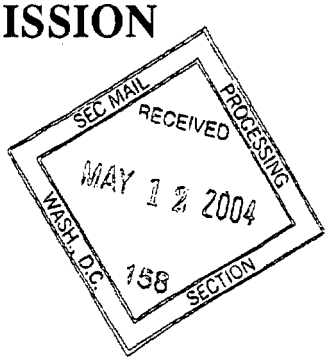
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K



(Mark One)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2003

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal period from _____ to _____

Commission file number 0-20991

CAMBRIDGE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**13-3679946**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1 Oak Park Drive, Bedford, MA	**01730**
(Address of Principal Executive Offices)	(Zip Code)

(781) 271-1200

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 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 the Form 10-K. ☐

Indicate by check mark if the Company is an accelerated filer as defined in Rule 12b-2. ☐ Yes ☒ No

The aggregate market value of voting common stock held by non-affiliates of the registrant was $11,371,848 based on the last reported sale price of the common stock on the OTC Bulletin Board on June 30, 2003.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 24,835,545 shares of $0.001 par value common stock as of March 26, 2004.

Documents incorporated by reference:

Document Description	**10-K Part**
Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on June 9, 2004	Part III

PART I

Item 1. *Business*

Company Overview

We are engaged in the research, development and commercialization of products for the non-invasive diagnosis of cardiac disease. Using innovative technologies, we are addressing a key problem in cardiac diagnosis—the identification of those at risk of sudden cardiac death. Our products incorporate our proprietary technology for the measurement of Microvolt T-Wave Alternans, and were the first diagnostic tools cleared by the U.S. Food and Drug Administration, which we call the FDA, to non-invasively measure Microvolt levels of T-Wave Alternans. Microvolt T-Wave Alternans is an extremely subtle beat-to-beat fluctuation in the t-wave segment of a patient's heartbeat. The use of our products and technology in the performance of a Microvolt T-Wave Alternans Test can detect these tiny heartbeat variations, measured down to one millionth of a volt. The test is conducted by elevating the patient's heart rate through exercise, pharmacologic agents or pacing with electrical pulses. Our proprietary system and proprietary sensors, when placed on the patient's chest, can acquire and analyze the heartbeat for Microvolt T-Wave Alternans.

Published clinical data in a broad range of patients has shown that patients with symptoms of or at risk of life threatening arrhythmia who test positive for Microvolt T-Wave Alternans are at increased risk for subsequent sudden cardiac events including sudden death, while those who test negative are at minimal risk. We believe that this data demonstrates that our Microvolt T-Wave Alternans technology is the only non-invasive test comparable or superior to the invasive "gold standard" electrophysiology study in the prediction of sudden death. Sudden cardiac arrest accounts for approximately one-third of all cardiac deaths, or over 300,000 deaths, in the United States each year, and is the leading cause of death in people over the age of 45.

All of our products, including our Heartwave, CH 2000 and Micro-V Alternans Sensors, have received 510(k) clearance from the FDA for sale in the United States. They have also received the CE mark for sale in Europe and have been approved for sale by the Japanese Ministry of Health, Labor and Welfare. Our 510(k) clearance allows our Microvolt T-Wave Alternans Test to be used to test anyone with known, suspected, or at risk of ventricular tachyarrhythmia and/or sudden cardiac death and allows the claim that our Microvolt T-Wave Alternans Test is predictive of those events.

We are engaged in one industry segment. Additional information regarding our operating segment is presented in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K, and financial information is provided in the financial statements contained in this Annual Report on Form 10-K.

Cambridge Heart was incorporated in Delaware in 1990. Our executive offices are located at 1 Oak Park Drive, Bedford, Massachusetts 01730. We maintain a website with the address www.cambridgeheart.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to the rules of the Securities and Exchange Commission.

Principal Products and Applications

The Heartwave

Our Heartwave System is used to perform a Microvolt T-Wave Alternans Test. A Microvolt T-Wave Alternans Test requires an elevated heart rate to provide an accurate result. The required heart rate is typically achieved utilizing exercise as performed in a standard stress test. The heart rate can also be elevated through the use of pharmaceuticals or pacing the patient either through use of a pacemaker or electrode catheters used during an electrophysiologic study.

The Heartwave System can be used in conjunction with virtually all manufacturers' stress test systems to elevate the heart rate. The Microvolt T-Wave Alternans Test is typically performed as a stand alone diagnostic procedure, but can also be performed in conjunction with a standard exercise stress test. The necessary signals are captured by the Micro-V Alternans Sensors placed at designated locations on the patient's chest and analyzed by the Heartwave processor using our proprietary Analytic Spectral Method of measuring microvolt levels of t-wave alternans.

The Heartwave System includes:

- a Pentium processor that provides almost real-time Microvolt T-Wave Alternans computations and storage of the 10 most recent tests;
- a LCD touch screen that controls the operation of the processor, displays key test parameters and is the means of entering patient information;
- a digital ECG amplifier that, working in concert with our Micro-V Alternans Sensors, makes alternans measurements possible to levels below one microvolt; and
- a desk jet printer capable of providing printed trend reports with guided interpretation for quick, accurate analysis.

The CH 2000 Cardiac Stress Test System

Our CH 2000 is a diagnostic system designed to support a broad range of standard and physician-customized protocols for the conduct and measurement of cardiac exercise stress tests. When properly upgraded to activate our Microvolt T-Wave Alternans technology, it is also able to perform a Microvolt T-Wave Alternans Test. It is capable of controlling both treadmill and bicycle ergometers and is well suited for standard, nuclear or echocardiogram stress tests. The CH 2000 is compatible with standard electrodes for routine stress tests and our Micro-V Alternans Sensors for a Microvolt T-Wave Alternans Test.

Micro-V Alternans Sensors

Our Micro-V Alternans Sensors are single patient use, multi-segment electrodes. They are required to obtain good results from our Microvolt T-Wave Alternans Test as they work to reduce background noise and artifact, allowing the processor to properly and accurately analyze the heart's electrical signal.

Clinical Studies

Over the years, various studies have shown Microvolt T-Wave Alternans to be an effective diagnostic tool for the identification of patients at risk of sudden death and life-threatening ventricular arrhythmias. Additionally, a negative result from a Microvolt T-Wave Alternans Test has been demonstrated to be a strong indication that the patient is at very low risk of ventricular tachyarrhythmia or sudden death, both of which we sometimes refer to as a sudden cardiac event. Clinical studies conducted on several thousand patients in most of the major high risk cardiac populations have shown that a Microvolt T-Wave Alternans Test positive result is at least as accurate a

predictor of a future cardiac event as the current "gold standard" invasive electrophysiology study. These studies have also shown that patients testing negative for Microvolt T-Wave Alternans are at very low risk of dying suddenly from a cardiac event. These studies have been published in a variety of peer reviewed journals such as the *New England Journal of Medicine, Journal of Cardiovascular Electrophysiology, Journal of the American College of Cardiology*, and *The Lancet*.

Sudden cardiac death continued to receive an increased amount of attention during 2003 as the result of published data from the Guidant Corporation sponsored Madit II clinical study. This study, published in the *New England Journal of Medicine*, demonstrated that prophylactic placement of an implantable cardioverter defibrillator, which we call an ICD, in patients with a previous heart attack and poor pumping function (left ventricular ejection fraction of 30% or less), resulted in a 5.6 percent absolute reduction in mortality, as compared to standard drug therapy. This patient group is now referred to as Madit II type patients. The addition of Madit II type patients to the currently approved population of ICD candidates substantially increases the pool of patients eligible for ICD implantation. While Madit II type patients are generally acknowledged by the medical community as high risk patients, there has been significant concern expressed over the potential cost and morbidity if all Madit II type patients received an ICD. Consequently, many experts have emphasized the importance of finding risk stratification methods that can identify which of the Madit II type patients would most benefit from ICD therapy. Microvolt T-Wave Alternans testing, with its high negative predictive value, can play an important role in helping cardiologists to identify which of these patients is at low risk of dying suddenly and would therefore receive no benefit from ICD therapy.

In March 2003, Dr. Daniel M. Bloomfield of Columbia University College of Physicians and Surgeons, presented initial information from a study on the use of Microvolt T-Wave Alternans in patients with congestive heart failure at the Late Breaking Clinical Trials Session of the American College of Cardiology Meeting. The study, partially funded by us and the National Institutes of Health, presented the results from the testing of 542 congestive heart failure patients with Microvolt T-Wave Alternans. Included in this patient group were 164 Madit II type patients. The study revealed that patients were 9.7 times more likely to die if they tested positive for Microvolt T-Wave Alternans, than if they had a negative result from their Microvolt T-Wave Alternans Test. Additionally, when evaluating the subgroup of 164 Madit II type patients, there were no deaths in patients with a negative Microvolt T-Wave Alternans Test. Dr. Bloomfield concluded that Microvolt T-Wave Alternans was a strong predictor of mortality and that the test identifies high risk patients at risk of sudden cardiac death, as well as low risk patients that can be managed conservatively.

In July 2003, Dr. Stephan Hohnloser, Director of Electrophysiology at J.W. Goethe University, Frankfurt, Germany had a Research Letter published in *The Lancet* demonstrating that Madit II type patients who tested negative for Microvolt T-Wave Alternans had a very low risk of dying suddenly from a cardiac event. Dr. Hohnloser presented data on 129 Madit II type patients drawn from two previously published prospective clinical trials involving 957 patients. Microvolt T-Wave Alternans testing successfully identified a subgroup of Madit II type patients at low risk of dying suddenly and therefore would receive no benefit from ICD therapy. Dr. Hohnloser also concluded that Madit II type patients who do not test negative for Microvolt T-Wave Alternans would be expected to have a greater mortality benefit from ICD therapy than that reported in the original Madit II study.

In a presentation before the Medicare Coverage Advisory Committee in February 2003 and subsequently at the Microvolt T-Wave Alternans Symposium held at the May 2003 meeting of the North American Society of Pacing and Electrophysiology, Dr. Theodore Chow of the Ohio Heart Health Center, Cincinnati, Ohio presented data from a large Microvolt T-Wave Alternans study conducted in his practice in which a subgroup of 193 Madit II type patients underwent testing for Microvolt T-Wave Alternans. These patients were followed for an average of one year after testing. Dr. Chow reported that of the 57 patients that tested negative for Microvolt T-Wave Alternans only one individual had a sudden cardiac event within the follow-up period. Dr. Chow concluded that Madit II

type patients who test negative for Microvolt T-Wave Alternans are at low risk of sudden cardiac death and should therefore be treated conservatively, while Madit II type patients that do not test negative should either receive an electrophysiology study or proceed directly to ICD therapy.

We are participating in the Microvolt T-Wave Alternans Testing for Risk Stratification of Post MI Patients clinical trial (MASTER Study), which sponsored by Medtronic, Inc. The purpose of the study will be to show that Madit II type patients with a negative Microvolt T-Wave Alternans Test result are at very low risk of dying suddenly and do not require ICD therapy. Additionally, the study is intended to demonstrate that a non negative test results is a "call to action" for the cardiologist to refer these patients for further testing and ICD therapy. We expect that the study will enroll 600 patients that meet Madit II criteria (previous heart attack survivors with a poor heart pumping function). The study is currently taking place at over 50 leading medical centers in the U.S. An additional 1,200 patients with slightly better pumping function (ejection fraction of 30% to 40%) will be evaluated in a related registry. Results of the study are expected to be available in 2006.

We are also working in conjunction with St. Jude Medical on the Alternans Before Cardioverter Defibrallator Study, which we call ABCD. This trial of over 500 patients with coronary artery disease, ejection fraction < 40% and non-sustained ventricular tachycardia, compares the efficacy of the Microvolt T-Wave Alternans Test to invasive electrophysiology study, which we call EP. We believe that positive results against EP will be useful with both clinicians and insurance companies as further proof of the importance of the Microvolt T-Wave Alternans Test. Patient enrollment is anticipated to be complete in 2004.

Marketing and Sales

Our technology and products are directed towards identifying individuals at risk of sudden cardiac death. Typically our target patient populations include those individuals with underlying cardiac disease. In the U.S., those populations include 7.6 million patients who have suffered a myocardial infarction, more commonly know as a heart attack, 4.9 million patients suffering from congestive heart failure (poor pumping function), 500,000 syncope (fainting and dizziness) patients and over 50,000 patients with non-ischemic dilated cardiomyopathy (damaged and enlarged heart). Therefore, the aggregate at-risk patient population exceeds 10 million. Madit II type patients are a relatively small but highly visible and important subset of this at-risk patient population.

The target customer for our Heartwave System and Micro-V Alternans Sensors is the clinical cardiologist. Clinical cardiologists see the vast majority of patients with existing cardiac conditions. They control the referral pattern of their patients. They also prescribe and administer most diagnostic tests either in their office or as an outpatient procedure at the hospital. Our Microvolt T-Wave Alternans Test is a non-invasive tool used to identify which of their patients are at the highest risk of sudden cardiac death, and therefore should be referred for more extensive testing and therapy. Conversely, it identifies patients at low risk and can be treated more conservatively, typically through drug therapy. The electrophysiologist is a rhythm specialist and, as such, their knowledge and opinion on the value of the Microvolt T-Wave Alternans Test is often solicited by the clinical cardiologist, the primary user of our test.

One of the largest challenges we face as a single product company is gaining initial access to the cardiologist in order to introduce them to Microvolt T-Wave Alternans and Cambridge Heart. In an effort to add credibility to our efforts, we have attempted to establish relationships with field and management representatives of the major ICD and stress testing companies. The MASTER Study, conducted by Medtronic, Inc., is the largest formal relationship we have in place. It has provided us with increased access and credibility to new customers

During fiscal 2003, we maintained our sales coverage in the U.S. at 15 sales territories supplemented with 3 clinical specialists. These territories are in most of the major population centers

across the country. Our sales force is trained on the features, benefits and clinical use of our products and our Microvolt T Wave Alternans technology. Additionally, they must be knowledgeable about reimbursement dynamics in their territory. We also utilize a limited number of non-employee manufacturer's representatives to sell our products. The manufacturer's representatives also sell products of other non-competing companies. In addition to our direct sales efforts in the U.S., we have established partnerships and distribution agreements with third party organizations to expand our sales efforts both in the U.S. and around the world.

An initial sale typically includes a piece of capital equipment, the Heartwave System, and our single use proprietary Micro-V Alternans Sensors. Customers can purchase the hardware and disposable sensors under usual and customary direct purchasing terms. We also make the services of a third party leasing company available to all customers who want to acquire the products through standard leasing terms.

In 2000, we entered into a distribution and license agreement with Spacelabs Medical, Inc, a leading provider of integrated cardiology, monitoring and clinical information systems. The agreement was for the development of software and hardware that allows our Microvolt T-Wave Alternans technology to run on the Spacelabs' Burdick® Quest® exercise stress system. This agreement was renewed in August 2003 with Burdick, Inc., now a division of Quinton Cardiology Systems, Inc., The initial term of the agreement extends through July 31, 2005.

We utilize a number of independent distributors to market our products outside the U.S. During the years ending December 31, 2001, 2002 and 2003, sales to international customers accounted for 30%, 19% and 9% of our business, respectively. The decline in the percentage of our revenues derived from outside the U.S. reflects our planned efforts to focus a majority of our sales and marketing resources on penetrating the U.S. market for Microvolt T-Wave Alternans testing with our Heartwave System. We believe that the U.S. market represents our largest business opportunity and therefore, the majority of our sales and marketing efforts are directed towards this market.

Manufacturing

The in-house manufacturing process for our Heartwave and CH 2000 consists primarily of final assembly of purchased components, testing operations and packaging. Components and sub-assemblies are purchased according to our specifications and are subject to inspection and testing. We rely on outside vendors to manufacture major components, a number of which are currently supplied by sole source vendors. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. We purchase our Micro-V Alternans Sensors fully assembled and packaged from a third party supplier.

We perform a limited amount of final assembly of hardware and software components, and testing of our Heartwave and CH 2000 products at our corporate headquarters in Bedford, Massachusetts. We believe that this facility will be adequate to meet our requirements through November 30, 2005, the term of our current lease agreement. We are required to meet and adhere to the requirements of U.S. and international regulatory agencies, including Good Manufacturing Practices and Quality System Regulation requirements. Our manufacturing facilities are subject to periodic inspection by both U.S. and international regulatory agencies.

We last underwent a Quality System Regulation audit, conducted by the FDA, in August 2001. We passed the inspection with no observations. We are ISO 9001 certified allowing us to apply the CE Mark to all of our products. We are subject to semi-annual audits by our designated notified body, British Standards Institution, to maintain our ISO 9001 certification.

Research and Development

A substantial portion of our research and development investment is focused on our efforts to develop and design enhancements to our Microvolt T-Wave Alternans technology and products targeted at optimizing their functionality and ease of use. During fiscal 2003, we continued to support the Alternans Before Cardioverter Defibrillator clinical trial, known as the ABCD Trial, that is being sponsored by St. Jude Medical. We also initiated support of the MASTER Study, which is being sponsored by Medtronic, Inc.

We experienced some staff turnover in research and development during 2003. Replacements have been hired during the first quarter of 2004 and therefore, we expect total research and development costs in 2004 to increase modestly over those incurred in 2003. During 2004, our efforts will continue to be focused on the development and design of enhancements to our existing Microvolt T-Wave Alternans technology and products to maximize their functionality and ease of use. As of December 31, 2003, we had two full time employees engaged in research and development activities along with several independent research and engineering consultants whose services are utilized as necessary. We have increased the number of full time employees to four.

