



**CAMBRIDGE  
HEART**

INC

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**Annual Report**

**2005**

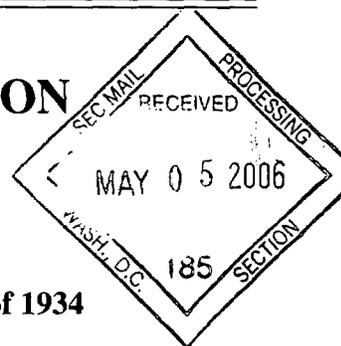
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**THOMSON  
FINANCIAL**

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, 2005

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

(State or Other Jurisdiction of  
Incorporation or Organization)

1 Oak Park Drive, Bedford, MA  
(Address of Principal Executive Offices)

13-3679946

(I.R.S. Employer  
Identification No.)

01730  
(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes  No

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

Indicate by check mark 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 whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company  Yes  No

The aggregate market value of the common stock held by non-affiliates of the registrant was \$10,736,272 computed by reference to the last reported sale price of the common stock on the OTC Bulletin Board on June 30, 2005.

As of March 28, 2006 60,229,690 shares of the registrant's common stock were outstanding.

Documents incorporated by reference:

Document Description

10-K Part

Portions of the registrant's Proxy Statement for its Annual Meeting of Stockholders, which will be filed within 120 days after the close of the registrants fiscal year ended December 31, 2005 .....

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 (“MTWA”), 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 to predict the risk of sudden cardiac death. 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 with heart disease has shown that patients with symptoms of or at risk of life threatening arrhythmias 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. Sudden cardiac arrest accounts for approximately one-third of all cardiac deaths, or over 400,000 deaths, in the U.S. each year, and is the leading cause of death in people over the age of 45.

All of our products, including our Heartwave and Heartwave II Systems, CH 2000 Cardiac Stress Test System and Micro-V Alternans Sensors, have received 510(k) clearance from the FDA for sale in the U.S. They have also received the CE mark for sale in Europe and our Heartwave System and CH 2000 System has 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 which we define as diagnostic cardiology equipment. Revenue from this segment was \$6,944,911, \$5,107,751, and \$4,198,871 for the years ended December 31, 2003, 2004 and 2005 respectively. 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](http://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 II System***

Our Heartwave II System, which has replaced our original 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 of 110-120 beats per minute is typically achieved utilizing exercise as performed on a treadmill similar to standard stress test. The heart rate can also be elevated through the use of pharmaceuticals or by directly pacing the patient often during an electrophysiology study.

In April 2005, we received clearance from the FDA to market our new Heartwave II System. The Heartwave II System is our next generation MTWA testing platform which eliminates the need for a host stress system. 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 electrocardiographic signals are captured by the Micro-V Alternans Sensors placed at designated locations on the patient's chest and analyzed by the Heartwave II processor using our proprietary Analytic Spectral Method of measuring microvolt levels of t-wave alternans.

The Heartwave II System includes:

- MTWA signal processing and analysis using our proprietary Analytic Spectral Method;
- Windows® XP operating system powered by an Intel® Pentium® processor;
- Large adjustable 15" color LCD display and multiple printer options, including Bluetooth or Thermal; and
- 3,000 test storage capacity, with real time or review mode editing capability.

### ***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 echocardiograph 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 (MTWA) 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 an 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*, *Circulation*, *Journal of Cardiovascular Electrophysiology*, *Journal of the American College of Cardiology*, and *The Lancet*.

In October 2004, the journal *Circulation* published the results of a National Institutes of Health sponsored prospective, multi-center study conducted by Dr. Daniel M. Bloomfield of Columbia University College of Physicians and Surgeons. The study of 177 patients with a previous heart attack and poor pumping function (left ventricular ejection fraction of 30% or less), which are called MADIT II type patients (a subset within a 549 patient heart failure study), compared the efficacy of our Microvolt T-Wave Alternans Test to QRS duration, a time measurement of a portion of the cardiac cycle, in predicting all cause mortality. The results of the study revealed that patients were 4.8 times more likely to die if they tested not-negative (positive or indeterminate) for Microvolt T-Wave Alternans than if they had a negative result. This result showed statistical significance ( $p=0.020$ ) while the use of QRS duration did not achieve any statistical significance in risk stratifying this group of patients. Dr. Bloomfield concluded that among MADIT II type patients, Microvolt T-Wave Alternans is better than QRS duration at identifying a high risk group and also better at identifying a low risk group unlikely to benefit from implantable cardioverter defibrillator (ICD) therapy.

The following month, November 2004, Dr. Otto Costantini, Assistant Professor of Medicine, Case Western Reserve University and Director, Arrhythmia Prevention Center, MetroHealth Medical Center, presented data at the American Heart Association Annual Meeting in New Orleans demonstrating the efficacy of Microvolt T-Wave Alternans testing in 282 non-ischemic cardiomyopathy patients with an ejection fraction of less than 40%. These patients represent a different subset of the same 549 patient study previously mentioned that was conducted by Dr. Daniel Bloomfield. Of the 282 non-ischemic patients, 34% had a normal (negative) Microvolt T-Wave Alternans Test result, while 66% tested abnormal (positive or indeterminate). Among the patients with a normal MTWA Test result, none experienced the study's primary endpoint of death or sustained arrhythmia, while 11.8% of the patients with an abnormal test result experienced the primary endpoint. Dr. Costantini concluded that a normal Microvolt T-Wave Alternans Test result predicts a negligible risk of death or sustained ventricular tachycardia among patients with non-ischemic cardiomyopathy and that Microvolt T-Wave Alternans performs better than QRS duration and ejection fraction in predicting death or sustained ventricular arrhythmia. Of significance, according to Dr. Costantini, is that MTWA has a high negative predictive accuracy in both ischemic and non ischemic patients and that the use of ICD prophylaxis in patients with a normal MTWA test and an ejection fraction of 30% or less may not be necessary.

In October 2005, Aroundas, et al, published a Meta Analysis of MTWA studies in the journal *Nature Clinical Practice*, entitled, "Can Microvolt T-Wave Alternans Testing Reduce Unnecessary Defibrillator Implantation. This Meta Analysis of studies performed in patient populations that were similar to populations reported on in primary prevention studies for implantable defibrillators. In evaluating 9 studies with 1,811 patients, the annual tachyarrhythmic event rate was 1.2% in individuals testing MTWA negative. Across the 9 studies, individuals were 7 times more likely to have a cardiac event if they were MTWA positive than if they were MTWA negative.

In December 2005 the Online version of the *Journal of The American College of Cardiology (JACC)*, published an expedited review of a 549 patient multi-center heart failure trial, led by Dr. Daniel Bloomfield and partially funded by the National Institutes of Health (NIH). The study which enrolled patients with a left ventricular ejection fraction of 40% or less and NY Heart Association Class I-III heart failure utilized MTWA testing and followed the patients for about two years. Those patients who had a MTWA abnormal test were 6.5 times more likely to have a cardiac event than those with a MTWA normal (negative) test. The results were highly statistically significant with a p value  $<0.001$ . The authors conclusions were, "Among patients with heart disease and LVEF  $\leq 40\%$ , MTWA can identify not only a high-risk group, but also a low-risk group unlikely to benefit from ICD prophylaxis." This clinical study was republished in the January 17, 2006 issue of *JACC*.

### *ABCD Study*

The ABCD Study enrolled approximately 600 patients under the sponsorship of St. Jude Medical. Each of the patients enrolled had coronary artery disease, left ventricular ejection fraction (LVEF) less than 40% and non-sustained ventricular tachycardia. Each patient was tested with the non-invasive MTWA test and had an invasive electrophysiology (EP) study as well. Patients who were positive for either test received an implantable defibrillator. The objective of the study was to compare efficacy of the two tests. Study enrollment has been completed, and follow-up will be completed mid-year 2006.

### *MASTER Study*

The 653 patient, multi-center, MASTER I (*Microvolt T-Wave Alternans Testing for Risk Stratification of Post MI Patients*) clinical trial, sponsored by Medtronic, Inc., completed its enrollment. The purpose of this study is to show that MADIT II type patients with a normal Microvolt T-Wave Alternans Test result are at very low risk of dying suddenly versus those that test abnormal and, therefore, may not require ICD therapy. Each of the 653 patients met MADIT II criteria, meaning that they had all experienced a heart attack and had an ejection fraction of 30% or less. All of the patients received a currently available Medtronic ICD as prophylactic therapy. Results of this study are expected to be available at the end of 2006 or early 2007. An additional 400 patients with slightly better pumping function (ejection fraction of 30% to 40%) are being evaluated in a related registry.

### *REFINE Study*

The enrollment in the 350 patient, multi-center, *Risk Estimation Following Infarction—Noninvasive Evaluation Study*, led by Dr. Derek Exner, University of Calgary Associate Professor of Medicine, Libin Cardiovascular Institute of Alberta, is completed. The primary hypothesis of the study is that Microvolt T-Wave Alternans testing will have a greater prognostic utility in predicting the endpoints of sudden cardiac death, resuscitated ventricular fibrillation or sustained ventricular tachycardia than various non-invasive parameters including signal averaged electrocardiogram, baroreceptor sensitivity and several Holter measures such as heart rate variability in patients who had experienced a recent myocardial infarction and have an ejection fraction of 50% or less. Study results are expected to be available in 2006.

### *CARISMA Study*

Enrollment in a 300 patient multi-center study, conducted by Dr. Heikki Huikuri, Professor of Medicine, Oulu University Central Hospital in Finland, was also recently completed. The goal of the study is to assess the value of Microvolt T-Wave Alternans and several other invasive and non-invasive risk stratification methods as predictors risk of arrhythmia events heart attack survivors with an ejection fraction of 40% or less. All patients received a loop recorder to record arrhythmic events.

### **Reimbursement**

Reimbursement to healthcare providers by Medicare/Medicaid and third party insurers is critical to the long-term success of our efforts to make the Microvolt T-Wave Alternans Test a 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, 2006, 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 \$322.

