspectional observations, Form FDA-483 (copy enclosed), which identified a number of significant QS regulation violations including, but not limited to, the following:

1. Failure to completely investigate and evaluate the cause of each medical adverse event as required by 21 CFR 803.50(b)(2) and failure to maintain complete deliberation results as required by 21 CFR 803.18(b)(1)(i) [FDA-483, Item 1]. For example, your firm has not provided adequate documentation of deliberations to support your firm's decision making process for explaining why your firm could not reach a conclusion about the cause of (a) device migration reported in complaint file # 200306-0477 (reference MDR report # 2003-00402); and (b) high lead impedance, device migration, increase in seizures, and subsequent patient death reported in complaint file # 200312-0567 (reference MDR report # 2004-00030).

2. Failure to establish and maintain adequate procedures for validating the device design to ensure that the device conforms to user needs and intended uses and include design testing under actual or simulated use conditions as required by 21 CFR 820.30(g) [FDA 483, item 2]. Evidence of your firm's design validation with regard to Model 102 is inadequate. For example:

a) Evidence of design validation lacked supporting documentation to demonstrate how your simulated testing of the generator and the lead connecting to a [redacted] load actually simulated use conditions. For example, in an [redacted] chamber [redacted] maintained at [redacted] evidence was not provided which demonstrated the equivalence to the actual implanted generator and electrode connecting to the vagus nerve which resides in a fluidal or wet condition in the chest cavity (actual implant environment); and

b) There was a lack of supporting documentation explaining why real time testing is not needed to verify the actual device longevity and a lack of evidence confirming the accuracy of your theoretical device life expectancy across patient programming ranges at the end of service voltage (actual use condition).

c) The design validation does not appear to address the impact of possible increase in lead impedance of the electrode and vagus nerve interface during the course of patient therapy on battery life. Therefore, the accuracy of your theoretical estimate of device longevity is called into question; and

d) The theoretical calculation of battery hours of operation does not appear to include or discuss the effect of the total number of patient magnet wipes (activations) on actual device longevity at nominal conditions in clinical settings (actual use condition); and

e) The design validation does not discuss or reference testing results of the ERI (Elective Replacement Indicator) flag under the various fault diagnostics conditions listed in the Physician's Manual (Section High Lead Impedance on a Diagnostic Test at Follow-up Visit).

3. Failure to investigate the cause of nonconformities relating to product, processes, and the quality system as required by 21 CFR 820.100(a)(2) [FDA-483, Items 3, 9, and 10]. For example:

a) Complaints of suspected end of service (EOS) were not considered as a product complaint, and there were no attempts to collect patient's programming data' to evaluate if the devices reached normal/expected EOS; and

b) Your firm has not documented the death data by age categories to support data analysis required in CAPA Investigation Report INV 01-0006, dated January 8, 2002 and February 19, 2003. Your firm then concluded that there was no relationship seen in seizure changes among the 81 patients but reported that the patients responses to the VNS therapy were unknown or there was no information for 28 of 81 patients. Your firm also had not collected programming history data to assess the relationship of the amount of stimulation therapy at the time of death: and

c) CAPA investigation to verify a physician's observations that the devices delivered less current therapy than what were programmed during the last 6 to 12 months of device life had incomplete explanation of the results of Phase II and III testing; and

d) Product analysis (PA) of explanted generators did not show testing of the devices using the patients programming history to confirm or duplicate the patient complaints or non-complaints. For example, PA #5243, 4935, and 5600; and

e) Incident # 200310-1077 reported that a pediatric patient was implanted on December 18, 2002 and explanted on October 8, 2003 due to suspected end of service (EOS). The generator was implanted for almost 10 months. Your firm has not explained why the implanted generator did not set the ERI flag as it was approaching EOS. The user reported that the ERI flag did not set in spite of a high lead impedance reading. Your firm did not conduct duplicate testing of the explanted generator using the user's actual programming parameters to confirm the user's complaint of EOS. Your firm's product analysts documented that the explanted generator met its electrical specifications but did not explain (a) how your firm's electrical testing results are related to the user's complaint, and (b) your firm's evaluation of the user report of normal diagnostics test results of high lead impedance in your product analysis report.