Patents, Trade Secrets and Proprietary Rights

Some of the initial methods that we used in the measurement of Microvolt T-Wave Alternans are covered by a U.S. patent issued to The Massachusetts Institute of Technology. This patent is covered by an exclusive license agreement with MIT that continues through the year 2007. The license will then convert to a nonexclusive agreement for the remaining life of the patent unless MIT agrees to an extension of exclusivity. We have been issued an additional sixteen U.S. patents that include claims covering substantial changes and modifications to the initial methods covered by the original MIT patent. The expiration dates of these patents range from 2013 to 2019. These additional patents cover a significant portion of the proprietary signal processing algorithms and our Micro-V Alternans Sensors currently utilized in the measurement of Microvolt T-Wave Alternans. Corresponding foreign patents are pending with respect to two issued U.S. patents.

We continue to maintain our license agreement with MIT since it includes the original patent covering certain methods for the measurement of Microvolt T-Wave Alternans. This license agreement imposes various commercialization, sublicensing, insurance, royalty, product liability indemnification and other obligations on us. Our failure to comply with these requirements could result in conversion of the licenses from being exclusive to nonexclusive in nature or, in some cases, termination of the license.

We believe that our intellectual property and expertise, as originally licensed from MIT and further developed by us, constitute an important competitive resource, and we continue to evaluate markets and products which are most appropriate to exploit the expertise licensed and developed by us. In addition, we maintain an active program of intellectual property protection, both to assure that the proprietary technology developed by us is appropriately protected, and, where necessary, to assure that there is no infringement of our proprietary technology by competitive technologies.

Reimbursement

Reimbursement to healthcare providers by third party insurers is critical to the long-term success of our efforts to make the Microvolt T-Wave Alternans Test the standard of care for patients at risk of ventricular tachyarrhythmia or sudden death. In January 2002, Current Procedural Terminology Code 93025, known as a CPT code, became available for use by healthcare providers for filing for reimbursement for the performance of a Microvolt T-Wave Alternans Test. This code may be used alone, or in conjunction with, other diagnostic cardiovascular tests. This unique CPT code provides a uniform language used by healthcare providers to describe medical services but does not guarantee payment for the test. Coding is used to communicate to third party insurers about services that have

been performed for billing purposes and can affect both the coverage decision and amount paid by third party insurers. Effective January 1, 2004, the Centers for Medicare and Medicaid Services, or CMS, published a revised Medicare payment amount for the CPT code for a Microvolt T-Wave Alternans Test of approximately $338.00. This represents an adjustment from the 2003 average of approximately $425.00.

Medicare carriers provide coverage for the Microvolt T-Wave Alternans Test in almost all 50 states. They are responsible for coverage of individuals who are a minimum of 65 years of age. This demographic is estimated to be more than 50% of the potential patient population for Microvolt T-Wave Alternans testing. We continue to work with the private insurance carriers where coverage for our Microvolt T-Wave Alternans Test is not uniform. Utilizing current clinical information, we are working with an outside reimbursement consulting firm to gain positive reimbursement decisions from private insurance carriers such as Aetna and United Health Care.

Competition

We have both direct and indirect competitors. GE Medical Systems gained FDA 510(k) concurrence during 2003 for their T-Wave Alternans Algorithm for use with their Case 8000 Stress Exercise System. At the present time, we are not aware of any published, prospectively enrolled clinical studies which support and validate the use of this algorithm. We believe that the publication of clinical data is necessary to successfully penetrate this emerging market. Indirect competition can come from other testing modalities such as invasive electrophysiology testing and the potential for implanting of ICD's in broad patient populations without the need for risk stratifying tests such as ours.

Government Regulation

We believe we have received all necessary and required regulatory clearances from the FDA to market our products in the U.S. Our Heartwave, CH 2000, and Micro-V Alternans Sensors have received 510(k) clearance from the FDA for sale in the United States. The 510(k) clearance for the Heartwave and the CH 2000 includes the claim that they can measure Microvolt T-Wave Alternans, and the presence of Microvolt T-Wave Alternans in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of ventricular tachyarrhythmia and sudden death.

Any products manufactured or distributed by us are subject to pervasive and continuing regulation by the FDA, including record keeping requirements, reporting of adverse experience with the use of the device, post-market surveillance, post-market registry and other actions deemed necessary by the FDA. The most recent FDA inspection of our record keeping, reporting and quality documentation system was concluded in August 2001. We passed the inspection with no observations.

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in these counties are similar to those of the FDA. We have obtained the requisite foreign regulatory approvals for sale of our Heartwave, CH 2000 and Micro-V Alternans Sensors in many foreign countries, including most of Western Europe. We believe that foreign regulations relating to the manufacture and sale of medical devices are becoming more stringent. The European Union adopted regulations requiring that medical devices such as our Heartwave, CH 2000 and Micro-V Alternans Sensors comply with the Medical Device Directives which establish the requirements for CE marking of all products prior to their importation and sale. In 2001, we received ISO-9001 and CE certification for our Heartwave, CH 2000 and Micro-V Alternans Sensors. The Japanese Ministry of Health, Labor and Welfare has also approved our products for sale. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Employees

As of December 31, 2003, we had 38 full-time employees. None of our employees are represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

Item 2. ***Properties***

Our facilities consist of approximately 11,000 square feet of office, research and manufacturing space located at 1 Oak Park Drive, Bedford, Massachusetts. This facility is under lease through November 30, 2005. We believe that suitable additional space will be available to us, when needed, on commercially reasonable terms.

Item 3. ***Legal Proceedings***

We are not party to any material legal proceedings.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the fourth quarter of the year ended December 31, 2003.

Executive Officers of the Registrant

The following table sets forth (i) the names and ages of our current executive officers; (ii) the position(s) presently held by each person named; and (iii) the principal occupations held by each person named for at least the past five years.

Name	Age	Position
David A. Chazanovitz	53	Chief Executive Officer, President, and Director
Robert B. Palardy	55	Vice President, Finance and Administration and Chief Financial Officer
James Sheppard	44	Vice President, Operations
Robert LaRoche	48	Vice President, Sales and Marketing

David A. Chazanovitz. Mr. Chazanovitz has been our Chief Executive Officer since February 2001 and the President and a Director since October 2000. From July 1998 to September 2000, Mr. Chazanovitz served as the President of the Neurosciences Division of NMT Medical Inc., a medical device firm. From June 1996 to July 1998, Mr. Chazanovitz served as the President of the Septal Repair Division of NMT, following the merger of Innerventions, Inc. with NMT. Mr. Chazanovitz was a founder in 1995 of Innerventions, a developer of septal repair devices. Mr. Chazanovitz also previously served as the President of several divisions of C.R. Bard, Inc., a medical products and services firm, including Bard Ventures, Bard Electrophysiology and USCI Angiography. Mr. Chazanovitz holds a B.S. in Biology from City College of New York and an M.B.A. in Marketing from Long Island University.

Robert B. Palardy. Mr. Palardy has been our Vice President, Finance and Administration and Chief Financial Officer since November 1997. From 1990 to February 1997, Mr. Palardy was Vice President, Finance and Information Services of Smith & Nephew Endoscopy, a company involved in the development, manufacture and sale of medical devices for arthroscopy. From February 1997 through October 1997, Mr. Palardy was an independent financial consultant. Mr. Palardy is a Certified Public Accountant and holds a B.S. degree in Accounting from LaSalle University.

James Sheppard. Mr. Sheppard has been our Vice President, Operations since August 1999. From 1996 to 1998, Mr. Sheppard was Vice President, Operations for NMT Medical, Inc., a medical device

company. From 1995 to 1996, Mr. Sheppard served as Director of Manufacturing for Summit Technology, an ophthalmic device company and from 1982 to 1994 he served in several senior management positions at C.R. Bard, Inc., a healthcare products company. Mr. Sheppard holds a B.S. in Industrial Engineering from Virginia Polytechnic Institute and State University.

Robert LaRoche. Mr. LaRoche became our Vice President of Marketing in February 2003 and assumed the role of Vice President of Sales and Marketing in April 2003. From January 1999 to January 2003, Mr. LaRoche was the President of Octant Marketing, Inc., a marketing consulting services company he founded specializing in the medical products industry. From 1997 to January 1999, Mr. LaRoche served as Director of Marketing/Business Development for Circe Biomedical, a developer of bio-artificial organs and cell therapy. From 1994 to 1997, he was Vice President of Marketing and Sales for Vision Sciences, Inc., a medical device company and from 1985 to 1994 he held a variety of senior sales and marketing positions at C.R. Bard, Inc., a healthcare products company. Mr. LaRoche holds a B.S. in Marine Fisheries Biology from the University of Massachusetts.

Our executive officers are elected by and serve at the discretion of the Board of Directors. There are no family relationships among any of our executive officers or directors.

PART II

Item 5. ***Market for Registrant's Common Equity and Related Stockholder Matters***

Market Information and Holders

Shares of our common stock were traded on the Nasdaq National Market under the symbol "CAMH" from August 2, 1996 until November 18, 2002 at which time our listing was moved to the Nasdaq SmallCap Market. On May 8, 2003, the listing of our shares moved from the Nasdaq SmallCap Market to the National Association of Securities Dealers' OTC Bulletin Board. Prior to August 2, 1996, our shares were not publicly traded. Our common stock is not traded on any market, foreign or domestic, other than the Over the Counter Bulletin Board. The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock as reported on the Nasdaq National Market, the Nasdaq SmallCap Market and the Over the Counter Bulletin Board during the two most recent fiscal years.

	2002		2003	
Period	High	Low	High	Low
First Quarter	$3.05	$1.36	$0.59	$0.30
Second Quarter	$1.74	$0.75	$0.80	$0.25
Third Quarter	$1.30	$0.42	$1.50	$0.60
Fourth Quarter	$0.77	$0.40	$1.50	$0.74

The depositary for our common stock is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005. On March 26, 2004, we had approximately 156 holders of Common Stock of record. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

Recent Sales of Unregistered Securities

On May 12, 2003, we issued and sold to Medtronic, Inc. and a group of private investors 696,825 shares of Series A convertible redeemable preferred stock at a purchase price of $4.42 per share, for total proceeds of approximately $3.1 million. Each share of the preferred stock is convertible into 13 shares of our common stock. The conversion price of the preferred stock is subject to adjustments in certain circumstances. As part of the financing, we issued to the investors, other than Medtronic, short-term warrants exercisable for a total of 705,852 shares of the preferred stock. There were six tranches of the short-term warrants that expired in equal monthly intervals starting September 1, 2003. The exercise price of these warrants was $4.42. We also issued to both Medtronic and the private investors long-term warrants exercisable for 30% of the total number of shares of preferred stock purchased through the initial investment and the exercise of the short-term warrants. The exercise price of Medtronic's long-term warrant is $4.42 and the exercise price of the long-term warrants issued to the other investors is $5.525. These long-term warrants expire on January 1, 2009. In connection with this financing and in order to address certain payment obligations in existing agreements with The Tail Wind Fund Ltd., we issued to Tail Wind short-term warrants exercisable for 67,872 shares of the preferred stock and a long-term warrant exercisable for 75% of the total number of shares of the preferred stock purchased through the exercise of Tail Wind's short-term warrants. The exercise prices and the expiration dates of Tail Wind's warrants are consistent with the warrants issued to the other private investors. We subsequently filed a registration statement with the Securities and Exchange Commission to register for resale all of the shares of common stock issuable upon conversion of the preferred stock. This registration statement was declared effective on June 20, 2003.

During the quarter ended December 31, 2003, short-term warrants for the purchase of 359,712 shares of preferred stock were exercised at a price of $4.42 per share providing us with additional gross proceeds of $1,589,927. During the quarter ended December 31, 2003, investors exercised their rights to convert 79,182 shares of preferred stock and were issued 1,029,366 shares of our common stock at $0.34 per share.

The shares of preferred stock, the warrants and the shares of common stock issuable upon conversion of the shares of preferred stock were issued without registration under the Securities Act of 1933 in reliance on the exemption provided by Section 4(2) of the Securities Act of 1933.

Dividends

We have never declared or paid cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, restrictions imposed by financing arrangements, if any, legal and regulatory restrictions on the payment of dividends, current and anticipated cash needs and other factors the board of directors deem relevant. In addition, if we were to pay dividends, such dividends would be paid to holders of our preferred stock, prior to any such distribution to holders of common stock, on a per share basis equal to the number of shares of common stock into which each share of preferred stock is then convertible.

Item 6. ***Selected Financial Data***

The following data, insofar as it relates to the years 1999, 2000, 2001, 2002 and 2003, have been derived from our audited financial statements. Our balance sheet dated as of December 31, 2002 and 2003 and the related statements of operations for each of the three years in the period ended December 31, 2003 are derived from the audited financial statements appearing elsewhere in this Annual Report on Form 10-K. This data should be read in conjunction with the financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results

of Operations" appearing elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 2,136	$ 1,910	$ 3,112	$ 4,307	$ 6,945
Cost of goods sold	2,007	1,879	2,431	3,061	3,203
Gross profit	129	31	681	1,246	3,742
Costs and expenses:					
Research and development	2,850	2,694	1,845	1,388	944
Selling, general and administrative	4,945	5,509	5,702	5,868	6,193
Total costs and expenses	7,795	8,203	7,547	7,256	7,137
Loss from operations	(7,666)	(8,172)	(6,866)	(6,010)	(3,395)
Interest income	331	585	413	104	20
Interest expense	—	(12)	(13)	(17)	(13)
Net loss	$ (7,335)	$ (7,599)	$ (6,466)	$ (5,923)	$ (3,388)
Beneficial Conversion Feature	—	—	—	—	(1,533)
Net loss attributable to common stockholders	$ (7,335)	$ (7,599)	$ (6,466)	$ (5,923)	$ (4,921)
Net loss per share—basic and diluted	$ (0.61)	$ (0.50)	$ (0.37)	$ (0.30)	$ (0.25)
Weighted average common shares outstanding—basic and diluted	11,933,261	15,331,565	17,340,789	19,450,062	19,663,460

	December 31,				
	1999	2000	2001	2002	2003
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 9,176	$ 11,455	$ 8,738	$ 3,093	$ 5,609
Working capital	8,950	11,258	8,669	3,152	6,389
Long term debt	0	0	101	6	4
Total assets	11,454	13,975	11,900	6,189	8,520
Total liabilities	1,404	1,293	1,981	2,032	1,620
Preferred stock	—	—	—	—	4,589
Warrants to acquire preferred stock	—	—	—	—	1,024
Accumulated deficit	(29,036)	(36,635)	(43,102)	(49,024)	(52,412)
Stockholders' equity	$ 10,049	$ 12,682	$ 9,918	$ 4,156	$ 1,287
Dividends—None					

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

Overview

We are engaged in the research, development and commercialization of products for the non-invasive diagnosis of cardiac disease. Using innovative technologies, we are addressing a key problem in cardiac diagnosis—the identification of those at risk of sudden cardiac arrest. Our proprietary technology and products are the only diagnostic tool cleared by the U.S. Food and Drug Administration to non-invasively measure Microvolt levels of T-Wave Alternans, an extremely subtle beat-to-beat fluctuation in a patient's heartbeat.

Our Microvolt T-Wave Alternans Test is performed using our primary products, the Heartwave System in conjunction with our single use Micro-V Alternans Sensors. We sell both products in the U.S. through our 15 person direct sales force supplemented by a limited number of independent

manufacturers' representatives and through independent distributors outside the U.S. There are approximately 400 Heartwave units that have been sold in the U.S. since the product was introduced at the end of fiscal 2000. Profitability for our business requires that we are successful in our efforts to expand the installed base of Heartwave units and continually increase the number of Microvolt T-Wave Alternans Tests being performed in order to increase the usage of our Micro-V Alternans Sensors. To be successful in our efforts, we utilize the help of established strategic partners to gain access to our primary customer, the clinical cardiologist, to inform them of the large amount of clinical data that has been presented and published on the value and importance of Microvolt T-Wave Alternans to their patients.

Revenue growth from both our Heartwave and Micro-V Alternans Sensors delivers improved gross profits since both products carry attractive profit margins and manufacturing overhead costs are leveraged with volume growth. This is evidenced by our increased gross profit margin percentage for fiscal 2003 of 54% compared to 29% for fiscal 2002. At December 31, 2003, approximately 60% of our total of 38 employees were engaged in the selling or marketing of our technology and products and account for approximately 57% of our total operating expenses incurred during fiscal 2003. An additional 21% of our employees are dedicated to product manufacturing and customer support, while the remainder of our organization is involved in either product research and development or administrative support.

During fiscal 2004, we will remain focused on the continuation of revenue growth from the sale of our Heartwave System and disposable Micro-V Alternans Sensors in the U.S. We will continue to enhance existing partnerships and explore opportunities to develop new relationships with partners in the field, in an effort to improve our access the clinical cardiologist. We anticipate that we will expand the number of sales territories in the U.S. from 15 at the end of fiscal 2003 to almost 20 by the end of fiscal 2004. We also expect to increase the number of field clinical specialists supporting customers in the U.S. from 3 at the end of fiscal 2003 to 4 by the end of fiscal 2004.