Local Medicare carriers have provided coverage for the Microvolt T-Wave Alternans Test, however, actual reimbursement has been inconsistent and in many instances administratively burdensome to physicians making it difficult to obtain. In addition to Medicare reimbursement at a local level, CMS issues National Coverage Determinations (NCD's) which represent approximately 10% of total Medicare coverage policies. In 2005, we applied to CMS for a NCD in order to gain broader and more uniform reimbursement coverage for our Microvolt T-Wave Alternans Test. After a nine month application process, which included two public comment periods. CMS released a draft of its NCD on December 21, 2005, which became final on March 21, 2006. This broad coverage policy allows for payment for MTWA testing of patients at risk of sudden cardiac death only when a MTWA test is done using the spectral analytic method, which is our patented and proprietary method of analysis.

In addition to federally funded reimbursement, we have been pursuing reimbursement from private insurers, which cover approximately 50% of the patient population we believe could benefit from a MTWA Test. In 2005, we received a positive reimbursement decisions from Horizon Blue Cross/Blue Shield units in New Jersey. In addition, we currently have payment policies from Blue Cross/Blue Shield in New York, Iowa, Maryland, Washington DC, Delaware, Michigan, South Dakota and Minnesota. In March 2006, we received broad reimbursement from Aetna which included the use of our patented algorithm. We will continue to work with the private insurance carriers to obtain additional reimbursement for our MTWA Test, with a focus on the larger national carriers.

### **Marketing and Sales**

Our technology and products are directed towards identifying individuals at risk of sudden cardiac death and those cardiac patients who may not be at risk. Typically our target patient populations include those individuals with underlying cardiac disease. In the U.S., those populations include more than 7 million patients who have suffered a myocardial infarction (heart attack), 5 million patients suffering from congestive heart failure (poor pumping function), and more than one million other patients suffering from conditions including syncope (fainting and dizziness) and non-ischemic dilated cardiomyopathy (damaged and enlarged heart). Therefore, we believe that the aggregate at-risk patient population that could benefit from our MTWA Test exceeds 10-12 million. MADIT II and Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) type patients are relatively small, but highly visible and important subsets of this at-risk patient population.

The target customer for our Heartwave II 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 who may be treated more conservatively, typically through drug therapy. The electrophysiologist is a cardiologist specializing in the electrical rhythm of the heart and, as such, their knowledge and opinion on the value of the MTWA Test is often solicited by the clinical cardiologist, the primary user of our test.

Throughout 2005, we significantly reduced the number of direct field sales representatives in the U.S., due to a lack of uniform Medicare coverage and low levels of private insurance coverage, which resulted in a number of unproductive sales territories. In order to conserve cash we decided to suspend our direct sales efforts in those territories which lacked adequate insurance coverage, and reduced our direct sales efforts to 3 territories. We attempted to supplement our direct sales effort by establishing relationships with a number of independent manufactures representatives. Although we were successful in establishing a number of these relationships, we found that these independent representatives were typically unable or unwilling to invest the time and effort required to sell the Heartwave II System.

During 2006, based on the recent Medicare NCD, we intend to increase our marketing efforts in order to build increased awareness of our Heartwave II System and MTWA Test with the cardiologist and

electrophysiologist community. We intend to expand our direct sales organization, targeting areas that have a relatively high percentage of Medicare patients, and areas where we expect to obtain additional reimbursement coverage by private insurers. We will also explore potential partnerships with companies that have existing cardiology-based distribution channels.

In 2005, approximately 22% of our total revenue came from sales of our products outside the U.S. We sell our products internationally through a network of 23 country specific distributors in Europe, Asia and the Middle East.

### **Manufacturing**

The in-house manufacturing process for our Heartwave II System and CH 2000 consists primarily of incoming inspection and final assembly of purchased components. Additionally, our operations group tests, inspects, packages and ships product. 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 believe that our facility in Bedford, Massachusetts will be adequate to meet our production requirements through November 30, 2006, the term of our current lease agreement, and that we will be able to secure adequate facilities upon the expiration of our current lease. 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 continuing efforts to develop functionality enhancements to our Microvolt T-Wave Alternans products, and on supporting existing clinical studies such as the Master and ABCD clinical studies. During 2005, we completed the development of and released our third generation Heartwave II System, which incorporates additional features intended to make our Microvolt T-Wave Alternans Test easier to perform and more beneficial for our customers.

As of December 31, 2005, 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.

### **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 (MIT). This patent is covered by an exclusive license agreement with MIT that continues through the year 2007. The license will then convert to a non-exclusive agreement for the remaining life of the patent unless MIT agrees to an extension of exclusivity. We have been issued an additional nineteen U.S. patents that include claims covering substantial changes and modifications to the initial methods covered by the original MIT patent. The spectral analytic method is the subject of new domestic and international patents issued in 2004. The expiration dates of these patents range from 2013 to 2021.

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 a conversion of the licenses from exclusive to non-exclusive in nature or, in some cases, termination of the license. We believe that we are in compliance with all of these obligations.

We believe that our intellectual property and expertise, developed by us, constitutes an important competitive resource, and we continue to evaluate the markets and products that are most appropriate to exploit this expertise. 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.

### **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 that support and validate the use of this algorithm. We believe that the publication of substantial clinical data is necessary to successfully penetrate this emerging market and gain Medicare and private insurer reimbursement. Indirect competition can come from other testing modalities such as invasive electrophysiology testing and the potential for implanting of ICDs in broad patient populations without the need for risk stratifying tests such as ours.

### **Government Regulation**

We have received all necessary and required regulatory clearances from the FDA to market our products in the U.S. Our Heartwave II System, CH 2000, and Micro-V Alternans Sensors have received 510(k) clearance from the FDA for sale in the U.S. The 510(k) clearance for the Heartwave Systems 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 comprehensive 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 countries are similar to those of the FDA. We have obtained the requisite foreign regulatory approvals for sale of our Heartwave Systems, 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 System, 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 original Heartwave System for sale, and we intend to apply for approval of the Heartwave II System. 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, 2005, we had 17 full-time and 4 part-time employees. None of our employees are represented by a collective bargaining agreement, and we have not 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, 2006, pursuant to a one year extension of the original lease agreement. 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, 2005.

## Item 4A. 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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
David A. Chazanovitz . . . . .	55	Chairman of the Board, Chief Executive Officer and President
Robert LaRoche . . . . .	50	Vice President, Sales and Marketing
Ali Haghighi-Mood . . . . .	46	Vice President, Research and Development
Roderick de Greef . . . . .	45	Chief Financial Officer

*David A. Chazanovitz.* Mr. Chazanovitz has been our Chief Executive Officer since February 2001 and the President and a Director since October 2000. He assumed the title of Chairman of the Board of Directors in 2004. 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 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.

*Ali Haghghi-Mood, Ph.D.* Dr. Haghghi-Mood has been our Vice President of Research and Development since July 2003. From January 2002 to July 2003, he served as our Director of Research and has worked in our research and development department since January 1997. Dr. Haghghi-Mood is the holder of several patents covering our Microvolt T-Wave Alternans technology including our proprietary Analytic Spectral Method for the measurement of T-wave Alternans. Dr. Haghghi-Mood holds a B.S. and an M.S. in Electrical Engineering from the University of Tehran and a Ph.D. in Biomedical Engineering from the University of Sussex in the U.K.

*Roderick de Greef.* Mr. de Greef has been our Chief Financial Officer since October 2005. From February 2001 to September 2005, Mr. de Greef was Executive Vice President and Chief Financial Officer of Cardiac Science, Inc., which merged with Quinton Cardiology, Inc. From 1995 to 2001, Mr. de Greef provided independent corporate advisory services to a number of early-stage companies. From 1986 to 1995, Mr. de Greef served as Chief Financial Officer of several publicly held, development stage medical technology companies. Mr. de Greef is a member of the board of directors of several companies in the medical technology field. Mr. de Greef has a B.A. in Economics and International Relations from California State University at San Francisco and earned his M.B.A from the University of Oregon.

Executive officers of the Company 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 are traded on the National Association of Securities Dealers' OTC Bulletin Board under the symbol "CAMH.OB". On May 8, 2003, the listing of our shares moved from The Nasdaq SmallCap Market to the OTC Bulletin Board. Prior to August 2, 1996, our shares were not publicly traded. 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 OTC Bulletin Board during the two most recent fiscal years.

<u>Period</u>	<u>2004</u>		<u>2005</u>	
	<u>High</u>	<u>Low</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$1.36	\$0.83	\$0.71	\$0.31
Second Quarter .....	\$1.10	\$0.54	\$0.47	\$0.25
Third Quarter .....	\$0.94	\$0.36	\$0.34	\$0.25
Fourth Quarter .....	\$0.72	\$0.42	\$0.94	\$0.24

The depository for our common stock is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005. On March 10, 2006, we had approximately 142 holders of common stock of record. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

#### 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 2001, 2002, 2003, 2004 and 2005, have been derived from our audited financial statements. Our balance sheet dated as of December 31, 2004 and 2005 and the related statements of operations for each of the three years in the period ended December 31, 2005 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. (See Note 2)

	Year Ended December 31,				
	2001	2002	2003	2004 (as restated)	2005
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenue .....	\$ 3,112	\$ 4,307	\$ 6,945	\$ 5,108	\$ 4,199
Cost of goods sold .....	2,431	3,061	3,203	2,342	1,980
Gross profit .....	681	1,246	3,742	2,766	2,219
Costs and expenses:					
Research and development .....	1,845	1,388	944	774	699
Selling, general and administrative .....	5,702	5,868	6,193	5,752	4,507
Total costs and expenses .....	7,547	7,256	7,137	6,526	5,206
Loss from operations .....	\$ (6,866)	\$ (6,010)	\$ (3,395)	\$ (3,760)	\$ (2,987)
Interest income .....	413	104	20	58	191
Interest expense .....	(13)	(17)	(13)	(1)	(4)
Change in valuation of Series B warrants .....	—	—	—	(44)	164
Net loss .....	\$ (6,466)	\$ (5,923)	\$ (3,388)	\$ (3,747)	\$ (2,636)
Beneficial conversion feature .....	—	—	(1,533)	(2,537)	—
Net loss attributable to common stockholders .....	\$ (6,466)	\$ (5,923)	\$ (4,921)	\$ (6,284)	\$ (2,636)
Net loss per share-basic and diluted ..	\$ (0.37)	\$ (0.30)	\$ (0.25)	\$ (0.21)	\$ (0.07)
Weighted average shares outstanding- basic and diluted .....	17,340,789	19,450,062	19,663,460	29,622,673	39,914,615

	December 31,				
	2001	2002	2003	2004 (as restated)	2005
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities .....	\$ 8,738	\$ 3,093	\$ 5,609	\$ 7,647	\$ 5,298
Working capital .....	8,669	3,152	6,389	6,537	4,538
Long term debt .....	101	6	4	2	—
Total assets .....	11,900	6,189	8,520	9,650	7,015
Total liabilities .....	1,981	2,032	1,620	2,740	2,279
Preferred stock .....	—	—	4,589	3,635	1,504
Warrants to acquire preferred stock .....	—	—	1,024	890	743
Accumulated deficit .....	(43,102)	(49,024)	(52,412)	(56,159)	(58,795)
Stockholders' equity .....	\$ 9,918	\$ 4,156	\$ 1,287	\$ 2,385	\$ 2,487
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 tools cleared by the U.S. FDA 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 product, the Heartwave System II in conjunction with our single patient use Micro-V Alternans Sensors. There are approximately 550 Heartwave units that have been sold in the U.S. since the product was introduced at the end of fiscal 2000.