4. Failure to analyze processes, work operations, and other sources of quality data to identify existing and potential causes of non-conforming product as required by 21 CFR 820.100(a)(1) [FDA-483, Item 4, 6, and 11]. For example:

a) Your firm has not documented, analyzed, and evaluated the reasons for both implants/reimplants and product returns to identify existing and potential causes of non-conforming product. Your firm does not know or explain how many reimplants were due to broken leads, suspected end of service (EOS), actual EOS, and high lead impedance; and

b) User reports (non-complaints) of suspected EOS and confirmed EOS, and collected data on adverse events of asystole and bradycardia were omitted from [redacted] CAPA meetings; and

c) Your firm has not analyzed complaints of high lead impedance, lead discontinuity, confirmed EOS, and suspected EOS to identify how many complaints were confirmed with an ERI (Elective Replacement Indicator) flag being set; and

d) Your firm has not described the possible meaning of complaint conclusion code 40 in order to explain how complaints or adverse events were resolved with this conclusion code. It was found that conclusion code 40 was often used when the adverse events were resolved by device explants and reimplants. Review of complaint data queried by conclusion code 40 showed that your firm had classified 1081 complaints and 524 MDR reports using this code; and

e) Your firm has neither collected nor analyzed patient programming history since 1997 in order to provide a theoretical estimate of actual device longevity over the entire implant population.

5. Failure to implement and record changes in methods and procedures needed to prevent and correct identified quality problems as required by 21 CFR 620.100(a)(5) [FDA-483, item 6]. For example, although your firm has listed several potential causes of high lead impedance, your firm has not implemented the necessary solutions and verified their effectiveness in order to address numerous complaints of high lead impedance. A complaint log entitled "Lead Discontinuity, Suspected Lead Discontinuity, or High Lead Impedance Incoming Complaints with Conclusions" for the period of January 1, 2002 through May 31, 2004 documented that 89 complaints were identified as a "design" issue.

6. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a) [FDA-483 Items 7 and 11]. For example, your firm (a) has not documented, analyzed, and evaluated the reasons for thousands of reimplants since 1997; (b) has not analyzed patient programming history data over the entire implant population; and (c) does not know how many reimplants were due to broken leads, suspected EOS, confirmed EOS, and high lead impedance, in order to validate input data used to calculate your firm's cumulative survival probability for the implanted generators. In addition, your firm has not explained how your device's survival probability curve matches the actual device longevity in clinical settings.

7. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a). For example, your firm has not defined how your firm differentiates user complaints of suspected EOS from complaints of confirmed EOS, or high lead impedance.

Cyberonics' Response

We acknowledge receiving your letters with attachments, dated September 17, October 7, and December 8, 2004, responding to the Form FDA-483, Inspectional Observations, issued to your firm at the conclusion of our inspection on September 15, 2004. We have completed our review and determined that your response is incomplete. Your December 8th response was incomplete and did not provide any supporting information or evidence relating to the longevity verification. Your responses have not satisfactorily addressed the underlying issues. For example:

1. Your response did not clearly explain whether or not your firm considers user reports of suspected end of service (EOS) as a product complaint to be treated in accordance with 21 CFR 820.198(a). Your firm has not been able to determine the causes associated with many user reports of suspected EOS or high lead impedance or that your firm has not determined and documented how many reimplants were due to normal/actual EOS, suspected EOS, or high lead impedance. See your firm's investigation reports INV 02-0014, 02-0024, and 03-0016. Your firm also has not (a) explained whether your firm will attempt to collect patient programming history to aid your firm's investigation of complaints of suspected EOS or high lead impedance; and (b) established procedures to indicate how your firm differentiates user complaints of suspected EOS from user complaints of actual EOS or high lead impedance to determine if in fact the devices were approaching or at their normal end of service based on the actual patient programming parameters. Your firm's investigation report 02-0014 was initiated in October, 2002 which recommended corrective actions to address user reports of high lead impedance. However, the completion dates for the proposed corrective actions were still classified "TBD" (To be Determined) at the time of the inspection.

2. Your firm has not been able to determine or explain how many reimplant cases were due to high lead impedance or other potential quality problems. Although your firm has identified several theoretical causes of high lead impedance complaints (user training, lead manufacturing defects, and design robustness), your firm has not completed the following proposed corrective actions. The effectiveness of these proposed corrective actions cannot be determined until you provide the results of your firm's monitoring of the high lead impedance complaints.