During fiscal 2004, we plan to focus time and resources in our continuing efforts to expand reimbursement for our Microvolt T-Wave Alternans Test for both Medicare and non-Medicare patients. We will be attempting to gain coverage for our Microvolt T-Wave Alternans Test from additional private insurance carriers, like Aetna and United Healthcare, who currently do not reimburse for performance of our test. If we are successful, we anticipate that this will provide additional support to our efforts to continue our revenue growth, which should lead to the improvement of our profit margins and cash position. Effective January 1, 2004, the Center for Medicare and Medicaid Services published a revised payment amount of approximately $338.00 for our Current Procedural Terminology Code 93025 used by healthcare providers to file for reimbursement for the performance of a Microvolt T-Wave Alternans Test. This represents an adjustment from approximately $425.00 in fiscal 2003. Medicare coverage across the country remains fairly good. We will continue our efforts in fiscal 2004 to expand the indications for use in many of the coverage policies.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of the financial condition and results of operations is based upon the financial statements which have been prepared in accordance with accounting principles generally accepted in the United States. Note 2 of the notes to the financial statements contained in this Annual Report on Form 10-K includes a summary of our significant accounting policies and methods used in the preparation of our financial statements. The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to incentive compensation, product returns, bad debts allowances, inventory valuation, investments, intangible assets, income taxes, financing operations, warranty obligations, and contingencies and litigation. We base our estimates on historical experience

and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies and estimates affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Revenue from the sale of product to all of our customers is recognized upon shipment of goods provided that risk of loss has passed to the customer, all of our obligations have been fulfilled, persuasive evidence of an arrangement exists, the fee is fixed or determinable, and collectibility is probable. Revenue from the sale of product to all of our third party distributors with whom we have a relationship is subject to the same recognition criteria. These distributors provide all direct repair and support services to their customers. Under Emerging Issue Task Force 00-21, in multiple element arrangements, separate elements can be considered separate units of accounting when the delivered unit has value to a customer on a stand alone basis and there is objective and reliable evidence of the fair value of the undelivered element. We regularly sell maintenance agreements with the Heartwave System. Revenue from maintenance contracts are recognized separately based on amounts charged when sold on a stand alone basis and is recognized over the term of the underlying agreement. Payments of $146,915 at December 31, 2003 ($15,490 at December 31, 2002) received in advance of services being performed is recorded as deferred revenue and included in current liabilities in the accompanying balance sheet.

Allowance for Doubtful Accounts

We maintain an allowance for doubtful accounts for estimated losses resulting from the non-payment of outstanding amounts due to us from our customers. We determine the amount of the allowance by evaluating the customer's credit history, current financial condition and payment history. We make a judgment as to the likelihood we will experience a loss of all or some portion of the outstanding balance. Our estimate of $100,000 represents 38% of the total unpaid balance in excess of 90 days past due date and 5% of our total accounts receivable at December 31, 2003. Our actual experience of customer receivables written off during fiscal 2003 and fiscal 2002 was immaterial. Accordingly, we believe we have an adequate allowance however additional write-offs could occur if future results significantly differ from our expectations.

Inventory Valuation

We write down our inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required that could materially affect our results of operations.

Capitalized Software

The establishment of technological feasibility and the ongoing assessment of recoverability of capitalized software development costs require that we exercise considerable judgment with respect to certain external factors, including, but not limited to, technological feasibility, anticipated future gross revenues, estimated economic life and changes in software and hardware technologies. The cost of consultants utilized in the development of new features and functionality of our Microvolt T-Wave Alternans software is capitalized as incurred and amortized on a straight-line basis over its estimated

life upon release to the market. The estimated life used for the amortization of the costs is three years. At each balance sheet date, these costs are evaluated for impairment by comparing the net realizable value of the product containing the software to the unamortized capitalized cost of that software. The amount by which the unamortized capitalized cost of the software exceeds this net realizable value, if any, is written off. As of December 31, 2003, no such write-offs have been made. The net realizable value is determined as the estimated future gross revenue from that product containing the software reduced by the estimated future costs of completing and disposing of that product. If no future revenues were achieved, then we would be required to write off the balance of the unamortized software costs, which is $157,573 at December 31, 2003.

Product Warranty

We warrant all of our non-disposable products as to compliance with their specifications and that the products are free from defects in material and workmanship for a period of 12 months from date of delivery. We maintain a reserve for the estimated costs of potential future repair of our products during this warranty period. The amount of reserve is based on our actual return and repair cost experience. If the rate and cost of future warranty activities materially differs from our historical experience, additional costs would have to be reserved that could materially effect our results of operations.

Results of Operations

The following table presents, for the periods indicated our revenue by product line and geographic region. This information has been derived from our Statement of Operations included elsewhere in this Annual Report on Form 10-K. You should not draw any conclusions about our future results from our revenue for any period.

	2001	% of Total	2002	% of Total	2003	% of Total	% Inc/(Dec) 2003 vs 2002	% Inc/(Dec) 2002 vs 2001
Alternans Products:								
U. S. (core business)	$1,643,797	53%	$2,522,503	59%	$5,127,570	74%	103%	54%
Europe	207,560	7%	136,651	3%	184,477	2%	35%	-34%
Asia/Pacific	207,085	6%	271,247	6%	54,300	1%	-80%	31%
Rest of World	4,200	0%	17,340	0%	1,200	0%	-93%	313%
Total	2,062,642	66%	2,947,741	68%	5,367,547	77%	82%	43%
Stress Products:								
U. S.	519,118	17%	981,699	23%	1,169,774	17%	19%	89%
Europe	486,575	16%	201,663	5%	190,032	3%	-5%	-59%
Asia/Pacific	34,902	1%	121,614	3%	192,198	3%	58%	248%
Rest of World	8,800	0%	54,660	1%	25,360	0%	-54%	521%
Total	1,049,395	34%	1,359,636	32%	1,577,364	23%	16%	30%
Total Revenues	$3,112,037	100%	$4,307,377	100%	$6,944,911	100%	61%	38%

Fiscal 2003 Compared to Fiscal 2002

REVENUE:

Total revenue for fiscal 2003 and 2002 was $6,944,911 and $4,307,377, respectively, an increase of 61%. Revenue from the sale of our Microvolt T-Wave Alternans products, which we call our Alternans Products, was $5,367,547 during fiscal 2003 compared to $2,947,741 during fiscal 2002, an increase of 82% and accounted for 77% and 68% of total revenue for fiscal 2003 and fiscal 2002, respectively.

During fiscal 2003, revenue from our core business, which consists of U.S. sales of our Heartwave, Micro-V Alternans Sensors and other Alternans Products sold through our distribution partners, increased 103% and accounted for 74% of total revenue for fiscal 2003 compared to 59% of total revenue for fiscal 2002. The average selling price of our Heartwave System in the U.S. increased 13% during fiscal 2003 compared to fiscal 2002, while the selling price of our Micro-V Alternans Sensors increased an average of 18% during the same period. The balance of the 103% increase in our revenue from the sale of Alternans Products is primarily the result of growth in units sold of all Alternans Products. During fiscal 2003, we sold approximately 50 Heartwave Systems to customers participating in the MASTER Study. Revenue from the sale of our Micro-V Alternans Sensors increased 87% in fiscal 2003 compared to fiscal 2002. This increase is due to the increase in the installed base of our Heartwave Systems in the U.S., which is now approaching 400 units. Revenue from the sale of disposable Micro-V Alternans Sensors accounted for 32% of our core business revenue in fiscal 2003 compared to 34% in fiscal 2002.

Revenue from the sale of Alternans Products outside the U.S. declined from $425,238 in fiscal 2002 to $239,977 in fiscal 2003. During 2002, our Japanese distributor, Fukuda Denshi, purchased an initial quantity of Heartwave systems in anticipation of receiving approval of their application for registration of our Heartwave System with the Japanese Ministry of Health, Labor and Welfare. The approval from the Japanese Ministry of Health, Labor and Welfare was delayed, and was not received until later in fiscal 2003. As a result, additional sales in Japan were delayed. We are now in discussions with our distributor regarding a new distribution agreement.

During fiscal 2003, revenue from the sale of our CH 2000 stress test system and associated product components was $1,577,364 compared to $1,359,636 in fiscal 2002, an increase of 16%. The increase is primarily from the growth in unit sales of product in the U.S. Revenue from the sale of these products accounted for 23% of total revenue in fiscal 2003 compared to 32% in fiscal 2002. Sales to our U.S. customers including our exclusive distributor Philips Medical Systems accounted for 74% of our total stress product sales in fiscal 2003 compared to 72% in fiscal 2002. Our distribution agreement with Philips Medical Systems that granted them exclusive rights to distribute our CH 2000 stress test system in the U.S. and non-exclusive rights outside the U.S. expired at the end of fiscal 2003. Revenue from sales of stress products under this agreement accounted for 14% and 19% of total revenue for fiscal 2003 and fiscal 2002, respectively.

GROSS PROFIT:

Gross profit was 54% of total revenue in fiscal 2003 compared to 29% in fiscal 2002. The impact of sales volume growth in fiscal 2003 from the sale of Heartwave Systems and disposable Micro-V Alternans Sensors in the U.S. accounted for approximately 73% of the increase in gross profit. Increases in average selling prices in the U.S. of these products represent the majority of the remaining gross profit improvement. We anticipate gross profit margins in fiscal 2004 will continue to be effected by sales volume and selling price changes.

OPERATING EXPENSES:

The following table presents, for the periods indicated our operating expenses. This information has been derived from our Statement of Operations included elsewhere in this Annual Report on

Form 10-K. You should not draw any conclusions about our future results from our operating expenses for any period.

	2001	% of Total Revenue	2002	% of Total Revenue	2003	% of Total Revenue	% Inc/(Dec) 2003 vs 2002	% Inc/(Dec) 2002 vs 2001
Operating Expenses:								
R & D	$1,845,331	59%	$1,387,946	32%	$ 944,325	14%	−32%	−25%
S.G. & A.	5,701,802	183%	5,867,795	136%	6,192,723	89%	6%	3%
Total	$7,547,133	242%	$7,255,741	168%	$7,137,048	103%	−2%	−4%

RESEARCH AND DEVELOPMENT:

Research and development expenses were $944,325 in fiscal 2003 compared to $1,387,946 in fiscal 2002, a decrease of 32%. We continue to focus our efforts on the development and design of enhancements to our existing Microvolt T-Wave Alternans technology. These programs are less costly than the product development programs funded during fiscal 2002 and therefore contribute to a large portion of the expense decrease in fiscal 2003. In addition, we experienced some staff turnover in the research and development organization during fiscal 2003 that also contributed to lower costs in fiscal 2003. These vacancies will be filled during the first quarter of 2004. We anticipate that research and development spending will increase modestly in fiscal 2004.

SELLING, GENERAL AND ADMINISTRATIVE:

Selling, general and administrative expenses were $6,192,723 in fiscal 2003 compared to $5,867,795 in fiscal 2002, an increase of 6%. Selling and marketing costs, which accounted for 66% of total SG&A increased 4% over fiscal 2002. Selling expenses increased 13% during fiscal 2003 compared to fiscal 2002 primarily as the result of increases in earned compensation by our U.S. sales personnel from the growth in revenue from our core business during fiscal 2003. Marketing expenses declined 26% in fiscal 2003 compared to fiscal 2002 primarily due to reductions in advertising and promotional expenditures. Administrative expenses increased 10% in fiscal 2003 compared to fiscal 2002 primarily as a result of a 33% increase in insurance costs and legal costs associated with our stock delisting and non-capitalized financing activities. We anticipate that selling, general and administrative expenses will continue to increase in fiscal 2004.

INTEREST INCOME/INTEREST EXPENSE:

Interest income was $20,297 in fiscal 2003 compared to $104,253 in fiscal 2002, a decrease of 81%. The decrease is primarily the result of lower amounts of invested cash during most of fiscal 2003 and the decline in short-term interest rates during fiscal 2003. Interest expense was $13,300 in fiscal 2003 compared to $17,053 in fiscal 2002. The decrease is the result of the repayment of our credit line with Silicon Valley Bank in October 2003.

NET LOSS:

As a result of factors described above, net loss attributable to common stockholders was $4,920,910 in fiscal 2003 as compared to a net loss of $5,922,685 in fiscal 2002. The reported amount for fiscal 2003 includes a non-cash financing charge associated with the sale of our Series A Redeemable Convertible Preferred Stock in May 2003, the terms of which are described in the Liquidity and Capital Resources section of this document, in the amount of $1,533,280. The amount of the beneficial conversion feature has been immediately accreted and the accretion will result in a deemed dividend as the preferred stock does not have a redemption term. The deemed dividend has been reflected as an adjustment to net loss applicable to common stockholders on our Statement of Operations. We reported a net loss of $3,387,630 for fiscal 2003 before the financing charge.

Fiscal 2002 Compared to Fiscal 2001

REVENUE:

Total revenue for fiscal 2002 and 2001 was $4,307,377 and $3,112,037, respectively, an increase of 38%. Revenue from the sale of our Microvolt T-Wave Alternans products, which we call our Alternans Products, was $2,947,741 during fiscal 2002 compared to $2,062,642 during fiscal 2001, an increase of 43%, and accounted for 68% and 66% of total revenues, for fiscal 2002 and fiscal 2001, respectively.

During fiscal 2002, revenue from our core business increased 54% and accounted for 59% of total revenue for fiscal 2002 compared to 53% of total revenue for fiscal 2001. The average selling prices of our Heartwave increased 14% in fiscal 2002 compared to fiscal 2001, while the average price of our Micro-V Alternans Sensors increased 7%. The remainder of the annual increase resulted from growth in units sold. Revenue from the sale of disposable Micro-V Alternans Sensors accounted for 34% of our core business revenue in fiscal 2002 compared to 22% in fiscal 2001. The increase is the result of the increased number of installed Heartwave Systems in the U.S. Revenue from sale of Heartwave and other Alternans Products accounted for the balance of core business revenue. Sales of all Alternans Products to customers outside the U.S. during fiscal 2002 increased 2% from fiscal 2001. Sales to the Asia/Pacific region accounted for 64% of total Alternans Product sales outside the U.S. during fiscal 2002 compared to 49% during fiscal 2001. During fiscal 2002, our Japanese distributor, Fukuda Denshi, initiated efforts to register our Heartwave System for sale with the Japanese Ministry of Health, Labor and Welfare.

During fiscal 2002, revenue from the sale of our CH 2000 stress test system was $1,359,636 compared to $1,049,395 during fiscal 2001, an increase of 30%. Growth in the volume of units sold accounted for all of the fiscal 2002 increase. Revenue from the sale of these products accounted for 32% of our total revenue during fiscal 2002 compared to 34% during fiscal 2001. Sales to our U.S. customers, including our exclusive U.S. distributor, Philips Medical Systems, accounted for 72% of total stress product sales during fiscal 2002 compared to 49% during fiscal 2001.

GROSS PROFIT:

Gross profit was 29% of total revenue in fiscal 2002 compared to 22% in fiscal 2001. The majority of the margin percentage improvement, 85%, reflects the effect of sales volume growth on the amount of labor and overhead costs allocated to each unit sold. The remainder of the improvement is the result of increases in average selling prices.

RESEARCH AND DEVELOPMENT:

Research and development expenses were $1,387,946 in fiscal 2002 compared to $1,845,331 in fiscal 2001, a decrease of 25%. During fiscal 2002, we had transferred the focus of our research and development expenditures from the development of new products to the development and design of enhancements to our existing Microvolt T-Wave Alternans technology and products to maximize their functionality and ease of use. During fiscal 2001 we completed work on the development of the *Microsoft Windows 2000® operating system for our CH 2000 stress test system distributed exclusively* in the U.S. by Philips Medical Systems.

SELLING, GENERAL AND ADMINISTRATIVE:

Selling, general and administrative expenses were $5,867,795 in fiscal 2002 compared to $5,701,802 in fiscal 2001, an increase of 3%. Selling and marketing costs which represent 67% of total SG&A expenses were virtually unchanged in fiscal 2002 compared to fiscal 2001. Total U.S. selling expenses increased 4% due primarily to the addition of two sales territories. Our focus on the U.S. sales opportunity for Microvolt T-Wave Alternans resulted in a decline in international selling expenses of

27%. Marketing costs for the year remained unchanged. Administrative costs increased 10% in fiscal 2002 compared to fiscal 2001. The costs associated with our status as a publicly traded entity accounted for the majority of this increase as they grew 40% primarily due to higher insurance costs, and the cost associated with the transfer of the listing of our common stock on the Nasdaq SmallCap Market. The registration of our common stock was transferred from the Nasdaq National Market to the Nasdaq SmallCap Market in November 2002.

INTEREST INCOME/INTEREST EXPENSE:

Interest income was $104,253 in fiscal 2002 compared to $412,553 in fiscal 2001, a decrease of 75%. The decrease resulted from a $5.6 million decrease in invested cash during fiscal 2002 compared to fiscal 2001 and to a lesser extent, the decline in short term interest rates during fiscal 2002. Interest expense was $17,053 in fiscal 2002 compared to $13,244 in fiscal 2001. The increase was the result of increased borrowing on our credit line with Silicon Valley Bank.

NET LOSS:

As a result of the factors described above, we had a net loss of $5,922,685 in fiscal 2002 as compared to a net loss of $6,466,433 in fiscal 2001.

Inflation and Income Taxes

Inflation did not have a significant effect on our results of operations for any of the years in the three year period ended December 31, 2003.