We spent considerable time in 2005 working on medical reimbursement issues to help ensure that our customers are paid for the performance of a Microvolt T-Wave Alternans Test. We believe reimbursement is a critical component to the overall success and revenue growth of the Company as our customers require profitability from the diagnostic tests that they employ. We rely on the Centers for Medicare and Medicaid Services (CMS), also known as Medicare, for approximately 50% of the potential reimbursement coverage for our test since approximately one-half of the potential base of patients is at least 65 years old. The remaining 50% of our potential patients are covered through private insurance plans such as Blue Cross/Blue Shield, Aetna, Cigna, Kaiser and United Healthcare. In December 2005, CMS issued a draft National Coverage Determination for reimbursement of our MTWA Test. The coverage policy, which became final on March 21, 2006, provides for broad and uniform Medicare reimbursement of the MTWA Test utilizing the spectral analytic method which is our patented method. In 2005, we also received positive coverage decisions from Horizon Blue Cross/Blue Shield of New Jersey. In March 2006, we received a broad reimbursement policy from Aetna which includes the use of our patented method of analysis.

Throughout 2005, in response to the reimbursement environment and in order to conserve cash resources, we significantly reduced the number of direct field sales representatives in the U.S. We attempted to supplement our direct sales effort by establishing relationships with a number of independent manufactures representatives. Although we were successful in establishing a number of these relationships, we found that these independent representatives were typically unable or unwilling to invest the time and effort required to sell the Heartwave II System.

In 2006, we intend to leverage the recent reimbursement decision by Medicare in order to gain additional private insurance coverage from the larger insurance companies. Based on the recent NCD, we intend to increase our marketing efforts with physicians in order to build increased awareness of our Heartwave II System and MTWA Test. We intend to expand our direct sales organization, targeting areas that have a relatively high percentage of Medicare patients and areas where we expect to obtain additional reimbursement coverage by private insurers. We will also explore potential partnerships with companies that have existing cardiology based distribution channels.

At December 31, 2005, approximately 50% of our 21 full and part-time employees were engaged in the selling or marketing of our technology and products, which accounts for approximately 50% of our total operating expenses incurred during 2005. An additional 14% of employees were dedicated to product manufacturing and customer support, while the remainder of our organization is involved in product research and development or administrative support.

### **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 the fair value of preferred stock and warrants, revenue recognition, incentive compensation, product returns, bad debt allowances, inventory valuation, investments, intangible assets, income taxes, 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.

### ***Accounting for Derivative Instruments***

In September 2000, the Emerging Issues Task Force issued EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," ("EITF 00-19") which requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required. In March 2006, in accordance with EITF 00-19, we determined that the outstanding warrants to purchase our Series B stock ("Series B warrants") should be separately accounted for as a liability. We had not classified these Series B warrants as liabilities in our historical financial statements. In order to reflect these changes, we restated our financial statements for the year ending December 31, 2004 to record the fair value of these Series B warrants on our balance sheet and to record the unrealized changes in the fair value of these Series B warrants in our consolidated statement of operations as "Gain (loss) on Series B warrants." The pricing model we use for determining the fair value of the Series B warrants is the Black Scholes pricing model. This model uses certain inputs such as interest rates, stock price volatility and estimates concerning the life of the derivatives. Selection of these inputs involves management's judgment and may impact net income. The fair value of the Series B warrants was calculated at using the Black Scholes valuation model, with the following significant assumptions utilized for the reporting periods from December 31, 2004 to December 31, 2005: a) Estimated Warrant Life – 3 to 15 months, b) Volatility Rate – 115 to 118%, c) Dividend Rate – 0%, d) Risk Free Rate – 3.72 to 4.51%, and e) Common Stock Price – \$0.29 to \$0.74. The Series A warrants which were classified in the temporary equity section, and the Series B warrants which have been restated as a liability, are accounted for differently due to certain net-cash settlement provisions found in the terms and conditions of the Series B warrants.

### ***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 ("EITF") 00-21 "Accounting for Revenue Arrangements with Multiple Deliverables", 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 is recognized separately based on amounts charged when sold on a stand alone basis and is recognized over the term of the underlying agreement. Additionally, revenue associated with the service of new

systems sold is recognized in the period in which the service is provided. Payments of \$71,518 at December 31, 2005 (\$162,575 at December 31, 2004) 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. As of December 31, 2005, our allowance for doubtful accounts was \$140,250. We believe we have an adequate allowance; however additional write-offs could occur if future results significantly differ from our expectations.

#### ***Inventory Valuation***

We regularly assess the value of our inventory for estimated obsolescence or unmarketable inventory. If necessary, we write-down our inventory value to the estimated fair 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 from time to time that could adversely affect our operating results for the fiscal period in which such write-downs are affected.

#### ***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, 2005, 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 \$5,461 at December 31, 2005.

#### ***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 the 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 the 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 affect our results of operations.

#### ***Restatement of Financial Statements to Reflect Derivative Accounting***

The financial statements for the year ended December 31, 2004 included in this Annual Report have been restated to reflect the classification of our Series B warrants, originally issued on December 6, 2004, as a liability, and to reflect additional non-operating gains and losses related to the changes in the fair value of those Series B warrants. In March 2006, we determined that certain features of the Series B warrants required us to

designate these warrants as liabilities in our financial statements. As a result, we reported the fair value of these Series B warrants as current liabilities on our balance sheet and we reported changes in the value of these Series B warrants as non-operating gains or losses on our statement of operations. The fair value of the Series B warrants is required to be recalculated (and resulting non-operating gains or losses reflected in our statement of operations and resulting adjustments to the associated liability amounts reflected on our balance sheet) on a quarterly basis, and is based on the Black Scholes pricing model. This model uses certain inputs such as interest rates, stock price volatility and estimates concerning the life of the derivatives. Selection of these inputs involves management's judgment and may impact net income.

Our financial statements for the year ended December 31, 2004 have been restated to give effect to the changes described above. The impact of the adjustments related to the classification of the fair value of our Series B warrants, and periodic changes thereto on our statement of operations for the year ended December 31, 2004 is summarized below:

**CAMBRIDGE HEART, INC.**  
**STATEMENT OF OPERATIONS**  
(in thousands except share and per share data)

	Year Ended December 31, 2004		
	As Previously Reported	Adjustment	As Restated
Gross profit .....	\$ 2,766		\$ 2,766
Costs and expenses:			
Research and development .....	774		774
Selling, general and administrative .....	5,752		5,752
Loss from operations .....	(3,760)	0	(3,760)
Interest income .....	58		58
Interest expense .....	(1)		(1)
Change in valuation of Series B warrants .....	—	(44)(1)	(44)
Net loss .....	\$ (3,703)	\$(44)	\$ (3,747)
Beneficial conversion feature (Note 8) .....	(2,604)	67(2)	(2,538)
Net loss attributable to common stockholders .....	\$ (6,307)	\$ 23	\$ (6,285)
Net loss per common share-basic and diluted .....	\$ (0.21)		\$ (0.21)
Weighted average common shares outstanding-basic and diluted .....	29,622,673		29,622,673

- (1) Change due to reduction in fair value of Series B warrant liability not previously recorded.  
(2) Change in beneficial conversion feature resulting from the classification of Series B warrants as current liabilities.

**Balance Sheet Impact of Restatement**

In addition to the effects on our 2004 statement of operations presented above, the restatement impacted our balance sheet as of December 31, 2004. The following table sets forth the effects of the restatement adjustments on our balance sheet as of December 31, 2004:

**CAMBRIDGE HEART, INC.**

**BALANCE SHEET**  
(in thousands)

	Year Ended December 31, 2004		
	As Previously Reported	Adjustment	As Restated
<b>Assets:</b>			
Current assets .....	\$ 9,275		\$ 9,275
Fixed assets, net .....	208		208
Other assets .....	167		167
Total Assets .....	<u>\$ 9,650</u>	<u>\$ —</u>	<u>\$ 9,650</u>
<b>Liabilities and Stockholders' Equity</b>			
Other current liabilities .....	991		991
Series B warrant liability .....	—	1,747(1)	1,747
Total current liabilities .....	991	1,747	2,738
Capital lease obligation, net of current portion .....	2	—	2
Total liabilities .....	993	1,747	2,740
Convertible Preferred Stock .....	3,702	(66)(2)	3,636
Warrants to acquire Convertible Preferred Stock .....	2,526	(1,637)(1)	889
	6,228	(1,703)	4,525
Common Stock .....	35		35
Additional paid-in capital .....	58,567		58,567
Accumulated deficit .....	(56,115)	(44)(3)	(56,159)
Less: deferred compensation .....	(58)		(58)
Total stockholders' equity .....	<u>2,429</u>	<u>(44)</u>	<u>2,385</u>
Total Liabilities and Stockholders' Equity .....	<u>\$ 9,650</u>	<u>\$ —</u>	<u>\$ 9,650</u>

- (1) Change due to recording a liability for Series B warrants determined to be derivatives.
- (2) Change in beneficial conversion feature resulting from the classification of Series B warrants s current liabilities.
- (3) Change due to increase in fair value of Series B warrant liability not previously recorded.