(a) Corrective Action Plan CAR 03-0003 addressing user training a potential cause of high lead impedance are in process without establishing an expected completion date; and

(b) Your response reported that Corrective Action Plan CAR 03-0004 addresses the handling of the Model 300 and Model 302 leads during manufacturing as a potential cause of high lead impedance was completed on July 16, 2004 during our inspection. You indicated manufacturing defects related to coil damage was not a significant cause of high lead impedance events. However, you have not explained what types of lead defects you found, specific steps your firm has taken or will take (a) to reduce incidents of lead manufacturing defects; (b) establish complaint investigation methods to differentiate user complaints of high lead impedance caused by a lack of user training from user complaints of high lead impedance caused by manufacturing lead defects; and

(c) [redacted] design project (DHF 0044) was initiated in [redacted] and is not expected to be completed until [redacted]

3. Your response implied that FDA's approval of your original PMA or subsequent PMA supplements means that FDA approves your firm's design controls. This is not true. Your firm's design control steps must be continuously maintained throughout the device design life cycle to ensure compliance with 21 CFR 820.30. Your response further stated that the investigator attempted to inspect the safety and effectiveness of your devices. We disagree. The investigator explained that she did not inspect the safety and effectiveness of your devices epilepsy indication but rather she questioned the adequacy of your firm's design validation process concerning simulated testing of actual device implant conditions and device longevity.

4. Regarding simulated testing of actual implant environment, as part of your device failure investigation process, some of the explanted generators were actually tested in a [redacted] solution in order to investigate the complaint issues of suspected end of service, high lead impedance, or generators not delivering enough therapeutic currents as programmed. See your investigation reports INV 03-0016 and 02-0024. These two investigation reports documented that the explanted devices were placed in a [redacted] solution to simulate the actual implant environment. Your firm failed to explain how this type of testing is appropriately related to the original design validation testing of Model 100 in 1997, 101, and 102 in 2002.

5. Regarding real time testing to confirm device longevity, your response explained that performing the real time testing is inappropriate because it would require [redacted] to complete, and your mathematical equation for device longevity was based on "proven laws of math." First, your response has not explained why it takes [redacted] to conduct real time testing across all programming parameters. Second, you have not explained if your firm has (a) trended and/or documented the actual implant times of the clinical patients enrolled in the prior E01 - E05 studies using Model 100, the patients enrolled in the current Depression clinical study, or current non-clinical patients implanted with model 101 and 102, in order to compare their projected (theoretical) implant times to their actual implant times. Third, in your firm's Table 20 [Nominal Longevity Estimates Begin of Life (BOL) to End of Service (EOS)] listed in the electrical characterization report, your firm's longevity equation calculated that the device longevity would last [redacted] at a heavy stimulation setting of [redacted] and [redacted]% duty cycle. Real time testing at this rapid simulation setting would take about [redacted] not [redacted] to verify the accuracy of your theoretical device longevity equation.

6. Magnet Activations by Patients, you responded that the occurrence of manual magnet activations by patients would not cause any significant reduction of device longevity when compared to normal device stimulation. However, you acknowledged that your firm's extrapolation of energy consumption and rationales were not explained and documented in the design validation documents, e.g., electrical characterization report.

7. Your firm's current complaint handling procedure requires that a reply letter be sent to the complainant (physician) if your firm's complaint investigation resulted in "user error", and the user has not been notified of the error. The use of the VNS device for pediatric patients younger than 12 years of age is an unapproved use (off-label use), and therefore, adverse events related to this use are considered user error. See 21 CFR 803.3(d). In this situation, your firm did not follow its complaint handling procedures in that your firm had not sent reply letters to the complainants to notify them of user error concerning medical adverse events occurring in pediatric patients younger than 12 years of age. Our inspection documented that your firm had received 197 serious injury reports, 53 death reports, and 99 malfunction reports that were coded 212 (unapproved use of device) from January 1, 2002 through May 14, 2004. Many of these medical adverse events were associated with the users using the VNS devices in pediatric patients younger than 12 years of age. We believe your firm should send a reply to each complainant in order to prevent further misuse, injury or other adverse situations from recurring. When the problem was caused by misuse, it is very important to advise the user to help prevent further misuse. If your firm, believes there may be cases where a reply is not necessary, the record should state that no reply was made and the reason for not replying. Finally, although not sending a reply letter to the complainant is not a deviation of 21 CFR 820.198(e)(8), when a reply is sent it must be kept as part of the complaint file.