We have not recorded a provision for income taxes for the years 1998 through 2003 because we incurred net losses in each of such years. At December 31, 2003, we had federal and state net operating loss carryforwards of approximately $43,892,000 and $29,246,000, respectively, as well as $1,150,000 of federal and $702,000 of state tax credit carryforwards, available to offset future taxable income and income tax liabilities, respectively. These carryforwards generally expire in the years 2003 through 2023 and may be subject to annual limitations as a result of changes in our ownership. There can be no assurance that changes in ownership in future periods or continuing losses will not significantly limit our use of net operating loss and tax credit carryforwards.

We have generated taxable losses from operations since inception and, accordingly, have no taxable income available to offset the carryback of net operating losses. In addition, although our operating plans anticipate taxable income in future periods, such plans provide for taxable losses over the near term and make significant assumptions, which cannot be reasonably assured including market acceptance of our products by customers. We have provided a full valuation allowance of approximately ($22,478,000) at December 31, 2003 for our deferred tax assets since, in our opinion, realization of these future benefits is not sufficiently assured (defined as a likelihood of slightly more than 50 percent).

Quarterly Financial Results

The following tables set forth a summary of our unaudited quarterly results of operations for 2003 and 2002. In the opinion of management, this information has been prepared on the same basis as the audited financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the quarterly information when read in conjunction with the audited financial statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. The quarterly operating results are not necessarily indicative of future results of operations.

	Three Months Ended (Unaudited)			
	March 31, 2003	June 30, 2003	Sept 30, 2003	Dec 31, 2003
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 1,104	$ 1,627	$ 1,954	$ 2,260
Cost of goods sold	711	730	880	881
Gross profit	393	897	1,074	1,379
Costs and expenses:				
Research and development	221	330	232	161
Selling, general and administrative	1,415	1,600	1,489	1,690
Total costs and expenses	1,636	1,930	1,721	1,851
Loss from operations	(1,243)	(1033)	(647)	(472)
Interest income	5	3	5	7
Interest expense	(6)	(3)	(2)	(2)
Net loss	$(1,244)	$(1,033)	$ (644)	$ (467)
Beneficial conversion feature	—	(1,533)	—	—
Net loss attributable to common stockholders	$(1,244)	$(2,566)	$ (644)	$ (467)
Net loss per common share—basic and diluted	$ (0.06)	$ (0.13)	$ (0.03)	$ (0.02)

	Three Months Ended (Unaudited)			
	March 31, 2002	June 30, 2002	Sept 30, 2002	Dec 31, 2002
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 909	$ 1,051	$ 1,273	$ 1,074
Cost of goods sold	697	763	787	814
Gross profit	212	288	486	260
Costs and expenses:				
Research and development	369	419	296	304
Selling, general and administrative	1,491	1,542	1,459	1,376
Total costs and expenses	1,860	1,961	1,755	1,680
Loss from operations	(1,648)	(1,673)	(1,269)	(1,420)
Interest income	39	30	22	13
Interest expense	(6)	(4)	(4)	(3)
Net loss	$(1,615)	$(1,647)	$(1,251)	$(1,410)
Net loss per common share—basic and diluted	$ (0.08)	$ (0.08)	$ (0.06)	$ (0.07)

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2003	June 30, 2003	Sept 30, 2003	Dec 31, 2003
Statement of Operations Data:				
Revenue	100%	100%	100%	100%
Cost of goods sold	64%	45%	45%	39%
Gross profit (loss)	36%	55%	55%	61%
Costs and expenses:				
Research and development	20%	20%	12%	7%
Selling, general and administrative	128%	98%	76%	75%
Total costs and expenses	148%	118%	88%	82%
Loss from operations	(112%)	(63%)	(33%)	(21%)
Interest income	0%	0%	0%	0%
Interest expense	(1%)	0%	0%	0%
Net loss	(113%)	(63%)	(33%)	(21%)
Beneficial conversion feature	—	(94%)	—	—
Net loss attributable to common stockholder	(113%)	(157%)	(33%)	(21%)

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2002	June 30, 2002	Sept 30, 2002	Dec 31, 2002
Statement of Operations Data:				
Revenue	100%	100%	100%	100%
Cost of goods sold	77%	73%	62%	76%
Gross profit (loss)	23%	27%	38%	24%
Costs and expenses:				
Research and development	41%	40%	23%	28%
Selling, general and administrative	164%	147%	115%	128%
Total costs and expenses	205%	187%	138%	156%
Loss from operations	(181%)	(159%)	(100%)	(132%)
Interest income	4%	3%	2%	1%
Interest expense	(1%)	0%	0%	0%
Net loss	(178%)	(157%)	(98%)	(131%)

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities were $5,609,244 at December 31, 2003 compared to $3,093,412 at December 31, 2002, an increase of $2,515,832. This increase is consistent with the net cash proceeds from the sale of our Series A Redeemable Convertible Preferred Stock of $5,826,648 net of cash used for operating activities of $2,534,099 and cash used for the repayment of debt of $802,829. Accounts receivable, net of allowance for doubtful accounts at December 31, 2003 increased $599,133, or 51%, reflecting the increase in sales at the end of fiscal 2003 compared with fiscal 2002. Inventory at December 31, 2003 decreased $198,078 or 30%, primarily as a result of the timing of vendor shipments at the end of fiscal 2003 compared to fiscal 2002. Prepaid expenses at December 31, 2003 decreased $90,713, or 36%, primarily reflecting a reduction in the amount of prepaid marketing supplies at the end of fiscal 2003 compared to fiscal 2002. Fixed asset additions during fiscal 2003 totaled $15,891.

On May 12, 2003, we entered into an agreement for the sale of up to $6.5 million of preferred stock to Medtronic, Inc. and a group of private investors. Under the terms of the financing, we issued and sold 696,825 shares of preferred stock at a purchase price of $4.42 per share, for total gross proceeds of approximately $3.1 million. Each share of the preferred stock is convertible into 13 shares

of our common stock. The conversion price of the preferred stock is subject to adjustments in certain circumstances. If we issue shares of common stock at a purchase price below the conversion price of the preferred stock prior to November 12, 2004, the conversion price of the preferred stock will be adjusted to equal such purchase price.

As part of the financing, we issued to the investors, other than Medtronic, short-term warrants exercisable for a total of 705,852 shares of the preferred stock. There were six tranches of the short-term warrants that expired in monthly intervals starting September 1, 2003. The exercise price per share of these warrants was the lower of $4.42 or 13 times the 20 day average closing price of our common stock prior to the date of expiration. We also issued to both Medtronic and the private investors long-term warrants exercisable for 30% of the total number of shares of preferred stock purchased through the initial investment and the exercise of the short-term warrants. The exercise price per share of Medtronic's long-term warrant is $4.42 and the exercise price per share of the long-term warrants issued to the other investors is $5.525. These long-term warrants expire on January 1, 2009.

In connection with this financing and in order to address certain payment obligations in existing agreements with The Tail Wind Fund Ltd., we issued to Tail Wind short-term warrants exercisable for 67,872 shares of the preferred stock and a long-term warrant exercisable for 75% of the total number of shares of the preferred stock purchased through the exercise of Tail Wind's short-term warrants. The exercise prices and the expiration dates of Tail Wind's warrants are consistent with the warrants issued to the other private investors. The holders of all of the warrants described above are not obligated to exercise all or any portion of those warrants, and there can be no assurance that we will receive any additional funds from the exercise of any of these warrants.

During the year ended December 31, 2003, short-term warrants for the purchase of 663,999 shares of preferred stock were exercised at a price of $4.42 per share providing us with gross proceeds of $2,934,876. Short-term warrants for the purchase of 109,725 additional shares of preferred stock with an expiration date from February 1, 2004 were available for exercise at December 31, 2003. During January 2004, investors exercised all of the remaining short-term warrants providing us with additional proceeds of $484,985. In addition, Medtronic and the private investors were vested in long-term warrants for the purchase of 438,790 shares of our common stock at December 31, 2003. As of January 31, 2004, they are vested in long-term warrants for the purchase of 471,703 shares of our common stock. We have issued a total of 1,360,824 shares of preferred stock as of December 31, 2003, which provided us with total gross proceeds of $6,014,843. As of January 31, 2004 we have issued a total of 1,470,549 shares of preferred stock, which provided us with total gross proceeds of $6,499,828. During the year ended December 31, 2003, investors exercised their rights to convert 79,182 shares of preferred stock into 1,029,366 shares of our Common Stock at $0.34 per share.

We received a Nasdaq Staff Determination dated March 18, 2003 indicating that we had failed to regain compliance with the $1.00 per share minimum bid price requirement for continued listing on The Nasdaq SmallCap Market under Nasdaq Marketplace Rule 4310(c)(4). The notice stated that we are not eligible for an additional 180 day compliance period because we do not meet the initial inclusion requirements under Nasdaq Marketplace Rule 4310(c)(2)(A). The notice stated that our common stock would be delisted from The Nasdaq SmallCap Market at the opening of business on March 27, 2003. On March 25, 2003, we filed an appeal and requested a hearing before a Nasdaq Listing Qualifications Panel to review the Staff Determination and to present a plan to regain compliance for continued listing. On May 7, 2003, we announced that we had withdrawn our appeal before the Nasdaq Listing Qualifications Panel and on May 8, 2003 our common stock began trading on the National Association of Securities Dealers' OTC Bulletin Board under the same trading symbol (CAMH).

On April 4, 2003, we received notice from Silicon Valley Bank that we were in default under our Loan and Security Agreement dated September 26, 2002 as a result of a "material adverse change in

our business, operations or condition." This notification was provided to us by the bank as a result of the report of our independent accountants on the completion of their audit of our financial statements for the year ended December 31, 2002, in which they expressed substantial doubt about our ability to continue as a going concern. Silicon Valley Bank advised us that this notification of an event of default would not result in the termination of our Loan and Security Agreement. On May 8, 2003, we entered into a Loan Modification Agreement with Silicon Valley Bank that amended selected financial covenants in the original Loan and Security Agreement and included a waiver of the April 4, 2003 event of default conditioned on our completion of the above described financing. As a result of this waiver, we were able to continue our normal utilization of the $1.2 million credit facility. Under the terms of the agreement, we issued a warrant to Silicon Valley Bank for the purchase of 21,053 shares of our common stock at an exercise price of $2.28 with certain anti-dilution provisions. As a result of the above mentioned financing, we were required to amend the number of shares issuable upon exercise of the warrant and the exercise price of the amended warrant to 37,015 shares and $1.30, respectively.

On September 25, 2003, we entered into an amendment to our Loan and Security Agreement with Silicon Valley Bank to extend the expiration date from September 25, 2003 to November 9, 2003. On October 22, 2003, we notified Silicon Valley Bank of our intent not to seek renewal of the Loan and Security Agreement or to negotiate a new agreement. On October 30, 2003, we paid the remaining $83,462 due under the Loan and Security Agreement. The Loan and Security Agreement formally terminated on November 9, 2003.

Under the terms of our license, consulting and technology agreements, we are required to pay royalties on sales of our products. Minimum license maintenance fees under these license agreements, which are creditable against royalties otherwise payable for each year, are $10,000 per year through 2007. We are committed to pay an aggregate of $40,000 of such minimum license maintenance fees subsequent to December 31, 2003. As part of these agreements, we are also committed to meet certain development and sales milestones, including a requirement to spend a minimum of $200,000 in any two-year period for research and development, clinical trials, marketing, sales and/or manufacturing of products related to certain technology covered by the consulting and technology agreements. As of December 31, 2003, we believe we were in full compliance with all requirements of these agreements.

We anticipate that our existing cash resources will be sufficient to satisfy our cash requirements for at least the next twelve months.

The Company's financial statements have been prepared on a going concern basis, which assumes the Company will realize its assets and discharge its liabilities in the normal course of business. The Company has experienced recurring losses from operations of $6,865,742, $6,009,885 and $3,394,627 for the fiscal years ended December 31, 2001, 2002 and 2003, respectively and recurring negative cash flow from operations of $6,368,236, $5,705,073 and $2,537,077 for the fiscal years ended December 31, 2001, 2002 and 2003, respectively. In addition, the Company has an accumulated deficit of $52,411,924 at December 31, 2003. The Company anticipates that it has sufficient cash reserves to satisfy their cash requirements through December 31, 2004. If the Company is unable to generate sufficient revenue to sustain operations, it may need to seek additional sources of financing. There is no certainty that such efforts would be successful.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2003 are included in the table below.

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Short-Term Debt Obligations	$ —	$ —	$ —	$ —	$ —
Capital Lease Obligations	$ 6,309	$ 2,103	$ 4,206	$ —	$ —
Operating Lease Obligations	$280,547	$142,028	$138,519	$ —	$ —
Purchase Obligations	$ 40,000	$ 10,000	$ 30,000	$ —	$ —
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet Under U.S. GAAP	$ —	$ —	$ —	$ —	$ —
Total	$326,856	$154,131	$172,725	$ —	$ —

Off-Balance Sheet Arrangements

We have not created, and are not party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of our business that are not consolidated into our financial statements. We do not have any arrangements or relationships with entities that are not consolidated into our financial statements that have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

New Accounting Pronouncements

In May 2003, the FASB issued SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after December 15, 2003. The adoption of SFAS 150 is not expected to have a material effect on the Company's financial statements.

Factors Which May Affect Future Results

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "intends" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements. These factors include, without limitation, those set forth below and elsewhere in this Annual Report on Form 10-K.

Risks Related to our Operations

We depend on our Microvolt T-Wave Alternans technology for a significant portion of our revenues and if it does not achieve broad market acceptance, our growth will be limited.

We believe that our future success will depend, in large part, upon the successful commercialization and market acceptance of our Microvolt T-Wave Alternans technology. Market acceptance will depend upon our ability to demonstrate the diagnostic advantages and cost-effectiveness of this technology. The failure of our Microvolt T-Wave Alternans technology to achieve broad market

acceptance, the failure of the market for our products to grow or to grow at the rate we anticipate, or a decline in the price of our products would reduce our revenues and limit our growth. This could have a material adverse effect on the market price of our common stock. We can give no assurance that we will be able to successfully commercialize or achieve market acceptance of our Microvolt T-Wave Alternans technology or that our competitors will not develop competing technologies that are superior to our technology.

We have not been able to fund our operations from cash generated by our business, and if we cannot meet our future capital requirements, we may not be able to continue as a going concern, develop or enhance our technology, take advantage of business opportunities and respond to competitive pressures.

We have principally financed our operations over the past three years through the private placement of shares of our common stock and preferred stock. If we do not generate sufficient cash from our business to fund operations, or if we cannot obtain additional capital through equity or debt financings, we will be unable to continue as a going concern, to grow as planned and may not be able to take advantage of business opportunities, develop new technology or respond to competitive pressures. This could have a material adverse effect on our operations and the market price of our common stock. In the current economic environment, financing for technology and medical device companies has become increasingly difficult to obtain. Any additional financing we may need in the future may not be available on terms favorable to us, if at all. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of Cambridge Heart by our stockholders would be reduced and the securities issued could have rights, preferences and privileges more favorable than those of our current stockholders.

We have a history of net losses, we expect to continue to incur net losses and may not achieve or maintain profitability.

We are engaged primarily in the commercialization, manufacture, research and development of products for the non-invasive diagnosis of heart disease. We have incurred substantial net losses through December 31, 2003. We may never generate substantial revenues or achieve profitability on a quarterly or annual basis. We expect that our selling, general and administrative expenses will increase significantly in connection with the expansion of our sales and marketing activities. Revenue generated from the sale of our products will depend upon numerous factors, including:

- the extent to which our products gain market acceptance;
- varying pricing promotions and volume discounts to customers;
- competition; and
- the availability and amount of third-party reimbursement.

We could issue additional shares of common stock, which might dilute the book value of our common stock.

We have authorized 75,000,000 shares of our common stock, of which 21,178,907 shares were issued and outstanding as of December 31, 2003. Our board of directors has the authority, without action or vote of our stockholders in most cases, to issue all or a part of any authorized but unissued shares of our common stock. Such stock issuances may be made at a price, which reflects a discount from the then-current trading price of our common stock. In addition, in order to raise capital that we may need at today's stock prices, we would likely need to issue securities, which are convertible into or exercisable for a significant number of shares of our common stock. These issuances would dilute your percentage ownership interest, which will have the effect of reducing your influence on matters on which our stockholders vote, and might dilute the book value of our common stock. You may incur additional dilution of net tangible book value if holders of stock options or warrants, whether currently outstanding or subsequently granted, exercise their options or warrants to purchase shares of our common stock.

During fiscal 2003, we issued a total of 1,360,824 shares of our preferred stock to private investors. These shares are initially convertible into up to 17,690,712 shares of our common stock. At December 31, 2003, investors hold warrants to acquire an additional 581,428 shares of our preferred stock, which is convertible into 7,558,564 shares of our common stock. The conversion price of the preferred stock is subject to adjustment in certain circumstances. If we issue shares of common stock at a purchase price below the conversion price of the preferred stock prior to November 12, 2004, the conversion price of the preferred stock will be adjusted to equal such purchase price. You would incur additional dilution of net tangible book value if the conversion price of the preferred stock is adjusted pursuant to this provision and the holders of preferred stock convert these shares of preferred stock into shares of our common stock. During fiscal 2003, investors exercised their rights to convert 79,182 shares of preferred stock into 1,029,366 shares of our common stock at $0.34 per share.

The sale of a large number of shares of our common stock could depress our stock price.