## 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.

	<u>2003</u>	<u>% of Total</u>	<u>2004</u>	<u>% of Total</u>	<u>2005</u>	<u>% of Total</u>	<u>% Inc/(Dec) 2005 vs 2004</u>	<u>% Inc/(Dec) 2004 vs 2003</u>
Alternans Products:								
U.S. ....	\$5,127,570	74%	\$3,479,831	68%	\$2,603,670	62%	-25%	-32%
Rest of World .....	<u>239,977</u>	3%	<u>338,076</u>	7%	<u>487,150</u>	12%	44%	41%
Total .....	5,367,547	77%	3,817,907	75%	3,090,820	74%	-19%	-29%
Stress Products:								
U.S. ....	1,169,774	17%	932,780	18%	676,095	16%	-28%	-20%
Rest of World .....	<u>407,590</u>	6%	<u>357,064</u>	7%	<u>431,956</u>	10%	21%	-12%
Total .....	<u>1,577,364</u>	23%	<u>1,289,844</u>	25%	<u>1,108,051</u>	26%	-14%	-18%
Total Revenues .....	\$6,944,911	100%	\$5,107,751	100%	\$4,198,871	100%	-18%	-26%

### 2005 Compared to 2004

#### REVENUE

Total revenue for 2005 and 2004 was \$4,198,871 and \$5,107,751, respectively, a decrease of 18%. Revenue from the sale of our Microvolt T-Wave Alternans products, which we call our Alternans Products, was \$3,090,820 during 2005 compared to \$3,817,907 during 2004, a decrease of 19%. Alternans Products accounted for 74% and 75% of total revenue for 2005 and 2004, respectively. The net decrease in revenue is primarily attributable to lower sales of Alternans products in the U.S. resulting from our transition from a direct to a hybrid distribution model, and the limited reimbursement coverage from our Microvolt T-Wave Alternans Test.

#### GROSS PROFIT

Gross Profit was 53% of total revenue in 2005 compared to 54% of total revenue in 2004. Reductions in manufacturing overhead expenses in effect for a portion of 2005 were more than offset by changes in our product mix resulting from lower domestic sales of our Alternans Products which have higher average selling prices and gross margins when compared to Alternans Products sold outside the U.S. We anticipate that gross margins in 2006 will improve slightly in accordance with an expected product mix and the realization of the full year impact of manufacturing overhead expense reductions.

#### 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.

	<u>2004</u>	<u>% of Total Revenue</u>	<u>2005</u>	<u>% of Total Revenue</u>	<u>% Inc/(Dec) 2005 vs 2004</u>
Operating Expenses:					
Research and development .....	\$ 774,285	15%	\$ 698,862	17%	-10%
Selling, general and administrative .....	<u>5,751,875</u>	113%	<u>4,507,479</u>	107%	-22%
Total .....	\$6,526,160	128%	\$5,206,341	124%	-20%

### *RESEARCH AND DEVELOPMENT*

Research and development expenses were \$698,862 in 2005 compared to \$774,285 in 2004, a decrease of 10%. The decrease is primarily attributable to reductions in staffing levels and lower levels of outside engineering consulting expenses as a result of the completion of our Heartwave II System. We expect research and development expenses in 2006 to remain near current levels.

### *SELLING, GENERAL AND ADMINISTRATIVE*

Selling, general and administrative expenses were \$4,507,479 in 2005 compared to \$5,751,875 in 2004, a decrease of 22%. Selling and marketing costs, which accounted for 58% of total SG&A in 2005, decreased 33% from 2004. Variable selling expenses were lower in 2005 due to lower sales of commissionable products in the U.S. Fixed selling expenses were also lower in 2005 as a result of a reduction in our direct sales force. Administrative costs accounted for 42% of total SG&A compared to 32% in 2004. Although administrative costs for 2005 increased as a percent of total SG&A when compared to 2004, the absolute dollar amount increased slightly as a result of lower legal and outside accounting fees, which were somewhat offset by severance costs and non-cash stock option compensation expenses. We anticipate that sales and marketing expenses will increase in 2006 as a result of a planned expansion of our direct distribution channel and increased levels of marketing in support of an enhanced reimbursement environment. We expect administrative expenses to increase modestly in 2006.

### *INTEREST INCOME/INTEREST EXPENSE*

Interest income was \$190,962 in 2005 compared to \$57,776 in 2004, an increase of 230%. The increase is primarily the result of increased amounts of invested cash received from the December 2004 sale of our preferred stock and the increases in short-term interest rates during 2005. Interest expense was \$3,919 in 2005 compared to \$799 in fiscal 2004.

### *NET LOSS*

As a result of factors described above, net loss attributable to common stockholders was \$2,636,486 in 2005 as compared to a net loss of \$6,284,251 in 2004. The reported net loss amount in 2004 includes non-cash financing charge related to the sale of our preferred stock in December 2004 of \$2,537,487. Excluding the impact of the financing related charge, we reported a net loss of \$2,636,486 and \$3,746,251 for 2005 and 2004, respectively.

### *Fiscal 2004 Compared to Fiscal 2003*

#### *REVENUE*

Total revenue for fiscal 2004 and 2003 was \$5,107,751 and \$6,944,911, respectively, a decrease of 26%. Revenue from the sale of our Alternans Products, was \$3,817,907 during fiscal 2004 compared to \$5,367,547 during fiscal 2003, a decrease of 29% and accounted for 75% and 77% of total revenue for fiscal 2004 and fiscal 2003, respectively. Approximately \$1.7 million of revenue recognized during fiscal 2003 came from the sale of equipment to participants in the MASTER Study as well as to Philips Medical Systems under a distribution agreement that expired at the end of fiscal 2003. During fiscal 2004, these non-recurring sales accounted for approximately 90% of our decline in total revenue and 64% of our decline in revenue from the sale of Alternans Products.

During fiscal 2004, 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, decreased 32% and accounted for 68% of total revenue for fiscal 2004 compared to 74% of total revenue for fiscal 2003. During fiscal 2004, the non-recurring sale of Alternans Products to participants in the MASTER Study accounted for approximately 60% of the revenue decrease. Revenue from the sale of Alternans Products outside the U.S. for fiscal 2003 and 2004 was \$239,977 and \$338,076, respectively, an increase of 41%.

The average selling price of our Heartwave System in the U.S. increased approximately 17% during fiscal 2004, while the average selling price of our Micro-V Alternans Sensors increased 6% during the same period.

During fiscal 2004, revenue from the sale of our CH 2000 stress test system and associated product components was \$1,289,844 compared to \$1,577,364 in fiscal 2003, a decrease of 18%. During fiscal 2003, approximately 70% of our revenue from the sale of CH 2000 stress test systems came from sales to Philips Medical Systems. In November 2004, we entered into a new non-exclusive distribution agreement with Del Mar Reynolds Medical.

#### *GROSS PROFIT*

Gross Profit was 54% of total revenue in fiscal 2004 unchanged from fiscal 2003. Manufacturing labor and overhead costs declined 9% in fiscal 2004 due to cost controls. Average selling prices in the U.S. for both the Heartwave and Micro-V Alternans Sensors increased in fiscal 2004.

#### *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.

	2003	% of Total Revenue	2004	% of Total Revenue	% Inc/(Dec) 2004 vs 2003
Operating Expenses:					
Research and development .....	\$ 944,325	14%	\$ 774,285	15%	-18%
Selling, general and administrative .....	<u>6,192,723</u>	89%	<u>5,751,875</u>	113%	-7%
Total .....	\$7,137,048	103%	\$6,526,160	128%	-9%

#### *RESEARCH AND DEVELOPMENT*

Research and development expenses were \$774,285 in fiscal 2004 compared to \$944,325 in fiscal 2003, a decrease of 18%. During fiscal 2004, we were able to substantially reduce the costs associated with third party consulting services, while filling staffing vacancies. We also funded a project to design and develop the next generation Heartwave System and continued our support of the ABCD Clinical Trial, the MASTER Study and several other clinical studies of our Microvolt T-Wave Alternans technology during fiscal 2004.

#### *SELLING, GENERAL AND ADMINISTRATIVE*

Selling, general and administrative expenses were \$5,751,875 in fiscal 2004 compared to \$6,192,723 in fiscal 2003, a decrease of 7%. Selling and marketing costs, which accounted for 68% of total SG&A in fiscal 2004, decreased 5% from fiscal 2003. While expenditures in support of our efforts to expand Medicare and private insurance reimbursement for our Microvolt T-Wave Alternans Test increased more than 500% during fiscal 2004, spending on marketing materials and advertising placements declined 37% from fiscal 2003. Administrative costs, which accounted for 32% of total SG&A in fiscal 2004, decreased 12% from fiscal 2003. Lower compensation costs accounted for the majority of the decrease.

#### *INTEREST INCOME/INTEREST EXPENSE*

Interest income was \$57,776 in fiscal 2004 compared to \$20,297 in fiscal 2003, an increase of 185%. The increase is primarily the result of increased amounts of invested cash during most of fiscal 2004 and the increases in short-term interest rates during fiscal 2004. Interest expense was \$799 in fiscal 2004 compared to \$13,300 in fiscal 2003. 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 \$6,284,251 in fiscal 2004 as compared to a net loss of \$4,920,910 in fiscal 2003. The reported amounts include non-cash financing charges associated with the sale of our preferred stock in December 2004 and May 2003. Details of these charges, which amounted to \$2,537,487 and \$1,533,280, for fiscal 2004 and 2003, respectively, are described in the Liquidity and Capital Resources section of this Annual Report on Form 10-K. The amounts of the beneficial conversion features have been immediately accreted and the accretions will result in deemed dividends as the preferred stock is immediately convertible. The deemed dividends have been reflected as adjustments to net loss applicable to common stockholders on our Statement of Operations. We reported a net loss of \$3,746,764 and \$3,387,630 for fiscal 2004 and 2003, respectively, before consideration of the beneficial conversion feature.