In summary of our review, your firm should implement a comprehensive QS action plan and provide FDA with status update reports outlining specific steps addressing the specific FDA-483 observations and issues identified in this letter and a global approach to correct and prevent any potential systemic problems.

Responding to This Letter

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken, or will take to identify and correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying

systems problems necessary to ensure that similar violations will not recur. It is recommended that after responding to this letter that you have a meeting concurrently with both Dallas District Office and the Center for Devices and Radiological Health in order to facilitate appropriate technical discussion surrounding this letter and the inspection.

Your reply should be directed to Thao Ta, Compliance Officer, at the address indicated on the above letterhead.

Sincerely,

/s/

Michael A. Chappell
Dallas District Director

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

40. Plaintiff incorporates all prior paragraphs by reference.

41. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

42. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Cyberonics publicly traded securities during the Class Period.

43. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Cyberonics publicly

traded securities. Plaintiff and the Class would not have purchased Cyberonics publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

44. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Cyberonics publicly traded securities during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

45. Plaintiff incorporates all prior paragraphs by reference.

46. The Individual Defendants acted as controlling persons of Cyberonics within the meaning of §20(a) of the 1934 Act. By reason of their positions as officers and/or directors of Cyberonics, and their ownership of Cyberonics stock, the Individual Defendants had the power and authority to cause Cyberonics to engage in the wrongful conduct complained of herein. Cyberonics controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Cyberonics are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

47. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Cyberonics publicly traded securities (the "Class") on the open market during the Class Period. Excluded from the Class are defendants.

48. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial

benefits to the parties and the Court. Cyberonics had more than 24 million shares of stock outstanding, owned by hundreds if not thousands of persons.

49. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;
- (e) Whether the prices of Cyberonics's publicly traded securities were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

50. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

51. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

52. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

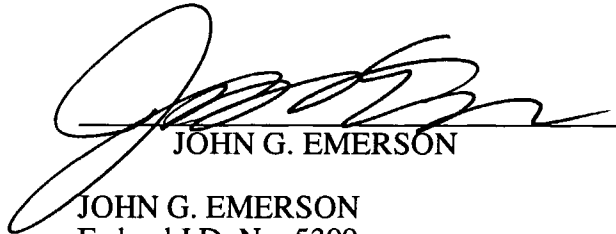
- A. Declaring this action to be a proper class action pursuant to FRCP 23;
- B. Awarding plaintiff and the members of the Class damages, interest and costs; and
- C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: June 17, 2005

EMERSON POYNTER LLP



JOHN G. EMERSON

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-and-
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Attorneys for Plaintiff

PLAINTIFF'S CERTIFICATE

Richard Darques ("Plaintiff") declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed the complaint against Cyberonics, Inc. ("CYBX"), and certain other defendants.
2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.
3. Plaintiff is willing to serve as a representative party on behalf of a class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as approved by the court.
5. Plaintiff made the following transactions during the Class Period in the common shares of CYBX:

Purchases

Date(s)	Number of Shares	Price
9/23/04	50	\$ 22.73

Sales

Date(s)	Number of Shares	Price
Note		

6. During the three years prior to the date of this Certification, Plaintiff has not sought to serve or served as a representative party for a class in an action filed under the federal securities laws.

7. I declare under penalty of perjury, this 10 day of June, 2005 that the information above is accurate.


Richard Darques

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Richard Darquea, On Behalf of Himself and All Others Similarly Situated

(b) County of Residence of First Listed Plaintiff Palm Beach County, FL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

John G. Emerson, Emerson Poynter LLP, 830 Apollo Lane, Houston, TX; Tel: 281.488.8854

DEFENDANTS

H 05 - 2121

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, CHECK THE LOCATION OF THE LAND INVOLVED. United States District Court Southern District of Texas
FILED

Attorneys (If Known)

JUN 17 2005

Michael N. Milby, Clerk

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input checked="" type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN

(Place an "X" in One Box Only)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation
- 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5

Brief description of cause:

Shareholder class action complaint against the Company and certain officers for violations of the federal securities statutes named above.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

6-17-05

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____