As of December 31, 2003, we have reserved 6,016,088 shares of common stock for issuance upon exercise of stock options and warrants and 1,079,250 shares for future issuances under our stock plans. We have also reserved 22,365,616 shares of common stock for issuance upon conversion of our preferred stock. As of December 31, 2003, holders of warrants and options to purchase an aggregate of 10,774,612 shares of our common stock may exercise those securities and transfer the underlying common stock at any time subject, in some cases, to Rule 144. In accordance with registration rights that we have granted to various individuals and entities requiring us to register their shares of common stock for public resale, we also have resale registration statements in effect registering 32,553,635 shares of our common stock. Included in the shares registered are the shares of common stock issuable upon conversion of the preferred stock that we issued and sold in the May 2003 financing and that are issuable upon exercise of the warrants issued in connection with the financing. Assuming no adjustments to the conversion price of the preferred stock (as described in the immediately preceding risk factor), the shares of preferred stock (including the shares of preferred stock issuable upon exercise of the warrants issued in the financing) are initially convertible into 25,249,276 shares of our common stock. In addition, as in the case of the May 2003 financing, in order to raise capital that we may need at today's stock prices, we will likely need to issue securities which are convertible into or exercisable for a significant amount of our common stock. The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales might also make it more difficult for us to sell equity securities in the future at a price that we think is appropriate, or at all.

Financial investors may have interests different than you or Cambridge Heart, and may be able to impact corporate actions requiring stockholder approval because they own a significant amount of our common stock.

In connection with the May 2003 financing, we issued securities, which are initially convertible into approximately 51% of the number of shares of our outstanding common stock. In future financings, we may also issue securities, which are convertible into or exercisable for a significant number of shares of our outstanding common stock. Financial investors may have short-term financial interests different from Cambridge Heart's long-term goals and the long-term goals of our management and other stockholders. In addition, based on the significant ownership of our outstanding common stock, financial investors may be able to impact corporate actions requiring stockholder approval.

We may need additional financing for our future capital needs and may not be able to raise additional funds on terms acceptable to us, or at all.

We believe that the financial resources available to us, including our current working capital, will be sufficient to finance our planned operations and capital expenditures for at least for the next 12 months. If we are unable to increase our revenue and achieve positive cash flow, we will need to raise additional funds. We may also need additional financing if:

- we need additional cash to fund research and development costs of products currently under development,
- we decide to expand faster than currently planned,
- we develop new or enhanced services or products ahead of schedule,
- we decide to undertake new sales and/or marketing initiatives,
- we are required to defend or enforce our intellectual property rights,
- sales of our products do not meet our expectations in the United States or internationally,
- we need to respond to competitive pressures, or
- we decide to acquire complementary products, businesses or technologies.

We can provide no assurance that we will be able to raise additional funds on terms acceptable to us, if at all. If future financing is not available or is not available on acceptable terms, we may not be able to fund our future needs which would significantly limit our ability to implement our business plan. In addition, we may have to issue securities that may have rights, preferences and privileges senior to our common stock. If we are unable to obtain sufficient additional funding when needed, we may have to significantly cut back our operations, sell some or all of our assets, license potentially valuable technologies to third parties and/or cease operations. In addition, if we raise additional capital by issuing additional equity or convertible debt securities, our existing stockholders would suffer significant dilution.

The results of future clinical studies may not support the usefulness of our technology.

We have sponsored and are continuing to sponsor clinical studies relating to our Microvolt T-Wave Alternans technology and Micro-V Alternans Sensors to more firmly establish the predictive value of such technology. Although studies on high risk patients to date have indicated that the measurement of Microvolt T-Wave Alternans to predict the vulnerability to ventricular arrhythmia and sudden death is excellent in various cardiac populations, we do not know whether the results of such studies will continue to be favorable. Any clinical studies or trials which fail to demonstrate that the measurement of Microvolt T-Wave Alternans is at least comparable in accuracy to alternative diagnostic tests, or

which otherwise call into question the cost-effectiveness, efficacy or safety of our technology, would have a material adverse effect on our business, financial condition and results of operations.

We may have difficulty responding to changing technology.

The medical device market is characterized by rapidly advancing technology. Our future success will depend, in large part, upon our ability to anticipate and keep pace with advancing technology and competitive innovations. However, we may not be successful in identifying, developing and marketing new products or enhancing our existing products. In addition, we can give no assurance that new products or alternative diagnostic techniques may be developed that will render our current or planned products obsolete or inferior. Rapid technological development by competitors may result in our products becoming obsolete before we recover a significant portion of the research, development and commercialization expenses incurred with respect to such products.

We depend exclusively on third parties to support the commercialization of our products internationally.

We market our products internationally through independent distributors. These distributors also distribute competing products under certain circumstances. The loss of a significant international distributor could have a material adverse effect on our business if a new distributor, sales representative or other suitable sales organization can not be found on a timely basis in the relevant geographic market. Because we rely on distributors for international sales, any revenues we receive in those territories will depend upon the efforts of our distributors. Furthermore, we cannot be sure that a distributor will market our products successfully or that the terms of any future distribution arrangements will be acceptable to us. In fiscal 2003, 8% of our revenue came from the sale of product to international distributors.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

Competition from competitors' medical devices that diagnose cardiac disease is intense and likely to increase. Our success will depend on our ability to develop products and apply our technology and our ability to establish and maintain a market for our products. We compete with manufacturers of electrocardiogram stress tests, the conventional method of diagnosing ischemic heart disease, as well as with manufacturers of other invasive and non-invasive tests, including EP testing, electrocardiograms, Holter monitors, ultrasound tests and systems of measuring cardiac late potentials. GE Medical Systems has introduced an analysis system it claims can measure t-wave alternans. GE Medical Systems has received concurrence from the FDA of its 510(k) allowing it to distribute the product in the U.S. The FDA concurrence does not include approval of any predictive claims regarding their measurement of t-wave alternans. Many of our competitors and prospective competitors have substantially greater capital resources, name recognition, research and development experience and regulatory, manufacturing and marketing capabilities. Many of these competitors offer broad, well-established product lines and ancillary services not offered by Cambridge Heart. Some of our competitors have long-term or preferential supply arrangements with physicians and hospitals which may act as a barrier to market entry.

We obtain critical components and subassemblies for the manufacture of our products from a limited group of suppliers, and if our suppliers fail to meet our requirements, we may be unable to meet customer demand and our customer relationships would suffer.

We do not have long-term contracts with our suppliers. Our dependence on a single supplier or limited group of smaller suppliers for critical components and subassemblies exposes us to several risks, including:

- a potential for interruption, or inconsistency in the supply of components or subassemblies, leading to backorders and product shortages,
- a potential for inconsistent quality of components or subassemblies supplied, leading to reduced customer satisfaction or increased product costs and delays in shipments of our products to customers and distributors, and
- inconsistent pricing.

Disruption or termination of the supply of these components and subassemblies could cause delays in the shipment of our products, resulting in potential damage to our customer relations and reduced revenue. From time to time in the past, we have experienced temporary difficulties in receiving timely shipment of key components from our suppliers. We can give no assurance that we would be able to identify and qualify additional suppliers of critical components and subassemblies in a timely manner. Further, a significant increase in the price of one or more key components or subassemblies included in our products could seriously harm our results of operations.

Risks Related to the Market for Cardiac Diagnostic Equipment

If we are not able to maintain adequate levels of third-party reimbursement, it would have a material adverse affect on our business.

Our revenues currently depend and will continue to depend, to a significant extent, on sales of our Heartwave and CH 2000 systems and Micro-V Alternans Sensors. Our ability to successfully commercialize these systems depends in part on maintaining adequate levels of third-party reimbursement for use of these systems by our customers. The amount of reimbursement in the United States that is available for clinical use of the Microvolt T-Wave Alternans Test may vary. In the United States, the cost of medical care is funded, in substantial part, by government insurance programs, such as Medicare and Medicaid, and private and corporate health insurance plans. Third-party payers may deny reimbursement if they determine that a prescribed device is not used in accordance with cost-effective treatment methods as determined by the payer, or is experimental, unnecessary or inappropriate. Our ability to commercialize the Heartwave and CH 2000 systems successfully will depend, in large part, on the extent to which appropriate reimbursement levels for the cost of performing a Microvolt T-Wave Alternans Test continue to be available from government authorities, private health insurers and other organizations, such as health maintenance organizations. We do not know whether the reimbursement level in the United States for the Microvolt T-Wave Alternans Test will increase in the future or that reimbursement amounts will not reduce the demand for, or the price of, the Heartwave and CH 2000 systems. Difficulties in obtaining reimbursement, or the inadequacy of the reimbursement obtained, for Microvolt T-Wave Alternans Tests using the Heartwave and CH 2000 systems could have a material adverse effect on our business.

We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims.

The testing, manufacture, marketing and sale of medical devices entails the inherent risk of liability claims or product recalls. Although we maintain product liability insurance in the United States and in other countries in which we conduct business, including clinical trials and product marketing and sales,

such coverage may not be adequate. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or product recall could inhibit or prevent commercialization of the CH 2000 and the Heartwave systems, or cause a significant financial burden on Cambridge Heart, or both, and could have a material adverse effect on our business, financial condition, and ability to market both systems as currently contemplated.

We may not be able to obtain or maintain patent protection for our products.

Our success will depend, in large part, on our ability to develop patentable products, enforce our patents and obtain patent protection for our products both in the United States and in other countries. However, the patent positions of medical device companies, including Cambridge Heart, are generally uncertain and involve complex legal and factual questions. We can give no assurance that patents will issue as a result of any patent applications we own or license or that, if patents do issue, the claims allowed will be sufficiently broad to protect our proprietary technology. In addition, any issued patents we own or license may be challenged, invalidated or circumvented, and the rights granted under issued patents may not provide us with competitive advantages. We also rely on unpatented trade secrets to protect our proprietary technology, and we can give no assurance that others will not independently develop or otherwise acquire substantially equivalent techniques, or otherwise gain access to our proprietary technology, or disclose such technology or that we can ultimately protect meaningful rights to such unpatented proprietary technology.

Others could claim that we infringe their intellectual property rights.

Our commercial success will depend in part on our ability to avoid infringing patents issued to others and breaching the licenses upon which our products are based. We have licensed significant technology and patents from third parties, including patents and technology relating to Microvolt T-Wave Alternans licensed from The Massachusetts Institute of Technology. Our license of patents and patent applications impose various commercialization, sublicensing, insurance, royalty and other obligations on our part. If we fail to comply with these requirements, licenses could convert from being exclusive to nonexclusive in nature or could terminate.

We could become involved in litigation over intellectual property rights.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Litigation, which would likely result in substantial cost to us, may be necessary to enforce any patents issued or licensed to us and/or to determine the scope and validity of others' proprietary rights. In particular, our competitors and other third parties hold issued patents and are assumed to hold pending patent applications, which may result in claims of infringement against us or other patent litigation. We also may have to participate in interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial cost, to determine the priority of inventions. Furthermore, we may have to participate at substantial cost in International Trade Commission proceedings to abate importation of products, which would compete unfairly with our products.

If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us.

We rely on unpatented trade secrets to protect our proprietary technology. We can give no assurance that others will not independently develop or acquire substantially equivalent technologies or otherwise gain access to our proprietary technology or disclose such technology or that we can ultimately protect meaningful rights to such unpatented proprietary technology. We rely on confidentiality agreements with our collaborators, employees, advisors, vendors and consultants. We may not have adequate remedies for any breach by a party to these confidentiality agreements. Failure

to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on us.

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

We own financial instruments that are sensitive to market risk as part of our investment portfolio. The investment portfolio is designed to preserve our capital until it is used to fund operations, including research and development activities. None of these market-risk sensitive instruments are held for trading purposes. These investments are subject to risk of default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. We invest our cash primarily in money market mutual funds and U.S. government and other investment grade debt securities. These investments are evaluated quarterly to determine the fair value of the portfolio. We have implemented policies regarding the amount and credit ratings of investments. Due to the conservative nature of these policies, we do not believe our portfolio has a material exposure due to market risk.

See note 2 to the financial statements contained in the Annual Report on Form 10-K for a description of our other financial instruments. We carry the amounts reflected in the balance sheet of cash and cash equivalents, trade receivables, and trade payables at fair value at December 31, 2003 due to the short maturities of these instruments.

We have not had any material exposure to factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. As our sales are made in U.S. dollars, a strengthening of the U.S. dollar could cause our products to be less attractive in foreign markets.

Item 8. *Financial Statements and Supplementary Data*

CAMBRIDGE HEART, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Stockholders of
Cambridge Heart, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Cambridge Heart, Inc. at December 31, 2002 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Boston, Massachusetts
March 25, 2004

CAMBRIDGE HEART, INC.
BALANCE SHEET

	December 31, 2002	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 1,092,181	$ 5,609,244
Marketable securities	2,001,231	—
Accounts receivable, net of allowance for doubtful accounts of $45,000 and $100,000 at December 31, 2002 and 2003, respectively	1,163,752	1,762,885
Inventory	667,889	469,811
Prepaid expenses and other current assets	253,934	163,221
Total current assets	5,178,987	8,005,161
Fixed assets, net	461,344	235,875
Other assets	548,379	278,511
	$ 6,188,710	$ 8,519,547
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 703,948	$ 644,723
Accrued expenses	519,741	969,077
Short term debt	803,029	2,103
Total current liabilities	2,026,718	1,615,903
Long term debt	5,584	3,681
Total liabilities	2,032,302	1,619,584
Commitments and contingencies (Note 13)		
Series A Redeemable Convertible Preferred Stock, $.001 par value; 2,000,000 shares authorized at December 31, 2002 and 2003, respectively; 0 and 1,281,642 shares issued and outstanding at December 31, 2002 and 2003, respectively. Liquidation preference of $0 and $5,664,858 as of December 31, 2002 and 2003, respectively	—	4,588,814
Warrants to acquire Series A Redeemable Convertible Preferred Stock	—	1,024,150
	—	5,612,964
Stockholders' equity:		
Common Stock, $0.001 par value; 75,000,000 shares authorized; 19,503,340 and 21,178,907 shares issued and outstanding at December 31, 2002 and 2003, respectively	19,503	21,179
Additional paid-in capital	53,161,199	53,770,911
Accumulated deficit	(49,024,294)	(52,411,924)
Less: deferred compensation	—	(93,167)
Total stockholders' equity	4,156,408	1,286,999
	$ 6,188,710	$ 8,519,547

The accompanying notes are an integral part of these financial statements.

CAMBRIDGE HEART, INC.
STATEMENT OF OPERATIONS

	Year Ended December 31,		
	2001	2002	2003
Revenue	$ 3,112,037	$ 4,307,377	$ 6,944,911
Cost of goods sold	2,430,646	3,061,521	3,202,490
Gross Profit	681,391	1,245,856	3,742,421
Costs and expenses:			
Research and development	1,845,331	1,387,946	944,325
Selling, general and administrative	5,701,802	5,867,795	6,192,723
Loss from operations	(6,865,742)	(6,009,885)	(3,394,627)
Interest income	412,553	104,253	20,297
Interest expense	(13,244)	(17,053)	(13,300)
Net loss	$ (6,466,433)	$ (5,922,685)	$ (3,387,630)
Beneficial conversion feature (Note 8)	—	—	(1,533,280)
Net loss attributable to common stockholders	$ (6,466,433)	$ (5,922,685)	$ (4,920,910)
Net loss per common share—basic and diluted	$ (0.37)	$ (0.30)	$ (0.25)
Weighted average common shares outstanding—basic and diluted	17,340,789	19,450,062	19,663,460

The accompanying notes are an integral part of these financial statements.

CAMBRIDGE HEART, INC.
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional paid-in capital	Accumulated deficit	Deferred compensation	Total stockholders' equity
	Number of Shares	Par value				
Balance at December 31, 2000	17,052,597	$17,053	$ 49,326,663	$(36,635,176)	$ (26,291)	$12,682,249
Issuance of common stock through exercise of stock options, warrants and employee stock purchase plan	633,695	634	873,466			874,100
Compensation related to non-employee stock options granted			67,525			67,525
Amortization of deferred compensation			(3,208)		16,828	13,620
Sale of common stock through a private placement net of fees	1,580,459	1,580	2,745,617			2,747,197
Net loss				(6,466,433)		(6,466,433)
Balance at December 31, 2001	19,266,751	$19,267	$ 53,010,063	$(43,101,609)	$ (9,463)	$ 9,918,258
Issuance of common stock through exercise of warrants and employee stock purchase plan	236,589	236	208,596			208,832
Compensation related to non-employee stock options granted			(57,460)			(57,460)
Amortization of deferred compensation					9,463	9,463
Net loss				(5,922,685)		(5,922,685)
Balance at December 31, 2002	19,503,340	$19,503	$ 53,161,199	$(49,024,294)	—	$ 4,156,408
Conversion of Series A preferred stock to common	1,029,366	1,029	204,420			205,449
Issuance of common stock through exercise of stock options, warrants and employee stock purchase plan	155,576	156	51,194			51,350
Compensation related to non-employee stock options granted			137,440			137,440
Issuance of restricted stock	490,625	491	216,658		(175,332)	41,817
Amortization of deferred compensation					82,165	82,165
Net loss				(3,387,630)		(3,387,630)
Balance at December 31, 2003	21,178,907	$21,179	$ 53,770,911	$(52,411,924)	$ (93,167)	$ 1,286,999

The accompanying notes are an integral part of these financial statements.

CAMBRIDGE HEART, INC.