## *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, 2005.

We have not recorded a provision for income taxes for the years 1999 through 2005 because we incurred net losses in each of such years. At December 31, 2005, we had federal and state net operating loss carryforwards of approximately \$48,308,000 and \$34,809,000, respectively, as well as \$1,150,000 of federal and \$691,000 of state tax credit carryforwards, available to offset future taxable income and income tax liabilities, respectively. These carryforwards generally expire in the years 2005 through 2024 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 \$24,668,000 at December 31, 2005 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 and restated quarterly results of operations for 2005 and 2004. As a result of the restatement of the Series B warrants as a liability beginning in the period ending December 31, 2004, the periodic change in fair value of the Series B warrant is now recorded on a quarterly basis. The Quarterly Financial Results presented below differ from the company's previously released quarterly results in that they have been restated to include the gain or (loss) resulting from the change in fair value of the Series B warrants. This gain or (loss) is included in the line item labeled "Change in valuation of Series B warrants" which appears in the quarterly statement of operations below. (See Note 2).

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 and Restated)			
	March 31, 2005	June 30, 2005	Sept 30, 2005	Dec 31, 2005
	(in thousands, except per share data)			
<b>Statement of Operations Data:</b>				
Revenue .....	\$1,010	\$1,183	\$ 917	\$ 1,089
Cost of goods sold .....	480	546	489	465
Gross profit .....	530	637	428	624
Costs and expenses:				
Research and development .....	213	176	144	166
Selling, general and administrative .....	1,254	1,239	941	1,074
Total costs and expenses .....	1,467	1,415	1,085	1,240
Loss from operations .....	(937)	(778)	(657)	(616)
Interest income .....	41	46	51	53
Interest expense .....	(1)	—	(3)	—
Change in valuation of Series B warrants .....	1,047	321	184	(1,387)
Net loss .....	\$ 150	\$ (411)	\$ (425)	\$ (1,950)
Beneficial conversion feature .....	—	—	—	—
Net loss attributable to common stockholders .....	\$ 150	\$ (411)	\$ (425)	\$ (1,950)
Net loss per common share—basic and diluted .....	\$ 0.00	\$ (0.01)	\$ (0.01)	\$ (0.05)

	Three Months Ended (Unaudited and Restated)			
	March 31, 2004	June 30, 2004	Sept 30, 2004	Dec 31, 2004
	(in thousands, except per share data)			
<b>Statement of Operations Data:</b>				
Revenue .....	\$ 1,266	\$ 1,168	\$ 1,279	\$ 1,395
Cost of goods sold .....	<u>565</u>	<u>586</u>	<u>583</u>	<u>608</u>
Gross profit .....	701	582	696	787
Costs and expenses:				
Research and development .....	163	172	203	236
Selling, general and administrative .....	<u>1,560</u>	<u>1,615</u>	<u>1,311</u>	<u>1,266</u>
Total costs and expenses .....	<u>1,723</u>	<u>1,787</u>	<u>1,514</u>	<u>1,502</u>
Loss from operations .....	(1,022)	(1,205)	(818)	(715)
Interest income .....	7	8	15	28
Interest expense .....	—	—	—	(1)
Change in valuation of Series B warrants .....	—	—	—	(44)
Net loss .....	<u>\$(1,015)</u>	<u>\$(1,197)</u>	<u>\$ (803)</u>	<u>\$ (732)</u>
Beneficial conversion feature .....	—	—	—	(2,537)
Net loss attributable to common stockholders .....	<u>\$(1,015)</u>	<u>\$(1,197)</u>	<u>\$ (803)</u>	<u>\$(3,269)</u>
Net loss per common share—basic and diluted .....	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.03)</u>	<u>\$ (0.10)</u>

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2005	June 30, 2005	Sept 30, 2005	Dec 31, 2005
<b>Statement of Operations Data:</b>				
Revenue .....	100%	100%	100%	100%
Cost of goods sold .....	<u>48%</u>	<u>46%</u>	<u>53%</u>	<u>43%</u>
Gross profit .....	52%	54%	47%	57%
Costs and expenses:				
Research and development .....	21%	15%	16%	15%
Selling, general and administrative .....	<u>124%</u>	<u>105%</u>	<u>103%</u>	<u>99%</u>
Total costs and expenses .....	<u>145%</u>	<u>120%</u>	<u>118%</u>	<u>114%</u>
Loss from operations .....	-93%	-66%	-72%	-57%
Interest income .....	4%	4%	6%	5%
Interest expense .....	0%	0%	0%	0%
Change in valuation of Series B warrants .....	104%	<u>27%</u>	<u>20%</u>	<u>-127%</u>
Net loss .....	15%	-35%	-46%	-179%
Beneficial conversion feature .....	0%	0%	0%	0%
Net loss attributable to common stockholders .....	<u>15%</u>	<u>-35%</u>	<u>-46%</u>	<u>-179%</u>

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2004	June 30, 2004	Sept 30, 2004	Dec 31, 2004
<b>Statement of Operations Data:</b>				
Revenue .....	100%	100%	100%	100%
Cost of goods sold .....	45%	50%	46%	44%
Gross profit .....	55%	50%	54%	56%
Costs and expenses:				
Research and development .....	13%	15%	16%	16%
Selling, general and administrative .....	123%	138%	103%	91%
Total costs and expenses .....	136%	153%	118%	107%
Loss from operations .....	-81%	-103%	-64%	-51%
Interest income .....	1%	1%	1%	2%
Interest expense .....	0%	0%	0%	0%
Change in valuation of Series B warrants .....	0%	0%	0%	-3%
Net loss .....	-80%	-102%	-63%	-52%
Beneficial conversion feature .....	0%	0%	0%	-182%
Net loss attributable to common stockholders .....	-80%	-102%	-63%	-234%

### Liquidity and Capital Resources

Cash, cash equivalents and marketable securities were \$5,297,834 at December 31, 2005 compared to \$7,646,963 at December 31, 2004, a decrease of \$2,349,129. This net decrease is primarily attributable to our use of cash in support of operations of \$2,474,860 in 2005. Accounts receivable, net of the allowance for doubtful accounts, at December 31, 2005 increased \$36,192 or 4%. Inventory at the 2005 year end decreased \$71,338 or 15% primarily due to lower revenue levels.

Our financial statements have been prepared on a "going concern basis," which assumes we will realize our assets and discharge our liabilities in the normal course of business. We have experienced recurring losses from operations of \$3,394,627, \$3,759,830 and \$2,987,663 for the years ended December 31, 2003, 2004 and 2005, respectively, and recurring negative cash flow from operations of \$2,537,077, \$3,082,833 and \$2,474,860 for the years ended December 31, 2003, 2004 and 2005, respectively. In addition, we have an accumulated deficit at December 31, 2005 of \$58,795,174. We anticipate that our existing cash resources will be sufficient to satisfy our cash requirements for at least the next twelve months. If in the future, we are unable to generate sufficient revenue to sustain operations, we would need to seek additional sources of financing. There is no certainty that such efforts would be successful.

From January 1, 2006 to March 30, 2006, we have received \$4,087,032 in gross proceeds from the exercise of outstanding warrants to purchase shares of Series A and B stock, and outstanding warrants and options to purchase shares of our common stock.

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 \$20,000 of such minimum license maintenance fees subsequent to December 31, 2005.

## Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2005 are included in the table below.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
<b>Contractual Obligations</b>					
Capital Lease Obligations .....	\$ 1,578	\$ 1,578	\$ —	\$ —	\$—
Operating Lease Obligations .....	\$151,168	\$142,676	\$ 6,176	\$2,316	\$—
Purchase Obligations .....	\$ 20,000	\$ 10,000	\$10,000	\$ —	\$—
Total .....	\$172,746	\$154,254	\$16,176	\$2,316	\$—

## 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

FASB Statement No. 123 (Revised 2004), Share-Based Payment (SFAS 123R) was issued in December, 2004. SFAS 123R replaces SFAS 123, Accounting for Stock-Based Compensation (SFAS 123), and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123R requires that we recognize the compensation cost related to share-based payment transactions with employees in our financial statements beginning with the first interim reporting period that begins after June 15, 2005 (the effective date). The compensation cost will be measured based upon the fair value of the instrument issued. Share-based compensation transactions with employees covered within SFAS 123R include share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans.

SFAS 123 included a fair-value-based method of accounting for share-based payment transactions with employees, but allowed us to continue to apply the guidance in APB 25 provided that we disclose in the footnotes to our financial statements the pro forma net income if the fair-value-based method been applied. We currently report share-based payment transactions with employees in accordance with APB 25 and provide the required disclosures (see Note 2 to the financial statements included in this annual report). Beginning with the first interim reporting period beginning after the effective date, we will be adopting the modified prospective application of SFAS 123R. The modified prospective application transition method requires the application of this standard to all new awards issued after the effective date, all modifications, repurchased or cancellations of existing awards after the effective date, and unvested awards at the effective date.

For unvested awards, the compensation cost related to the remaining "requisite service" that has not been rendered at the effective date will be determined by the compensation cost calculated currently for pro forma disclosures under SFAS 123. Based on the current options outstanding, we anticipate the adoption of this statement to result in approximately \$319,000 of compensation cost to be recognized in the year of adoption.

On October 20, 2005, the Board of Directors approved the acceleration of vesting of all unvested, non-qualified stock options. The closing price of our common stock on October 24, 2005 was \$1.30. The terms and conditions applicable to such options, including the exercise prices, remain the same. We will use 230,008 unvested shares of our common stock with a weighted average exercise price of \$1.30, ranging from \$0.45 to \$1.30, which would otherwise have vested over the next

38 months, became fully vested. None of the options for which vesting was accelerated were held by the Company's executive officers or directors. The Board of Directors determined to accelerate the vesting of these options to reduce future compensation expense that would otherwise be required to be recorded in the statements of operations of the Company in periods following the effectiveness of SFAS 123R.