STATEMENT OF CASH FLOWS

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

	Year ended December 31,		
	2001	2002	2003
Cash flows from operating activities:			
Net loss	$(6,466,433)	$(5,922,685)	$(3,387,630)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	617,886	575,413	505,012
Loss on disposal of fixed assets	—	2,004	—
Stock based compensation expense (benefit)	81,145	(47,997)	350,834
Provision for allowance for bad debts	(18,197)	8,390	55,000
Changes in operating assets and liabilities:			
Accounts receivable	(359,660)	(176,666)	(654,133)
Inventory	(267,570)	5,777	198,078
Prepaid expenses and other current assets	(69,210)	(112,666)	90,713
Other assets	(31,884)	(28,844)	4,838
Accounts payable and accrued expenses	145,687	(7,799)	300,211
Net cash used for operating activities	(6,368,236)	(5,705,073)	(2,537,077)
Cash flows from investing activities:			
Purchases of fixed assets	(185,898)	(131,597)	(12,913)
Capitalization of software development costs	(326,910)	(75,900)	(1,600)
Proceeds from the maturity of marketable securities	3,573,361	4,574,805	2,001,231
Net cash provided by investing activities	3,060,553	4,367,308	1,986,718
Cash flows from financing activities:			
Proceeds from issuance of Series A convertible redeemable preferred stock, net of issuance costs of $188,195	—	—	5,826,648
Proceeds from issuance of common stock, net of issuance costs of $80,000 in 2001	3,621,297	208,832	43,603
Proceeds from (payment on) bank credit line	542,845	58,810	(802,829)
Net cash provided by financing activities	4,164,142	267,642	5,067,422
Net increase (decrease) in cash and cash equivalents	856,459	(1,070,123)	4,517,063
Cash and cash equivalents, beginning of year	1,305,845	2,162,304	1,092,181
Cash and cash equivalents, end of year	$ 2,162,304	$ 1,092,181	$ 5,609,244

The accompanying notes are an integral part of these financial statements.

Supplemental Disclosure of Cash Flow Information

During 2001, 2002 and 2003 the Company paid $13,244, $17,053 and $13,300, respectively, in interest expense.

During 2003, investors exercised their rights to convert 79,182 shares of Series A Redeemable Convertible Preferred Stock into 1,029,366 shares of the Company's Common Stock at a conversion price of $0.34 per share.

CAMBRIDGE HEART, INC.
NOTES TO FINANCIAL STATEMENTS

1. The Company

Cambridge Heart, Inc. (the "Company") was incorporated in Delaware on January 16, 1990 and is engaged in the research, development and commercialization of products for the non-invasive diagnosis of cardiac disease. The Company sells its products primarily to cardiology group practices, hospitals and research institutions. The Company is subject to risks common to companies in the biotechnology, medical device and diagnostic industries, including but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulations.

The Company's financial statements have been prepared on a going concern basis, which assumes the Company will realize its assets and discharge its liabilities in the normal course of business. The Company has experienced recurring losses from operations of $6,865,742, $6,009,885 and $3,394,627 for the fiscal years ended December 31, 2001, 2002 and 2003, respectively and recurring negative cash flow from operations of $6,368,236, $5,705,073 and $2,537,077 for the fiscal years ended December 31, 2001, 2002 and 2003, respectively. In addition, the Company has an accumulated deficit of $52,411,924 at December 31, 2003. The Company anticipates that it has sufficient cash reserves to satisfy their cash requirements through December 31, 2004. If the Company is unable to generate sufficient revenue to sustain operations, it may need to seek additional sources of financing. There is no certainty that such efforts would be successful.

2. Summary of Significant Accounting Policies

Significant accounting policies followed by the Company are as follows:

Cash Equivalents and Marketable Securities

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. Marketable Securities consist of money market accounts, short-term securities of state government agencies, and short-term corporate bonds and commercial paper of companies with strong credit ratings and in diversified industries. The short-term securities of state government agencies are redeemable at their face value, and bear interest at variable rates which are adjusted on a frequent basis. Accordingly, these investments are subject to minimal credit and market risk. The short-term corporate bonds and short-term securities of state government agencies with maturities greater than three months from date of purchase, totaling $2,001,231 and $0 at December 31, 2002 and 2003, respectively, are classified as held to maturity, and mature within one year. The short-term commercial paper, short-term securities of state government agencies with maturities less than three months from date of purchase and money market securities, totaling $195,116 and $4,612,732 at December 31, 2002 and 2003, respectively, are classified as cash equivalents. All of these investments have been recorded at amortized cost, which approximates fair market value. No realized or unrealized gains or losses have been recognized.

Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, accounts receivable, accounts payable, and accrued expenses approximate their fair values at December 31, 2002 and 2003.

2. Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are stated at the lower of cost or market. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out method.

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is provided using the straight-line method based on estimated useful lives. Repair and maintenance costs are expensed as incurred. Upon retirement or sale, the costs of the assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the determination of net income.

Segment

Management uses consolidated financial information in determining how to allocate resources and assess performance. For this reason, the Company has determined that it is engaged principally in one industry segment. See Note 15 with respect to significant customers and with respect to sales in other geographic areas.

Revenue Recognition

Revenue from the sale of product to all of the Company's customers is recognized upon shipment of goods provided that risk of loss has passed to the customer, all of the Company's obligations have been fulfilled, persuasive evidence of an arrangement exists, the fee is fixed or determinable, and collectibility is probable. Revenue from the sale of product to all of our third party distributors with whom we have a relationship is subject to the same recognition criteria. These distributors provide all direct repair and support services to their customers. Under Emerging Issue Task Force ("EITF") 00-21, in multiple element arrangements, separate elements can be considered separate units of accounting when the delivered unit has value to a customer on a stand alone basis and there is objective and reliable evidence of the fair value of the undelivered element. The Company regularly sells maintenance agreements with the Heartwave System. Revenue from maintenance contracts are recognized separately based on amounts charged when sold on a stand alone basis and is recognized over the term of the underlying agreement. Payments of $146,915 at December 31, 2003 ($15,490 at December 31, 2002) received in advance of services being performed is recorded as deferred revenue and included in current liabilities in the accompanying balance sheet.

Research and Development and Capitalized Software Development Costs

Research, engineering and product development costs, except for certain software development costs, are expensed as incurred. Capitalization of software development costs begins upon the establishment of technological feasibility of both the software and related hardware as defined by Statement of Financial Accounting Standards No. 86, "Accounting for the Cost of Computer Software to be Sold, Leased, or Otherwise Marketed," and ceases upon the general release of the products to the public. The establishment of technological feasibility and the ongoing assessment of recoverability of capitalized software development costs require considerable judgment by management with respect to certain external factors, including, but not limited to, technological feasibility, anticipated future gross revenues, estimated economic life and changes in software and hardware technologies.

2. Summary of Significant Accounting Policies (Continued)

The Company amortizes software development costs on a straight-line basis over the estimated economic life of the product generally 3 years. The Company evaluates these costs for impairment at each balance sheet date by comparing the net realizable value of the product containing the software to the unamortized capitalized costs of that software. The amount by which the unamortized capitalized cost of the software exceeds the net realizable value of the software is written off. The net realizable value is determined as the estimated future gross revenues from that product containing the software reduced by the estimated future costs of completing and disposing of that product.

Costs capitalized at December 31, 2003, which are included in other assets in the accompanying balance sheet, were $1,482,728, ($1,481,128 at December 31, 2002), net of $1,325,155 of accumulated amortization ($1,070,000 at December 31, 2002).

Licensing Fees and Patent Costs

The Company has entered into a licensing agreement giving the Company the exclusive rights to certain patents and technologies and the right to market and distribute any products developed, subject to certain covenants. Payments made under this licensing agreement and costs associated with patent applications have generally been expensed as incurred, because recovery of these costs is uncertain. However, certain costs associated with patent applications for products and processes which have received regulatory approval and are available for commercial sale have been capitalized and are being amortized over their estimated economic life of 5 years. The amount of unamortized cost capitalized at December 31, 2003 was $112,380 compared to $129,129 at December 31, 2002, which is included in other assets in the accompanying balance sheet.

Stock-Based Compensation

Statement of Financial Accounting Standards No. 123 (SFAS 123), "Accounting for Stock-Based Compensation," requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value, or provide pro forma disclosure of net income (loss) and net income (loss) per share in the notes to the financial statements. At December 31, 2003, the Company has four stock-based compensation plans, which are described more fully in Note 10. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for the Company's employee stock option plans. Had compensation cost for the awards under those plans been determined based on the grant date fair values, consistent with the method required under SFAS 123,

2. Summary of Significant Accounting Policies (Continued)

the Company's net income (loss) and net income (loss) per share would have been reduced to the pro forma amounts indicated below:

	Year ended December 31,		
	2001	2002	2003
Net loss attributable to common stockholders:			
As reported	$ 6,466,433	$5,922,685	$ 4,920,910
Stock-based compensation expense included in reported net loss	$ (81,145)	$ 47,997	$ (350,834)
Total stock-based compensation under the fair-value-based method for all awards	$ 908,337	$ 697,240	$ 825,681
Pro forma	$ 7,293,625	$6,667,922	$ 5,395,757
Net loss per share:			
As reported—basic and diluted	$ 0.37	$ 0.30	$ 0.25
Pro forma—basic and diluted	$ 0.42	$ 0.34	$ 0.27

The fair value of each option grant under SFAS 123 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions used for grants in 2001, 2002 and 2003, respectively: (i) dividend yield of 0% for all periods; (ii) expected volatility of 50% for all periods; (iii) risk free interest rates of 4.56%, 3.82%, and 2.43%; and (iv) expected option terms of 4 years for 2001, 2002 and 2003. SFAS 123 requires that volatility be considered in the calculation of the fair value of an option grant only for grants made when an entity has publicly traded securities or has filed a registration statement to do so. Accordingly, a volatility of 0% was utilized for options granted by the Company prior to the initial filing of its Registration Statement on Form S-1 in 1996.

Use of Estimates

The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to incentive compensation, product returns, bad debts allowances, inventory valuation, investments valuation, intangible assets, income taxes, financing operations, warranty obligations, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Net Loss Per Share

Consistent with Statement of Financial Accounting Standards No. 128, "Earnings Per Share," basic loss per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted loss per share amounts are based on the weighted average number of shares of common stock and potential common stock outstanding during the period. The impact of options to purchase 2,954,000, 3,196,200 and 5,049,518 shares of common stock, warrants for

2. Summary of Significant Accounting Policies (Continued)

the purchase of 1,548,326, 1,370,400 and 1,319,695 shares of common stock, warrants for the purchase of 0, 0, and 548,515 shares of Series A Redeemable Convertible Preferred Stock and 0, 0, and 1,281,642 shares of Series A Redeemable Convertible Preferred Stock have been excluded from the calculation of diluted weighted average share amounts as their inclusion would have been anti-dilutive for 2001, 2002 and 2003 respectively.

Comprehensive Income

Comprehensive income is comprised of two components, net income and other comprehensive income. For the years ended December 31, 2001, 2002 and 2003 the Company had no other comprehensive income.

New Accounting Pronouncements

In May 2003, the FASB issued SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after December 15, 2003. The adoption of SFAS 150 is not expected to have a material effect on the Company's financial statements.

3. Inventory

Inventories consisted of the following at December 31, 2002 and 2003, respectively:

	December 31, 2002	December 31, 2003
Raw materials	$579,586	$394,650
Work in process	9,976	5,895
Finished goods	78,327	69,266
	$667,889	$469,811

4. Fixed Assets

Fixed assets consist of the following:

	Estimated useful lives (years)	December 31, 2002	December 31, 2003
Computer equipment	3-5	$ 634,777	$ 657,760
Manufacturing equipment	5	418,158	418,158
Office furniture	7	87,028	87,028
Sales demonstration and clinical equipment	3	1,008,972	993,200
		2,148,935	2,156,146
Less—accumulated depreciation		1,687,591	1,920,271
		$ 461,344	$ 235,875

The Company recorded depreciation expense of $330,273 and $238,382 for the years ended December 31, 2002 and 2003, respectively.

5. Other Assets

Other assets consist of the following:

	Estimated useful lives (years)	December 31, 2002	December 31, 2003
Capitalized software development costs	3	$1,481,128	$1,482,728
Patents	5	198,557	193,719
Other assets		8,557	8,557
		1,688,242	1,685,004
Less—accumulated amortization		1,139,863	1,406,493
		$ 548,379	$ 278,511

The Company recorded amortization expense of $245,140 and $266,630 for the years ended December 31, 2002 and 2003, respectively.

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2002	December 31, 2003
Accrued employee compensation	$212,316	$439,062
Deferred revenue	15,490	146,915
Accrued consulting costs	0	89,900
Accrued product warranty costs	40,260	58,202
Accrued clinical trial costs	23,900	0
Accrued sales taxes	37,896	107,931
Accrued professional fees	54,755	56,000
Accrued other	135,124	71,067
	$519,741	$969,077

For the years ended December 31, 2001, 2002 and 2003, the Company incurred product warranty expenses of $127,944, $12,185 and $26,144, respectively.

7. Line of Credit

On September 25, 2003, the Company entered into an amendment to its Loan and Security Agreement with Silicon Valley Bank to extend the expiration date from September 25, 2003 to November 9, 2003. On October 22, 2003, the Company notified Silicon Valley Bank of its intent not to seek renewal of the Loan and Security Agreement or to negotiate a new agreement. On October 30, 2003, the Company paid the remaining $83,462 due under the Loan and Security Agreement. The agreement provided a borrowing base of 80% of eligible accounts receivable as defined in the Security and Loan agreement, up to a maximum borrowing of $1,200,000, payable on demand. Under the terms of the Security and Loan agreement in effect prior to its expiration on November 9, 2003, up to $300,000 was available as a term loan, amortized over 24 months commencing January 1, 2002, for financing the purchase of eligible capital equipment, including computer hardware and manufacturing molds and tooling as defined in the agreement, through December 31, 2002. The remaining unused portion of the $1,200,000 facility was available to finance eligible customer receivable balances as defined in the agreement. Interest was payable in arrears at the bank's prime rate plus 2% (6.25% at December 31, 2002). The entire outstanding balance was collateralized by all of the Company's tangible assets excluding intellectual property. Under the terms of the agreement, the Company issued a warrant to Silicon Valley Bank for the purchase of 21,053 shares of its common stock at an exercise price of $2.28 with certain anti-dilution provisions on September 26, 2002. As a result of the May 2003 financing, the Company was required to adjust the number of shares issuable upon exercise of the warrant and the exercise price of the warrant to 37,015 shares and $1.30, respectively. The amount outstanding on the line of credit was $800,926 and $0 at December 31, 2002 and 2003, respectively. The Company incurred interest expense of $17,053 in 2002 and $13,300 in 2003.

8. Sale of Series A Redeemable Convertible Preferred Stock

The Company's Board of Directors has authorized 2,000,000 shares of the Company's $0.001 par value preferred stock. The preferred stock may be issued at the discretion of the Board of Directors of the Company (without stockholder approval) with such designations, rights and preferences as the Board of Directors may determine from time to time. This preferred stock may have dividend,

8. Sale of Series A Redeemable Convertible Preferred Stock (Continued)

liquidation, redemption, conversion, voting or other rights, which may be more expansive than the rights of the holders of the common stock. At December 31, 2003 the Company has 1,281,642 shares of Series A Redeemable Convertible Preferred Stock outstanding.

On May 12, 2003, the Company entered into an agreement for the sale of up to $6.5 million of Series A Redeemable Convertible Preferred Stock ("preferred stock") to Medtronic, Inc. and a group of private investors. Under the terms of the financing, the Company issued and sold 696,825 shares of preferred stock at a purchase price of $4.42 per share, for total gross proceeds of $3,079,967. Each share of the preferred stock is convertible into 13 shares of the Company's common stock. The conversion price of the preferred stock is subject to adjustment if the Company issues shares of common stock at a purchase price below the conversion price of the preferred stock prior to November 12, 2004, the conversion price of the preferred stock will be adjusted to equal such purchase price.

The preferred stock is entitled to dividends when and if declared by the Board of Directors prior to the payment of any such dividends to the holders of common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the company, the holders of the preferred stock then outstanding are entitled to be paid out of the assets of the corporation before any payment is made to the holders of common stock. Each holder of the preferred stock is entitled to the number of votes equal to the number of shares of common stock the preferred stock is convertible into on any matter preserved to the stockholders of the Company for their action at any meeting of the stockholders of the corporation.

As part of the financing, the Company issued to the investors, other than Medtronic, short-term warrants exercisable for a total of 705,852 shares of the preferred stock. There were six tranches of the short-term warrants that expired in equal monthly intervals starting September 1, 2003. The exercise price per share of these warrants was $4.42. At December 31, 2003, short-term warrants for the purchase of 663,999 shares of preferred stock have been exercised by the investors at a price of $4.42 per share providing the Company with additional gross proceeds of $2,934,876. Short-term warrants for the purchase of 109,725 additional shares of preferred stock with an expiration date of February 1, 2004 remain available for exercise by the investors at December 31, 2003. During January 2004, investors execercised short-term warrants for the purchase of 109,725 shares of preferred stock at a price of $4.42 per share providing the Company with additional gross proceeds of $484,985.

The Company also issued to both Medtronic and the private investors long-term warrants exercisable for 30% of the total number of shares of preferred stock purchased through the initial investment and the exercise of the short-term warrants. The exercise price of Medtronic's long-term warrant is $4.42 and the exercise price per share of the long-term warrants issued to the other investors is $5.525. These long-term warrants expire on January 1, 2009. At December 31, 2003, long-term warrants for the purchase of 67,873 and 320,013 of preferred stock have been issued to Medtronic and the investors, respectively.

In connection with this financing and in order to address certain payment obligations in existing agreements with The Tail Wind Fund Ltd. and a private investor, the Company issued to Tail Wind short-term warrants exercisable for 67,872 shares of the preferred stock and a long-term warrant exercisable for 75% of the total number of shares of the preferred stock purchased through the exercise of Tail Wind's short-term warrants. The exercise prices and the expiration dates of Tail Wind's warrants are consistent with the warrants issued to the other private investors. At December 31, 2003,

8. Sale of Series A Redeemable Convertible Preferred Stock (Continued)

short-term warrants for the purchase of 67,872 shares of preferred stock have been exercised by Tail Wind at a price of $4.42 per share providing the Company with additional gross proceeds of $299,994. In addition, the Company agreed to adjust the original exercise price of $2.28 per share of previously issued warrants, acquired pursuant to a previously completed private equity transaction, for the purchase of 459,770 and 172,414 shares of the Company's common stock issued to Tail Wind and a private investor to $0.285 per share.

The Company filed a registration statement with the Securities and Exchange Commission to register all of the shares of common stock issuable upon conversion of the preferred stock and upon exercise of all of the warrants. This registration statement was declared effective on June 20, 2003.

The net proceeds from the sale of the securities have been allocated between the preferred stock and the warrants based on their relative fair values, on the Company's Balance Sheet. The terms of the financing provide that the conversion price of the preferred stock and warrants is subject to adjustment in certain circumstances. Therefore, the actual conversion price may be below the market price of the Company's common stock at the time of conversion. The final closing price of the Company's common stock as listed on the National Association of Securities Dealers' OTC Bulletin Board on May 12, 2003 was $0.46 per share and as a result, the Company has valued the warrants and the beneficial conversion feature reflecting the May 12, 2003 commitment date and the most beneficial per share discount available to the preferred shareholders and warrant holders. A beneficial conversion feature is recorded when the consideration allocated to the convertible security, divided by the number of common shares into which the security converts, is below the fair value of the common stock at the convertible instruments issuance. The value of the beneficial conversion feature related to the preferred stock financing is $1,533,280. The amount of the beneficial conversion feature has been immediately accreted and the accretion will result in a deemed dividend as the preferred stock does not have a redemption term. The deemed dividend has been reflected as an adjustment to net loss applicable to common stockholders on the Company's Statement of Operations. The issuance of additional shares of preferred stock or warrants under this financing may result in an additional beneficial conversion feature being recorded.

9. Stockholders' Equity

Common Stock

The Company's Board of Directors has authorized 75,000,000 shares of the Company's $0.001 par value common stock. At December 31, 2003, the Company has 21,178,907 shares outstanding.

Warrants

During 2001, the Company had entered into agreements with holders of previously issued warrants for the purchase of 737,832 shares of common stock. Pursuant to these agreements, the exercise price per share of each warrant was reduced to $1.50 in exchange for a shortened exercise period and the requirement that the warrants be exercised for cash. Of these amended warrants, warrants for the purchase of 183,629 and 539,203 shares of common stock were exercised in 2002 and 2001, respectively. These warrants were originally granted in connection with the sale of the Company's common stock, and as such, any value associated with these warrants was accounted for entirely within the equity section of the financial statements at the time of sale and all cash received for the sale of the Company's common stock and these warrants in excess of their par value was recorded as additional

9. Stockholders' Equity (Continued)

paid-in-capital at the time of sale. Therefore, all adjustments resulting from the repricing and subsequent exercise of these warrants during 2001 and 2002, was recorded as additional paid-in-capital. There were no warrants with amended terms outstanding at December 31, 2002.

A roll-forward of outstanding warrants for the purchase of common stock of the Company for the years ended December 31, 2001, 2002 and 2003 are summarized as follows:

	December 31, 2001		December 31, 2002		December 31, 2003	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Outstanding at beginning of year	1,455,345	$3.63	1,548,326	$2.76	1,370,400	$2.94
Issued	1,387,516	2.13	21,053	2.28	119,515	0.64
Exercised	(539,203)	1.68	(183,629)	1.50	—	—
Canceled	(755,332)	3.87	(15,350)	1.50	(170,220)	3.43
Outstanding at end of year	1,548,326	$2.76	1,370,400	$2.94	1,319,695	$1.71

Total warrants to purchase common stock outstanding at December 31, 2003 by expiration date were as follows:

	Number of Shares	Exercise Price Per Share	Expiration Date
Common stock	76,414	$3.500	October 6, 2004
Common stock	11,582	$4.200	December 9, 2004
Common stock	480,000	$3.500	September 14, 2005
Common stock	82,500	$0.340	September 14, 2005
Common stock	632,184	$0.285	December 21, 2006
Common stock	37,015	$1.297	September 26, 2007
	1,319,695		

10. Stock Plans

2001 Stock Incentive Plan

During 2003, the Board of Directors authorized and the Stockholders approved an amendment of the 2001 Stock Incentive Plan to increase the total number of shares authorized for issuance under the plan from 1,700,000 to 5,000,000 shares of the Company's common stock to eligible employees, officers, directors, consultants and advisors in the form of stock options or shares of restricted stock up to a maximum of 770,000 shares. During 2003, a total of 490,625 shares of restricted stock were granted under the 2001 Plan, of which restrictions had lapsed for 137,500 shares at December 31, 2003. The total number of shares of common stock that may be issued pursuant to the exercise of options granted under the 2001 Plan are 3,430,125. Of this amount 1,129,000 are exercisable at December 31, 2003. Under the terms of the plan, incentive stock options may not be granted at less than fair market value of the Company's common stock at the date of the grant and for a term not to exceed ten years.

10. Stock Plans (Continued)

All options granted during 2001, 2002 and 2003 have exercise prices equal to the fair market value of the common stock at the date of grant. Transactions under all of the Company's stock option plans during the years ended December 31, 2001, 2002 and 2003 are summarized as follows:

	December 31, 2001		December 31, 2002		December 31, 2003	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at beginning of year	1,979,250	$2.79	2,954,000	$2.63	3,196,200	$2.43
Granted	1,140,000	2.45	403,950	1.23	2,557,875	0.65
Exercised	(60,000)	0.20	—	—	(7,500)	0.46
Canceled	(105,250)	4.52	(161,750)	3.09	(1,050,182)	2.20
Outstanding at end of year	2,954,000	$2.63	3,196,200	$2.43	4,696,393	$1.50
Exercisable at end of year	1,434,067	$2.49	2,060,897	$2.52	2,324,222	$2.09
Weighted average fair value of options granted during the year		$0.45		$0.43		$0.69

The following table summarizes information about stock options outstanding under all of the Company's stock option plans at December 31, 2003:

Range of exercise prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number of Options Exercisable	Weighed Average Exercise Price of Options Exercisable
$0.20-$0.50	1,005,768	5.57	$0.36	746,268	$0.34
$.0.51-$1.00	1,415,625	6.08	$0.58	102,375	$0.75
$1.01-$2.50	718,500	9.45	$1.33	149,705	$1.69
$2.51-$4.00	1,378,500	6.58	$2.76	1,147,875	$2.77
$4.01-$9.38	178,000	4.56	$6.24	178,000	$6.24
	4,696,393	6.24	$1.40	2,324,222	$2.09

At December 31, 2003, 4,696,393 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there are 1,079,250 options available for future grant. Outstanding options generally vest on a pro rata basis over a period of three to five years.

The Company has recorded compensation expense (benefit) related to options granted to non-employee consultants for services rendered, totaling $67,525 in 2001, $(57,460) in 2002, and $227,341 in 2003 based on the market price of our common stock.

1996 Employee Stock Purchase Plan

In June 2002, the Stockholders voted to increase the number of shares authorized under the plan to from 100,000 to 300,000 shares of the Company's common stock to eligible employees. Under the Purchase Plan, the Company is authorized to make one or more offerings during which employees may

10. Stock Plans (Continued)

purchase shares of common stock through payroll deductions made over the term of the offering. The term of individual offerings, which are set by the Board of Directors, may be for periods of twelve months or less and may be different for each offering. The per-share purchase price at the end of each offering is equal to 85% of the fair market value of the common stock at the beginning or end of the offering period (as defined by the Purchase Plan), whichever is lower.

The Company issued 34,200, 52,960 and 148,076 shares of common stock at an average price of $1.56, $0.80 and $0.32 during 2001, 2002 and 2003 respectively. At December 31, 2003, the Company had 12,214 shares of common stock reserved for issuance under the Purchase Plan.

11. Income Taxes

The income tax benefit (expense) consists of the following:

	Year ended December 31,		
	2001	2002	2003
Federal	$ 2,324,271	$ 2,179,333	$ 1,592,941
State	387,456	(45,865)	(213,348)
	$ 2,711,727	$ 2,133,468	$ 1,379,593
Deferred tax asset valuation allowance	(2,711,727)	(2,133,468)	(1,379,593)
	$ —	$ —	$ —

Deferred tax assets (liabilities) are comprised of the following:

	December 31,		
	2001	2002	2003
Net operating loss carryforwards	$ 14,313,684	$ 16,201,442	$ 17,168,246
Research and development tax credit carryforwards	1,465,918	1,609,747	1,606,446
Capitalized research and development	3,430,042	3,518,767	3,668,370
Other	187,893	113,731	211,410
Gross deferred tax assets	19,397,537	21,443,687	22,654,472
Capitalized software	(331,305)	(249,497)	(64,881)
Fixed assets	(63,695)	(71,774)	(65,737)
Patent costs	(38,017)	(24,428)	(46,272)
Net deferred tax assets	$ 18,964,520	$ 21,097,988	$ 22,477,582
Deferred tax asset valuation allowance	(18,964,520)	(21,097,988)	(22,477,582)
	$ —	$ —	$ —

The Company has generated taxable losses from operations since inception and, accordingly, has no taxable income available to offset the carryback of net operating losses. In addition, although management's operating plans anticipate taxable income in future periods, such plans provide for taxable losses over the near term and make significant assumptions which cannot be reasonably assured including approval of the Company's products and labeling claims by the U.S. Food and Drug Administration and market acceptance of the Company's products by customers. Based upon the weight of all available evidence, the Company has provided a full valuation allowance for its deferred tax

11. Income Taxes (Continued)

assets since, in the opinion of management, realization of these future benefits is not sufficiently assured (defined as a likelihood of slightly more than 50 percent).

Approximately $1,367,491 of the deferred tax asset attributable to net operating loss carryforwards was generated by the exercise of certain non-qualified stock options. Any future utilization of this amount will be credited directly to additional paid-in-capital, and not the income tax provision.

Income taxes computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	Year ended December 31,		
	2001	2002	2003
Statutory U.S. federal tax rate	(35.0)%	(35.0)%	(35.0)%
State taxes, net of federal tax benefit	(6.0)	(6.2)	(5.6)
Non-deductible expenses	0.7	0.2	2.4
Federal research and development credits	(2.2)	(1.3)	(0.1)
Expiration of state net operating loss carryforwards	—	—	12.4%
Other	0.5	6.3	(1.4)
Valuation allowance on deferred tax assets	42.0	36.0	27.4%
	—%	—%	—%

As of December 31, 2003, the Company has approximately $43,892,000 federal and $29,246,000 state net operating loss carryforwards and $1,150,000 and $702,000 of federal and state research and development credits, respectively, which may be used to offset future federal and state taxable income and tax liabilities, respectively. In 2003, approximately $6,787,000 of state net operating loss carryforwards expired. The credits and carryforwards expire in various years ranging from 2004 to 2023.

An ownership change, as defined in the Internal Revenue Code, resulting from the Company's issuance of additional stock may limit the amount of net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income and tax liabilities. The amount of the annual limitation is determined based upon the Company's value immediately prior to the ownership change. The Company has determined that ownership changes have occurred at the time of the Series A Preferred Stock issuance in 1993 and the Series B Preferred Stock issuance in 1995, but has not yet determined the amount of the annual limitations. However, management does not believe that such limitations would materially impact the Company's ability to ultimately utilize its carryforwards, provided sufficient taxable income is generated in future years, although the limitations may impact the timing of such utilization. Any other significant changes in ownership could further affect the limitations in future years.

12. Savings Plan

In January 1995, Cambridge Heart adopted a retirement savings plan for all employees pursuant to Section 401(k) of the Internal Revenue Code. Employees become eligible to participate on the first day of the calendar quarter following their hire date. Employees may contribute any whole percentage of their salary, up to a maximum annual statutory limit. The Company is not required to contribute to this plan. The Company made no contributions to this plan in 2001, 2002 or 2003.

13. Commitments and Contingencies

Guarantor Arrangements

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners and customers. Under these provisions the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company maintains a products liability insurance policy that limits its exposure. Based on the Company's historical activity in combination with its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2003.

The Company warrants all of its non-disposable products as to compliance with their specifications and that the products are free from defects in material and workmanship for a period of 12 months from date of delivery. The Company maintains a reserve for the estimated costs of potential future repair of our products during this warranty period. The amount of reserve is based on the Company's actual return and repair cost experience. The Company has $58,202 of accrued warranties at December 31, 2003.

Operating Leases

The Company has various non-cancelable operating leases for office space and equipment which expire through 2005. Certain of these leases provide the Company with various renewal options. Total rent expense under all operating leases was approximately $226,441, $198,150 and $193,029 for the years ended December 31, 2001, 2002 and 2003, respectively.

At December 31, 2003, future minimum rental payments under the non-cancelable leases are as follows:

2004	$142,028
2005	138,519

Contingencies

The Company has certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

License Maintenance Fees

Under the terms of certain license, consulting and technology agreements, the Company is required to pay royalties on sales of its products. Minimum license maintenance fees under the license agreement, which can be credited against royalties otherwise payable for each year, are $10,000 per year through 2007. The Company is committed to pay an aggregate of $40,000 of such minimum license maintenance fees subsequent to December 31, 2003 as the technology is used. License maintenance fees paid during 2001 and 2002 amounted to $40,000 and $30,000 respectively, in each year. License

13. Commitments and Contingencies (Continued)

maintenance paid during 2003 totaled $10,000. The future minimum license maintenance fee commitments at December 31, 2003 are approximately as follows:

2004	$10,000
2005	10,000
2006	10,000
2007	10,000
	$40,000

During the term of these license agreements, the Company is obligated to pay a royalty (ranging from 1.5% to 2.0%) based on net sales of any products developed from the licensed technologies. The license maintenance fees described above are creditable against royalties otherwise payable for such year.

14. Related Party Transactions, Including Royalty Obligations

License Agreement/Consulting and Technology Agreement

The Company is party to a consulting and technology agreement with a member of the Company's Board of Directors. This individual is also Chairman of the Company's Scientific Advisory Board. This agreement required the Company to pay consulting fees of $135,329 and $135,000 during fiscal 2001 and 2002, respectively. The agreement, which was amended effective May 7, 2003 and extends through May 31, 2015, required the Company to pay consulting fees of $45,000 in fiscal 2003 and to make a restricted stock award of 100,000 shares of its common stock. The restrictions on these shares lapsed on January 1, 2004. In connection with these restricted shares in 2003, the Company recorded additional non-cash consulting fees associated with this award of $89,900. All cash and non-cash consulting fees are included in research and development expense in the accompanying statement of operations. The agreement also required that the Company pay, during fiscal 2001 and 2002, a royalty of 1% of net sales of products developed from certain technologies developed by this individual. The agreement as amended in fiscal 2003 requires that the Company pay a royalty of 1% of net sales of these products up to the total net sales of these products recorded by the Company during fiscal 2002 and a royalty of 1.5% of net sales of these products for all fiscal 2003 sales above the net sales of these products recorded by the Company during fiscal 2002. This formula for the payment of royalties is in effect through the end of fiscal 2004. Beginning in fiscal 2005, the royalty payment formula will require the Company to pay a royalty equal to 1.5% of all net sales of products developed from certain technologies developed by this individual.

If the Company chooses to sublicense these products to an unrelated third party, the royalty will be based on 7% of the gross revenue received from the unrelated third party for products developed from the technology. The agreement also required the Company to grant a stock option to this individual to purchase 35,000 shares of its common stock vesting annually over a 4 year period during fiscal 2001. The agreement as amended in fiscal 2003, required the Company to grant a stock option to purchase 300,000 shares vesting on the date of the grant.

The Company recognized royalty expense in connection with these agreements of $33,765, $49,302 and $113,131 during fiscal 2001, 2002 and 2003, respectively.

15. Major Customers, Export Sales and Concentration of Credit Risk

Three customers accounted for 27%, 15%, and 10% of total revenues for the year ended December 31, 2001 and 45%, 6% and 14% of the account receivable balance as of December 31, 2001, respectively. One customer accounted for 19% and 14% of total revenues and 29% and 10% of the accounts receivable balance as of December 31, 2002 and 2003, respectively. During the years ended December 31, 2001, 2002 and 2003, international sales accounted for 30%, 19% and 9% of the total revenues, respectively. Company policy does not require collateral on accounts receivable balances.

16. Quarterly Financial Results (unaudited)

The following tables set forth a summary of our unaudited quarterly results of operations for 2003 and 2002.