FASB Statement No. 153, *Exchanges of Nonmonetary Assets—An Amendment of APB Opinion No. 29* (SFAS 153) was issued on December 16, 2004. APB Opinion No. 29, *Accounting for Nonmonetary Transactions* (APB 29) required that nonmonetary exchanges be accounted for at fair value, subject to certain exceptions. SFAS 153 has removed the exception for nonmonetary exchanges of similar productive assets, and replaced it with an exception for exchanges that lack commercial substance. The provisions of SFAS 153 are effective prospectively for all nonmonetary asset exchanges in fiscal periods beginning after June 15, 2004. We do not anticipate that this pronouncement will have any impact on our reported results.

Emerging issues Task Force 03-06, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share*, was issued in March 2004. EITF 03-06 is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on our financial position, results of operations or cash flows as we incurred a net loss for 2003, 2004 and 2005. This pronouncement will have an impact if and when we incur net income and at that time we will evaluate whether our existing securities meet the definition of a "participating security" under the provisions of EITF 03-06.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154), a replacement for APB Opinion No. 20, *Accounting Changes* (APB 20), and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. This statement changes the requirements for the accounting for and reporting of a change in accounting principle. It applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement requires voluntary changes in accounting principles be recognized retrospectively to financial statements for prior periods, rather than recognition in the net income of the current period. Retrospective application requires restatements of prior period financial statements as if that accounting principle had always been used. This statement carries forward without change the guidance contained in APB 20 for reporting the correction of an error in previously issued financial statements and a change in accounting estimate. We are required to adopt the provisions of SFAS 154 for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005. At this time, we do not believe the adoption of this standard will have a material impact on our results of operations.

In November 2005, the FSAB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4* (SFAS 151). SFAS 151, a product of the FASB's efforts to achieve short-term convergence with the International Accounting Standards Board (IASB), clarifies that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. The guidance is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after November 23, 2005. The Company does not believe the adoption of this standard will have a material impact on results of operations.

#### **Factors Which May Affect Future Results**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning 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*

*"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 ability to execute our business plan and achieve meaningful revenues will be limited.**

We believe that our ability to succeed in the future 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 due to competitive pressures or a decline in the availability of reimbursement, would reduce our revenues and further limit our ability to succeed. 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 perceived to be superior to our technology.

**We have never been able to fund our operations from cash generated by sales of our products, and if we cannot meet our capital requirements through the sale of debt or equity securities on terms favorable to us, we may not be able to continue as a going concern.**

We have incurred substantial operating losses through December 31, 2005 and may never generate substantial revenues or achieve profitability on a quarterly or annual basis. We have financed our operating losses through the public and private sale of shares of our common stock and preferred stock. We do not expect to generate sufficient cash from our business to fund our operations for the foreseeable future, so that if we cannot obtain additional capital through equity or debt financings we will likely be unable to continue as a going concern. This would 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 may not be available in the amount we need or 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.

**Our sale of additional shares of common stock or any other securities exchangeable for shares of common stock may dilute the book value of our common stock.**

Our authorized capital includes 150,000,000 shares of common stock, of which 51,717,982 shares were issued and outstanding as of December 31, 2005 (assuming the conversion of all shares of preferred stock outstanding on such date). Our board of directors has the authority, without further action or vote of our stockholders, 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. 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.

At December 31, 2005, 45,248 shares of our Series A stock were outstanding, which are currently convertible into 588,224 shares of our common stock. At December 31, 2005, investors held warrants to acquire an additional 403,830 shares of our Series A stock, which are currently convertible into 5,249,790 shares of our common stock. At December 31, 2005, 2,173 shares of our Series B stock were outstanding, which are currently convertible into 4,828,889 shares of our common stock. At December 31, 2005, investors held warrants to acquire an additional 2,375 shares of our Series B stock, which are currently convertible into 5,277,778 shares of our common stock. In addition, common stock warrants were given to the placement agent to acquire an additional 953,333 shares of our common stock.

You will incur additional dilution of net tangible book value if the holders of our preferred stock convert their shares of preferred stock into shares of our common stock. As of December 31, 2005, investors had exercised their rights to convert 1,455,343 shares of Series A stock into 18,919,459 shares of our common stock and 2,952 shares of Series B stock into 6,559,999 shares of our common stock. From January 1, 2006 to March 30, 2006, investors exercised their rights to convert 45,248 shares of Series A stock into 588,224 shares of our common stock and 2,143 shares of Series B stock into 4,762,222 shares of common stock. Additionally, during this period, investors exercised warrants to purchase 149,310 Series A stock, which they converted into 1,941,030 shares of our common stock, and they exercised warrants to purchase 2,360 Series B shares, which they converted into 5,244,444 shares of our common stock. We received gross proceeds of \$3,327,189 from the exercise of the Series A and B warrants subsequent to December 31, 2005.

**Our quarterly revenues, operating results and profitability will vary from quarter to quarter, which may result in volatility in our stock price.**

Our quarterly revenues and operating results have varied in the past and are likely to continue to vary significantly from quarter to quarter. This may lead to volatility in our stock price. These fluctuations are due to several factors relating to the sale of our products, including:

- the timing, of our sales transactions;
- unpredictable sales cycles;
- the timing of introduction and market acceptance of new products or product enhancements by us or our competitors;
- changes in our operating expenses;
- product quality problems; and
- personnel changes and fluctuations in economic and financial market conditions.

We believe that period-to-period comparisons of our results of operations are not necessarily meaningful. There can be no assurance that future revenues and results of operations will not vary substantially. It is also possible that in future quarters our results of operations will be below the expectations of investors, analysts or our announced guidance, if any. In any such case, the price of our common stock could be materially adversely affected.

**Financial investors may have interests different than you or our management, 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 December 2004 financing, we issued securities which are currently convertible into approximately 44.3% of the total number of shares of our common stock (on an as-converted basis) that were outstanding immediately prior to such issuance. Under certain circumstances, these securities may become convertible into an even greater number of shares of common stock. In future financings we may also issue securities that 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 our long-term goals and the long-term goals of our other stockholders. In addition, based on the significant ownership of our outstanding common stock, financial investors may be able to affect corporate actions requiring stockholder approval.

**We will likely need additional financing for our future capital needs and may not be able to raise additional funds on terms acceptable to us, if 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 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 sooner if:

- we decide to accelerate our research and development efforts;
- we decide to expand our marketing and sales capabilities 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 could suffer dilution.

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

We are continuing to participate in clinical studies relating to our Microvolt T-Wave Alternans technology and Micro-V Alternans Sensors in order to more firmly establish the predictive value of such technologies. 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 cardiac death is excellent in certain patient populations, we do not know whether the results of such studies on other patient populations 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 technologies, 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 cannot 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 2005, 22% of our revenue came from the sale of product to international distributors.

**We face substantial competition in the market for cardiac diagnostic devices from substantially larger and better financed competition, which may result in others discovering, developing or commercializing competing products 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 technologies, as well as 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 United States. Many of our current as well as 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 also enjoy 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 sub-assemblies exposes us to several risks, including:

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

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 sub-assemblies in a timely manner. Further, a significant increase in the price of one or more key components or sub-assemblies 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 both obtain and maintain adequate levels of third-party reimbursement for our products, it would have a material adverse affect on our business.**

Our revenues are primarily derived from sales of our Heartwave II Systems and Micro-V Alternans Sensors. Our ability to successfully commercialize these products depends on our first obtaining, and then maintaining, adequate levels of third-party reimbursement for use of these products by our customers. The amount of reimbursement in the U.S. that is available for clinical use of the Microvolt T-Wave Alternans Test varies. In the U.S., 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 will seek to 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, investigations unnecessary or inappropriate. 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 II System. Difficulties in obtaining reimbursement, or the inadequacy of the reimbursement obtained, for Microvolt T-Wave Alternans Tests using the Heartwave II System 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 entail the inherent risk of liability claims or product recalls. Although we maintain product liability insurance in the U.S. 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 our Heartwave II Systems, cause a significant financial burden on Cambridge Heart, or both, which in either case could have a material adverse effect on our business, financial condition and ability to market both systems as currently contemplated.

**Our ability to build a successful business depends on our ability to first obtain, and then maintain, patent protection for our products and technologies.**

Our success will depend, in large part, on our ability to obtain patent protection for our products both in the U.S. and in other countries and then enforce these patents. 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 technologies. 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 technologies, 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 technologies, or disclose such technology or that we can ultimately protect meaningful rights to such unpatented proprietary technologies.

**Any claim by others that we infringe their intellectual property rights, whether intentionally or otherwise, could materially and adversely affect our business.**

Our success will depend, in part, on our ability to avoid infringing the intellectual property rights of others and/or breaching the licenses upon which our products and technologies 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 non-exclusive in nature or could terminate, either of which would adversely affect our business.

**Any future litigation over intellectual property rights would likely involve significant expense on our part as well as distract our management from day-to-day business operations.**

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 to determine the priority of inventions, which could result in substantial cost.

#### **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 used 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. We invest our cash primarily in money market mutual funds and U.S. government and other investment grade debt securities. We evaluate these investments quarterly to determine the fair value of the portfolio. Our investment portfolio includes only marketable securities with active secondary or resale markets to help assure liquidity. 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, 2005 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**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Cambridge Heart, Inc. as of December 31, 2004 and 2005, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cambridge Heart, Inc. as of December 31, 2004 and 2005, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

/s/ Vitale, Caturano & Company, Ltd.

VITALE, CATURANO & COMPANY, LTD.