	Three Months Ended (Unaudited)			
	March 31, 2003	June 30, 2003	Sept 30, 2003	Dec 31, 2003
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 1,104	$ 1,627	$ 1,954	$ 2,260
Cost of goods sold	711	730	880	881
Gross profit	393	897	1,074	1,379
Costs and expenses:				
Research and development	221	330	232	161
Selling, general and administrative	1,415	1,600	1,489	1,690
Total costs and expenses	1,636	1,930	1,721	1,851
Loss from operations	(1,243)	(1033)	(647)	(472)
Interest income	5	3	5	7
Interest expense	(6)	(3)	(2)	(2)
Net loss	$(1,244)	$(1,033)	$ (644)	$ (467)
Beneficial conversion feature	—	(1,533)	—	—
Net loss attributable to common stockholders	$(1,244)	$(2,566)	$ (644)	$ (467)
Net loss per common share—basic and diluted	$ (0.06)	$ (0.13)	$ (0.03)	$ (0.02)

	Three Months Ended (Unaudited)			
	March 31, 2002	June 30, 2002	Sept 30, 2002	Dec 31, 2002
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 909	$ 1,051	$ 1,273	$ 1,074
Cost of goods sold	697	763	787	814
Gross profit	212	288	486	260
Costs and expenses:				
Research and development	369	419	296	304
Selling, general and administrative	1,491	1,542	1,459	1,376
Total costs and expenses	1,860	1,961	1,755	1,680
Loss from operations	(1,648)	(1,673)	(1,269)	(1,420)
Interest income	39	30	22	13
Interest expense	(6)	(4)	(4)	(3)
Net loss	$(1,615)	$(1,647)	$(1,251)	$(1,410)
Net loss per common share—basic and diluted	$ (0.08)	$ (0.08)	$ (0.06)	$ (0.07)

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

Not applicable.

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

(a) *Evaluation of Disclosure Controls and Procedures.*

General. Our management, with the participation of our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act) as of December 31, 2003. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our CEO and CFO concluded that, except as described below, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our CEO and CFO by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Disclosure Controls and Internal Controls. Disclosure controls are procedures designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls are also designed to ensure that this information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Internal controls are procedures designed to provide reasonable assurance that (1) our transactions are properly authorized, (2) our assets are safeguarded against unauthorized or improper use, and (3) our transactions are properly recorded and reported, all to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

Scope of the Controls Evaluation. The evaluation of our disclosure controls and our internal controls included a review of the controls' objectives and design, our implementation of the controls and the effect of the controls on the information generated for use in this Annual Report on Form 10-K. In the course of the controls evaluation, we sought to identify data errors, controls problems or acts of fraud, and confirm that appropriate corrective actions, including process improvements, were being undertaken. This type of evaluation is performed on a quarterly basis so that the conclusions of management, including our CEO and CFO, concerning the effectiveness of our controls can be reported in our Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Our internal controls are also evaluated by other personnel in our finance organization. The overall goals of these various evaluation activities are to monitor our disclosure controls and our internal controls, and to modify them as necessary. Our intent is to maintain the disclosure controls and the internal controls as flexible systems that change as conditions warrant.

Among other matters, we sought in our evaluation to determine whether there were any "significant deficiencies" or "material weaknesses" in our internal controls, and whether we had identified any acts of fraud involving personnel with a significant role in the our internal controls. In professional auditing literature, "significant deficiencies" are referred to as "reportable conditions," which are control deficiencies that adversely affect a company's ability to initiate,

authorize, record, process, or report external financial data reliably in accordance with generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the company's annual or interim financial statements that is more than inconsequential will not be prevented or detected. Auditing literature defines "material weakness" as a particularly serious reportable condition where the internal control does not reduce to a relatively low level the risk that misstatements caused by error or fraud may occur in amounts that would be material in relation to the financial statements and the risk that such misstatements would not be detected within a timely period by employees in the normal course of performing their assigned functions. We also sought to address other controls matters in the controls evaluation, and in each case, if a problem was identified, we considered what revision, improvement and/or correction to make in accordance with our ongoing procedures.

As described below under "Changes in Disclosure Controls and Internal Controls," we have identified certain deficiencies in our controls and procedures. However, we believe the corrective actions we are taking and the additional procedures we have performed, as described below in more detail, provide us with reasonable assurance that the identified control weaknesses will not limit the effectiveness of our controls and procedures.

Changes in Disclosure Controls and Internal Controls. In connection with the audit of our financial statements for the year ended December 31, 2003, the independent auditors informed us that they had discovered a number of issues that constituted a material weakness in our internal control over financial reporting. Management and the Audit Committee are aware of conditions relating primarily to our product return and sales order processing policies and procedures that are considered to be a material weakness in our disclosure controls and our internal controls for the year ended December 31, 2003 under standards established by the American Institute of Certified Public Accountants. In particular, the weaknesses in both our disclosure controls and internal controls pertain to the following areas:

- proper authorization of exceptions to the company's product return policy to include the appropriate finance personnel,
- compliance with company policies requiring the inclusion of all agreements and commitments with customers on the customer's order documents, and
- as a consequence, the failure, in a limited number of instances, to properly integrate and evaluate product returns and non-standard conditions of sale as part of the revenue recognition review process.

Management and the Audit Committee have taken actions with respect to these weaknesses, including (1) retraining all sales personnel on the company's polices regarding product returns and sales order processing, (2) establishment of mandatory procedures for authorization of exceptions to the company's product returns policy to insure inclusion of appropriate financial personnel, (3) requiring all sales personnel to certify on a quarterly basis, that no terms or conditions of sale exist beyond those contained in the applicable executed customer purchase order, (4) implementing a policy to ensure that the appropriate sales personnel receive a copy of executed customer purchase orders, (5) adopting a code of business conduct and ethics which applies to all of our employees, and (6) enhanced training of sales, operations and finance personnel regarding the foregoing.

In addition, management believes that the corrective actions, when taken, will provide us with reasonable assurance that the identified issues will not limit the effectiveness of our disclosure controls or internal controls. Management believes that we are in the process of implementing procedures addressing the weakness in our controls.

(b) *Changes in Internal Controls.*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, as described above, we are in the process of implementing procedures designed to address our control deficiencies, and enhancing our overall internal control over financial reporting.

PART III

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

The information with respect to directors required under this item is also incorporated by reference to the information set forth under the section entitled "*Directors*" in our proxy statement for our 2004 Annual Meeting of Stockholders to be held on June 9, 2004. The name, age, and position of each of our executive officers is set forth under the heading "*Executive Officers of the Registrant*" in Part I of this Annual Report on Form 10-K, which information is incorporated herein by reference. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2004 proxy statement under the section entitled "*Section 16(a) Beneficial Ownership Reporting Compliance*" and is incorporated herein by reference. The information required under this item pursuant to Item 401(h) and 401(i) of Regulation S-K relating to an Audit Committee financial expert and identification of the Audit Committee of our Board of Directors is contained in our 2004 proxy statement under the caption "*Corporate Governance*" and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics on our website which is located at www.cambridgeheart.com.

Item 11. *Executive Compensation*

Information required by this Item 11 is set forth in our 2004 proxy statement under the headings "*Compensation of Directors*" and "*Executive Officers,*" "*Report of the Compensation Committee on Executive Compensation*" and "*Stock Performance Chart*" which information is incorporated herein by reference. The sections entitled "*Report of the Compensation Committee*" and "*Comparative Stock Performance Graph*" in our 2004 proxy statement are not incorporated herein by reference.

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

Information required by this Item 12 is set forth in our 2004 proxy statement under the headings "*Securities Authorized for Issuance under Equity Compensation Plans*" and "*Security Ownership of Certain Beneficial Owners and Management,*" which information is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions*

Information required by this Item 13 is set forth in our 2004 proxy statement under the headings "*Director Compensation*" and "*Employment and Consulting Agreements and Other Arrangements,*" which information is incorporated herein by reference.

Item 14. *Principal Accountant Fees and Services*

Information required by this Item 14 is set forth in our 2004 proxy statement under the heading "*Independent Auditor's Fees and Other Matters,*" which information is incorporated herein by reference.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K***

(a) *Financial Statements.*

For a list of the consolidated financial information included herein, see Index to the Consolidated Financial Statements on page of this Annual Report on Form 10-K.

(b) *Reports on Form 8-K.*

On October 28, 2003, we furnished a Current Report on Form 8-K to the Securities and Exchange Commission announcing our financial results for the fiscal quarter ended September 30, 2003. The date of this Current Report on Form 8-K is October 28, 2003.

On January 7, 2004, we furnished a Current Report on Form 8-K to the Securities and Exchange Commission announcing our preliminary revenue results for the quarter and year to date ended December 31, 2003. The date of this Current Report on Form 8-K is January 7, 2004.

On February 25, 2004, we furnished a Current Report on Form 8-K to the Securities and Exchange Commission announcing our financial for the quarter and year to date ended December 31, 2003. The date of this Current Report on Form 8-K is February 25, 2004.

(c) *List of Exhibits.*

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Annual Report on Form 10-K.

(d) *Financial Statement Schedules.*

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying financial statements or notes thereto.

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, on March 30, 2004.

CAMBRIDGE HEART, INC.

By: /s/ DAVID A. CHAZANOVITZ
David A. Chazanovitz
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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/ DAVID A. CHAZANOVITZ David A. Chazanovitz	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2004
/s/ ROBERT B. PALARDY Robert B. Palardy	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2004
/s/ DANIEL M. MULVENA Daniel M. Mulvena	Chairman of the Board of Directors	March 30, 2004
/s/ RICHARD J. COHEN Richard J. Cohen	Director	March 30, 2004
/s/ ROBERT J. DEPASQUA Robert J. DePasqua	Director	March 30, 2004
Eric Hecht	Director	March 30, 2004
/s/ ROBERT P. KHEDERIAN Robert P. Khederian	Director	March 30, 2004
Jeffrey J. Langan	Director	March 30, 2004

David A. Chazanovitz
President and CEO

April, 2004

Dear Fellow Shareholders:

2003 represents the most successful year in Cambridge Heart's history! We ended the year with total revenues of $6.9 million, representing a 61% increase from the $4.3 million which we generated in 2002. Of significant importance is the fact that our core U.S. Microvolt T-Wave Alternans business more than doubled, growing from $2.5 million in 2002 to $5.1 million in 2003. We also decreased our net loss, reduced our cash burn and increased our gross margins in 2003. I hope you will agree that we made significant progress last year. Allow me to spend a few minutes recapping some of the events of the year and sharing some of the continuing challenges we face, as we work to make Microvolt T-Wave Alternans (MTWA) a standard of medical care.

FUNDING

As you know, almost one year ago we announced an equity financing that provided us with gross proceeds of $6.5 million from the sale of Series A Convertible Preferred Stock. The investors in the financing included Medtronic, Inc., and a group of private investors led by Bob Khederian, a member of our Board of Directors. The funding was important as it allowed us to continue our mission of establishing MTWA within the cardiology community.

RISK STRATIFICATION AND THE EVOLVING WORLD OF ICD STUDIES

Many of you have asked about the role for Microvolt T-Wave Alternans in an environment where new and important studies, such as Madit II and SCD-HeFT, suggest that Implantable Cardiac Defibrillators (ICDs) are more effective in saving lives than standard drug therapy. The Madit II study sponsored by Guidant, was a study of Post MI (heart attack) patients with an ejection fraction (measure of the heart's pumping ability) of 30% or less. The SCD-HeFT study, sponsored by Medtronic, Wyeth and the National Institutes of Health, was the largest ICD study ever conducted, with over 2,500 patients evaluated. This heart failure study included Class II and III heart failure patients with an ejection fraction of less than or equal to 35% whether the cause of the heart failure was ischemic (related to blood flow) or non ischemic.

Each of these studies demonstrated a reduction in the mortality rate of patients that received an ICD versus drug therapy. In the case of Madit II, a 31% relative reduction from 19.8% to 14.2%, or a 5.6% absolute reduction in the death rate, was reported. The SCD-HeFT study reported a 23% relative reduction in mortality from 7.2% per year to approximately 5.6% per year, or a 1.7% absolute reduction. These gains are clearly important but the debate rages regarding how broadly this population of over one million patients can and should be treated with ICDs. This is a fairly significant public health issue as the cost of treating these large populations could run into the billions of dollars.

In the past one plus years, there have been a number of clinical studies on Microvolt T-Wave Alternans released suggesting that even in these high risk populations, a negative result from a Microvolt T-Wave Alternans test means that a patient is at substantially lower risk than any of the groups mentioned above regardless of their treatment. Therefore, we firmly believe that risk stratification still remains a priority. It is unlikely that all of the patients in these high risk populations will be referred by their cardiologist for ICD implantation. Physicians need reliable data to assist them in determining which of their patients remain at relatively low risk of sudden cardiac death (SCD) versus which are truly at high risk so that they can deploy health care resources efficiently and cost effectively.

CLINICAL VALIDATION AND CONTINUING CLINICAL EFFORTS

Since the time I have been at Cambridge Heart, I have had the privilege of reporting the results of many clinical trials to you with reference to MTWA. I have mentioned two separate studies on heart failure patients performed by Dr. Dan Bloomfield and Dr. Thomas Klingenheben. I have also reported on a study of Post MI or heart attack patients performed by Dr. Takanori Ikeda, three separate studies of Madit II type patients conducted by Dr. Theodore Chow, Dr. Dan Bloomfield, and Dr. Stefan Hohnloser, and two studies of Non-Ischemic Dilated Cardiomyopathy patients conducted by Dr. Stefan Hohnloser and Dr. Hidetsuna Kitamura. I will not take the space here to review the results, however, suffice it to say that these studies, performed on three different continents, confirm the consistent premise that those individuals who test positive with MTWA are at substantially higher risk of SCD than those who test negative and if negative, an individual's risk of sudden cardiac death is very low in the ensuing 1-2 year period.

More clinical information is always better than less. In September 2003 we initiated enrollment in the MASTER Study sponsored by Medtronic. This study is looking for risk stratification information in Madit II type patients. Aimed at over 50 centers, the study enrollments are ahead of schedule. A second element of the MASTER Study evaluates Post MI patients with slightly higher ejection fractions (30% to 40%) in a formal data registry. The ABCD Study, sponsored by St. Jude Medical is in its final phases of enrollment and has the objective of proving that the non-invasive MTWA test is at least as effective as electrophysiology study in determining patients at need of ICD therapy. We also anticipate results from a sub-study of SCD-HeFT patients to be available later in 2004. In addition to these major initiatives, there are other studies being conducted around the world. Individually, each study is important, however when taken cumulatively the power of the data becomes quite impressive.

REIMBURSEMENT

Reimbursement lies at the core of medicine. For good, or for bad, reimbursement often dictates the overall adoption curve for new technologies. This is no different for Cambridge Heart. As you know, our MTWA test has a unique Current Procedural Terminology (CPT) code which enables and facilitates the reimbursement of the test. The Centers for Medicare and Medicaid Services (CMS) has adjusted the average reimbursement on the test to approximately $338 for 2004. While down from the approximate $426 in 2003, it is up from the initial valuation of $267 when the CPT code first issued in 2002. Almost all states currently have Medicare policies in place to reimburse physicians and hospitals for the performance of a MTWA test. Many of the policies are quite broad with respect to the type of patients a physician can test and receive reimbursement. Some local policies have narrower indications which restrict the testing of patients at risk. We have been successful in working with a number of local Medicare carriers in 2003 to broaden their coverage policies. We will continue to work with those carriers we have identified as needing broader indications to achieve appropriate coverage for their insured. Recently we hired a highly experienced Manager of Reimbursement Services to facilitate these activities. We anticipate continued gains here.

Medicare covers approximately 50% of the patient population known to be at risk of dying suddenly from a ventricular tachyarrhythmic event. Most of the rest are covered by private insurance carriers like Aetna, Blue Cross/Blue Shield and United Healthcare. While we have received positive coverage decisions from some local private payers, national coverage from the big three has been more problematic. The establishment of coverage from these payers is one of our highest priorities. We have engaged the services of a well known reimbursement consulting firm to aid in these efforts. We anticipate that the submission of additional clinical study results will aid our efforts in this regard. The support of many members of the medical community advocating for the value of our test is also a significant plus in this endeavor.

WHERE DO WE GO IN 2004?

In 2003, we raised the profile of our Microvolt T-Wave Alternans technology. In addition to a record revenue year and improved financial results, we increased our installed base of Heartwave systems in the U.S. to approximately 400. We believe we have raised our visibility in the cardiology community through many activities including physician presentations made to CMS advocating the value of MTWA in the Madit II population. Additionally, new and important clinical studies have been released to the medical community. Our team now works with great enthusiasm to further penetrate the market. We are diligently working to improve the reimbursement in those areas already mentioned. While it is difficult to promise that we will not encounter various challenges along the way, we can promise continued dedication to the task of making Microvolt T-Wave Alternans a standard of care yielding the success we all desire.

Speaking for the Cambridge Heart family, we continue to appreciate your encouragement and support.

Respectfully,

David A. Chazanovitz

Statements contained in this press release about anticipated revenue growth, and all other statements that are not purely historical, are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. In some cases, we use words such as "believes", "expects", "anticipates", "plans", "estimates" and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements. Factors that may cause or contribute to such differences include failure to obtain funding necessary to develop or enhance our technology, adverse results in future clinical studies of our technology, failure to obtain or maintain patent protection for our technology, failure to obtain or maintain adequate levels of third-party reimbursement for use of our products and other factors identified in our most recent Annual Report on Form 10-K under "Factors Which May Affect Future Results", which is on file with the SEC. In addition, any forward-looking statements represent our estimates only as of today and should not be relied upon as representing our estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our estimates change.

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