Boston, Massachusetts  
March 30, 2006

## **Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the results of operations and cash flows of Cambridge Heart, Inc. for the year 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 audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 25, 2004

**CAMBRIDGE HEART, INC.**

**BALANCE SHEET**

	December 31,	
	2004	2005
	(As Restated)	
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents .....	\$ 2,896,963	\$ 547,834
Marketable securities .....	4,750,000	4,750,000
Accounts receivable, net of allowance for doubtful accounts of \$102,500 and \$140,250 at December 31, 2004 and 2005, respectively .....	982,796	1,018,988
Inventory .....	491,276	419,938
Prepaid expenses and other current assets .....	154,272	79,843
<b>Total current assets</b> .....	<b>\$ 9,275,307</b>	<b>\$ 6,816,603</b>
Fixed assets, net .....	207,761	85,771
Other assets .....	166,539	112,182
<b>Total Assets</b> .....	<b>\$ 9,649,607</b>	<b>\$ 7,014,556</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable .....	\$ 345,876	\$ 245,249
Accrued expenses .....	643,431	528,936
Current portion of capital lease obligation .....	2,103	1,577
Series B warrant liability .....	1,746,919	1,503,646
<b>Total current liabilities</b> .....	<b>2,738,329</b>	<b>2,279,408</b>
Capital lease obligation, net of current portion .....	1,578	—
<b>Total liabilities</b> .....	<b>2,739,907</b>	<b>2,279,408</b>
<b>Commitments and contingencies (Note 13)</b>		
Convertible Preferred Stock, \$.001 par value; 2,000,000 shares authorized at December 31, 2004 and 2005, respectively; 389,612 and 47,421 shares issued and outstanding at December 31, 2004 and 2005, respectively. Liquidation preference and redemption value of \$6,699,985 and \$2,372,996 as of December 31, 2004 and 2005, respectively .....	3,635,494	1,504,287
Warrants to acquire Series A Convertible Preferred Stock of 471,703 and 403,955 shares issued and outstanding at December 31, 2004 and 2005, respectively ...	889,545	743,440
	<b>4,525,039</b>	<b>2,247,727</b>
<b>Stockholders' equity:</b>		
Common Stock, \$.001 par value; 150,000,000 shares authorized; 34,730,964 and 46,300,869 shares issued and outstanding at December 31, 2004 and 2005, respectively .....	34,731	46,301
Additional paid-in capital .....	58,566,847	61,259,587
Accumulated deficit .....	(56,158,688)	(58,795,174)
Deferred compensation .....	(58,229)	(23,293)
<b>Total stockholders' equity</b> .....	<b>2,384,661</b>	<b>2,487,421</b>
<b>Total Liabilities and Stockholders' Equity</b> .....	<b>\$ 9,649,607</b>	<b>\$ 7,014,556</b>

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

**CAMBRIDGE HEART, INC.**  
**STATEMENT OF OPERATIONS**

	Year Ended December 31,		
	2003	2004 (As restated)	2005
Revenue .....	\$ 6,944,911	\$ 5,107,751	\$ 4,198,871
Cost of goods sold .....	3,202,490	2,341,421	1,980,193
Gross profit .....	3,742,421	2,766,330	2,218,678
Costs and expenses:			
Research and development .....	944,325	774,285	698,862
Selling, general and administrative .....	6,192,723	5,751,875	4,507,479
Loss from operations .....	(3,394,627)	(3,759,830)	(2,987,663)
Interest income .....	20,297	57,776	190,962
Interest expense .....	(13,300)	(799)	(3,919)
Change in valuation of Series B warrants .....	—	(43,911)	164,134
Net loss .....	\$ (3,387,630)	\$ (3,746,764)	\$ (2,636,486)
Beneficial conversion feature (Note 8) .....	(1,533,280)	(2,537,487)	—
Net loss attributable to common stockholders .....	\$ (4,920,910)	\$ (6,284,251)	\$ (2,636,486)
Net loss per common share-basic and diluted .....	\$ (0.25)	\$ (0.21)	\$ (0.07)
Weighted average common shares outstanding-basic and diluted ...	19,663,460	29,622,673	39,914,615

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

**CAMBRIDGE HEART, INC.**

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

	Common stock, \$.001 par value		Additional paid-in Capital	Accumulated deficit	Deferred compensation	Total stockholders' equity
	Number of Shares	Par Value				
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 stock	1,029,366	\$ 1,029	\$ 204,420			\$ 205,449
Issuance of common stock through the 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
Conversion of Series A preferred stock to common stock	13,087,814	\$13,088	\$ 4,097,308			\$ 4,110,396
Issuance of warrants to non-employees			\$ 457,409			\$ 457,409
Issuance of common stock through the exercise of stock options, warrants and employee stock purchase plan	358,368	\$ 358	\$ 77,775			\$ 78,133
Compensation related to non-employee stock options granted			\$ 24,204			\$ 24,204
Issuance of restricted stock	105,875	\$ 106	\$ 139,240		\$ (49,340)	\$ 90,006
Amortization of deferred compensation					\$ 84,278	\$ 84,278
Net loss (as restated)				\$ (3,746,764)		\$(3,746,764)
Balance at December 31, 2004 (as restated)	34,730,964	\$34,731	\$58,566,847	\$(56,158,688)	\$ (58,229)	\$ 2,384,661
Conversion of Series A preferred stock to common stock	4,802,278	\$ 4,803	\$ 991,018			\$ 995,821
Conversion of Series B preferred stock to common stock	6,559,999	\$ 6,560	\$ 1,434,201			\$ 1,440,761
Issuance of common stock through the exercise of stock options, warrants and employee stock purchase plan	160,528	\$ 160	\$ 45,394			\$ 45,554
Compensation related to non-employee stock options granted			\$ 29,730			\$ 29,730
Compensation related to option exchange agreement			\$ 165,597			\$ 165,597
Issuance of restricted stock	47,100	\$ 47	\$ 26,800		\$ (26,800)	\$ 47
Amortization of deferred compensation					\$ 61,736	\$ 61,736
Net loss				\$ (2,636,486)		\$(2,636,486)
Balance at December 31, 2005	46,300,869	\$46,301	\$61,259,587	\$(58,795,174)	\$ (23,293)	\$ 2,487,421

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

**CAMBRIDGE HEART, INC.**  
**STATEMENT OF CASH FLOWS**

	Year ended December 31,		
	2003	2004 (restated)	2005
Cash flows from operating activities:			
Net loss .....	\$(3,387,630)	\$(3,746,764)	\$(2,636,486)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization .....	505,012	315,490	171,530
Loss on disposal of fixed assets .....	—	—	4,817
Stock based compensation expense .....	350,834	111,477	269,043
Provisions for allowance for bad debts .....	55,000	2,500	37,750
Change in valuation of Series B warrants .....	—	43,911	(164,134)
Changes in operating assets and liabilities:			
Accounts receivable .....	(654,133)	777,589	(73,942)
Inventory .....	198,078	(21,464)	71,338
Prepaid expenses and other current assets .....	90,713	8,949	74,429
Other assets .....	4,838	(34,829)	—
Accounts payable and accrued expenses .....	300,211	(539,692)	(229,206)
Net cash used for operating activities .....	<u>(2,537,077)</u>	<u>(3,082,833)</u>	<u>(2,474,861)</u>
Cash flows from investing activities:			
Purchases of fixed assets .....	(12,913)	(140,576)	—
Capitalization of software development costs .....	(1,600)	—	—
Purchases of marketable securities .....	—	(4,750,000)	—
Proceeds from the maturity of marketable securities .....	2,001,231	—	—
Net cash provided (used in) by investing activities .....	<u>1,986,718</u>	<u>(4,890,576)</u>	<u>—</u>
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs of \$759,505 and \$0 in 2004 and 2005, respectively .....	5,826,648	5,182,889	80,131
Proceeds from issuance of common stock .....	43,603	78,239	45,601
Payment on bank credit line .....	(802,829)	—	—
Net cash provided by financing activities .....	<u>5,067,422</u>	<u>5,261,128</u>	<u>125,732</u>
Net increase (decrease) in cash and cash equivalents .....	4,517,063	(2,712,281)	(2,349,129)
Cash and cash equivalents, beginning of year .....	1,092,181	5,609,244	2,896,963
Cash and cash equivalents, end of year .....	<u>\$ 5,609,244</u>	<u>\$ 2,896,963</u>	<u>\$ 547,834</u>

**Supplemental Disclosure of Cash Flow Information**

During 2003, 2004 and 2005, the Company paid \$13,300, \$799 and \$3,919, respectively, in interest expense.

**Supplemental Disclosure of Non-Cash Financing Activities**

During 2004 and 2005, investors exercised their rights to convert 1,006,755 and 369,406 shares of Series A Convertible Preferred Stock into 13,087,814 and 4,802,278 shares of the Company's common stock, respectively, at a conversion price of \$0.34 per share. During the quarter ended March 31, 2005, Medtronic executed a cashless exercise of their warrant for 67,873 shares of Series A stock.

During 2005, investors exercised their rights to convert 2,952 of Series B Convertible Preferred Stock into 6,559,999 shares of the Company's common stock, respectively, at a conversion price of \$0.45 per share. During 2004, the Company issued a warrant for the purchase of 953,333 shares of its common stock to the agent in connection with the sale of the Series B stock. The warrant was valued using the Black Scholes model at \$457,409 and is recorded as a non-cash issuance cost.

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

**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 \$3,394,627, \$3,759,830 and \$2,987,663 for the fiscal years ended December 31, 2003, 2004 and 2005, respectively, and recurring negative cash flow from operations of \$2,537,077, \$3,082,833 and \$2,474,861 for the fiscal years ended December 31, 2003, 2004 and 2005, respectively. In addition, the Company had an accumulated deficit of \$58,795,174 at December 31, 2005. The Company anticipates that it has sufficient cash resources to satisfy its cash requirements through at least December 31, 2006.

**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 a remaining maturity of three months or less to be cash equivalents. Marketable securities consist of cash invested in municipal bonds with a triple "A" credit rating. In accordance with Statement of Financial Accounting Standards (SFAS) 115, "Accounting for Certain Investments in Debt and Equity Securities," these investments have been classified as available-for-sale securities and have been reported at fair value, with unrealized gains and losses, if any, excluded from earnings and reported as a separate component of shareholders' equity. These securities 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. These securities amount to \$4,750,000 and \$4,750,000 at December 31, 2004 and 2005, respectively, and no realized or unrealized gains or losses have been recognized during the periods presented. 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 \$2,727,591 and \$486,284 at December 31, 2004 and 2005, respectively, are classified as cash equivalents. The Company maintains its cash and cash equivalents in bank deposit accounts, which may, at times, exceed Federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

***Revenue Recognition and Accounts Receivable***

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") "Accounting for Revenue Arrangements with Multiple Deliverables" 00-21 in multiple element arrangements, separate elements can be considered separate unit of

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

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 is recognized separately based on amounts charged when sold on a stand alone basis and is recorded over the term of the underlying agreement. Payments of \$71,518 at December 31, 2005 (\$162,575 at December 31, 2004) received in advance of services being performed is recorded as deferred revenue and included in current liabilities in the accompanying balance sheet.

Accounts receivable are stated at the amount management expects to collect from outstanding balances. An allowance for doubtful accounts is provided for those accounts receivable considered to be uncollectible based upon historical experience and management's evaluation of outstanding accounts receivable at the end of the year. Bad debts are written off when identified. The Company's actual experience of customer receivables written off directly during fiscal 2005 was \$2,556 (\$14,900 during fiscal 2004). The Company provided \$37,750, \$2,500 and \$55,000 for allowance for doubtful accounts during the years ended December 31, 2005, 2004 and 2003, respectively. At December 31, 2005 and 2004 the allowance for doubtful accounts was \$140,250 and \$102,500, respectively.

***Stock-Based Compensation***

SFAS No. 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 market 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, 2004 and 2005, the Company had four stock-based compensation plans. The Company accounts for employee awards under those plans using the intrinsic value method 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 as amended by SFAS 148—"Accounting for Stock-Based Compensation—Transition and Disclosure" 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 market values, consistent with the method required under the recognition provisions of SFAS 148, the Company's net loss and net loss per share would have been reduced to the pro forma amounts indicated below:

	<u>Year ended December 31,</u>		
	<u>2003</u>	<u>2004</u>	<u>2005</u>
Net loss attributable to common stockholders:			
As reported .....	\$4,920,910	\$6,284,251	\$2,636,486
Stock-based compensation (expense) included in reported net loss .....	(350,834)	(111,477)	(269,042)
Total stock-based compensation under the fair-value-based method for all awards .....	<u>825,681</u>	<u>540,579</u>	<u>418,191</u>
Pro forma .....	<u>\$5,395,757</u>	<u>\$6,713,353</u>	<u>\$2,785,635</u>
Net loss per share:			
As reported-basic and diluted .....	\$ 0.25	\$ 0.21	\$ 0.07
Pro forma-basic and diluted .....	\$ 0.27	\$ 0.23	\$ 0.07

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 2003, 2004 and 2005, respectively: (i) dividend yield of 0% for all periods; (ii) expected volatility of 50% for 2003, 118% for 2004,

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

and 115% for 2005; (iii) risk free interest rates of 2.43%, 3.78% and 4.13%; and (iv) expected option terms of 4 years for all periods.

On August 15, 2005, four Company officers entered into option exchange agreements with the Company whereby an aggregate of 2,686,750 options, issued at varying times and varying prices, were cancelled and replaced with an aggregate 2,975,000 options with exercise prices of \$0.29, the last reported price that day. In the fourth quarter of 2005, the Company recorded a compensation expense of \$131,161 relating to the option exchange.

On September 19, 2005, five members of the Board of Directors entered into individual option exchange agreements with the Company whereby an aggregate of 805,000 options, issued at varying times with varying prices, were cancelled and replaced with an aggregate of 805,000 options with exercise prices of \$0.30, the last reported price that day. In the fourth quarter of 2005, the Company recorded a compensation expense of \$34,436 relating to the option exchange.

On October 24, 2005, the Company's Board of Directors approved the acceleration of vesting of all unvested out-of-the-money employee stock options. As a result, options to purchase 230,008 unvested shares of the Company's common stock with a weighted average exercise price of \$0.73 and exercise prices ranging from \$0.45 to \$1.30, which would otherwise have vested over the next 38 months, became fully vested. The Company took this action in order to reduce future compensation expense that would otherwise be required to be recorded in the statements of operations in period following the effectiveness of the Financial Accounting Standards Board's new standard, Statement of Financial Accounting Standard No. 123R, "Share-Based Payment" which requires companies to recognize stock-based compensation expense associated with stock options based on the fair value method.

#### *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. The Company evaluates its estimates on an on-going basis, including those related to incentive compensation, revenue recognition, product returns, allowance for doubtful accounts, inventory valuation, investments valuation, intangible assets, income taxes, warranty obligations, the fair value of preferred stock and warrants, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which then 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 SFAS 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 dilutive common stock outstanding during the period. The impact of options to purchase 5,049,518, 5,267,625 and 5,507,625 shares of common stock, warrants for the purchase of 1,319,695, 2,102,532 and 1,622,532 shares of common stock, warrants for the purchase of 548,515, 471,703 and 403,830 shares of Series A Convertible Preferred Stock, warrants for the purchase of 0, 2,500 and 2,375 shares of Series B Convertible Preferred Stock, 1,281,642, 384,612 and 45,248 shares of Series A Convertible Preferred Stock and 0, 5,000 and 2,173 shares of Series B Convertible Preferred Stock have been excluded from the calculation of diluted weighted average share amounts as their inclusion would have been anti-dilutive for 2003, 2004 and 2005, respectively.

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

Emerging issues Task Force 03-06, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share*, was issued in March 2004. EITF 03-06 is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on our financial position, results of operations or cash flows as the Company incurred a net loss for 2003, 2004 and 2005. This pronouncement will have an impact if and when the Company incurs net income and at that time we will evaluate whether our existing securities meet the definition of a "participating security" under the provisions of EITF 03-06.

#### ***Comprehensive Income***

Comprehensive income is comprised of two components, net income and other comprehensive income. For the years ended December 31, 2003, 2004 and 2005, the Company had no other comprehensive income.

#### ***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, 2004 and 2005.

#### ***Inventories***

Inventories are stated at the lower of cost or market. Cost is computed using standard cost, which include allocations of labor and overhead. Standard cost 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 Reporting***

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.

#### ***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.

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(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, 2004 and 2005, which are included in other assets in the accompanying balance sheet, were \$1,482,728 and \$1,482,728, net of accumulated amortization of \$1,444,043 and \$1,477,267, respectively.

#### *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, 2005 was \$98,164 compared to \$119,297 at December 31, 2004, which is included in other assets in the accompanying balance sheet.

#### *New Accounting Pronouncements*

FASB Statement No. 123 (Revised 2004), Share-Based Payment (SFAS 123R) was issued in December, 2004. SFAS 123R replaces SFAS 123, Accounting for Stock-Based Compensation (SFAS 123), and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123R requires that the Company recognize the compensation cost related to share-based payment transactions with employees in financial statements beginning with the first interim reporting period that begins after June 15, 2005 (the effective date). The compensation cost will be measured based upon the fair value of the instrument issued. Share-based compensation transactions with employees covered within SFAS 123R include share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans.

SFAS 123 included a fair-value-based method of accounting for share-based payment transactions with employees, but allowed the Company to continue to apply the guidance in APB 25 provided that it discloses in the footnotes to our financial statements the pro forma net income if the fair-value-based method been applied. The Company currently reports share-based payment transactions with employees in accordance with APB 25 and provide the required disclosures (see Note 2 to the financial statements included in this annual report). Beginning with the first interim reporting period beginning after the effective date, the Company will be adopting the modified prospective application of SFAS 123R. The modified prospective application transition method requires the application of this standard to all new awards issued after the effective date, all modifications, repurchased or cancellations of existing awards after the effective date, and unvested awards at the effective date.

For unvested awards, the compensation cost related to the remaining "requisite service" that has not been rendered at the effective date will be determined by the compensation cost calculated currently for pro forma disclosures under SFAS 123. Based on the current options outstanding, we anticipate the adoption of this statement to result in approximately \$319,000 of compensation cost to be recognized in the year of adoption.

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

FASB Statement No. 153, *Exchanges of Nonmonetary Assets—An Amendment of APB Opinion No. 29* (SFAS 153) was issued on December 16, 2004. APB Opinion No. 29, *Accounting for Nonmonetary Transactions* (APB 29) required that nonmonetary exchanges be accounted for at fair value, subject to certain exceptions. SFAS 153 has removed the exception for nonmonetary exchanges of similar productive assets, and replaced it with an exception for exchanges that lack commercial substance. The provisions of SFAS 153 are effective prospectively for all nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not anticipate that this pronouncement will have any impact on our reported results.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154), a replacement for APB Opinion No. 20, *Accounting Changes* (APB 20), and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. This statement changes the requirements for the accounting for and reporting of a change in accounting principle. It applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement requires voluntary changes in accounting principles be recognized retrospectively to financial statements for prior periods, rather than recognition in the net income of the current period. Retrospective application requires restatements of prior period financial statements as if that accounting principle had always been used. This statement carries forward without change the guidance contained in APB 20 for reporting the correction of an error in previously issued financial statements and a change in accounting estimate. We are required to adopt the provisions of SFAS 154 for accounting changes and corrections of errors made in fiscal years beginning after December 31, 2005. At this time, we do not believe the adoption of this standard will have a material impact on our results of operations.

In November 2005, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4* (SFAS 151). SFAS 151, a product of the FASB's efforts to achieve short-term convergence with the International Accounting Standards Board (IASB), clarifies that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. The guidance is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after November 23, 2005. The Company does not believe the adoption of this standard will have a material impact on results of operations.

#### **Reclassifications**

Certain prior year's amounts have been reclassified to conform to the 2005 presentation.

#### **Summary of Restatement of Financial Statements to Reflect Derivative Accounting**

In March 2006, in accordance with EITF 00-19, the Company concluded that it was necessary to restate its financial results for the year ended December 31, 2004 to reflect the fair value of the outstanding to purchase shares of Series B Convertible Preferred Stock warrants as a derivative liability on the balance sheet and to record the unrealized changes in the values of these warrants in the statement of operations as "Gain (loss) on Series B warrants." The Company had previously classified the Series B warrants as equity. The financial statements for the year ended December 31, 2004 have been restated to reflect the classification of the Series B warrants, originally issued December 6, 2004, as a liability and to reflect additional non-operating gains and losses related to the changes in the fair value of those Series B warrants.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

Our financial statements for the year ended December 31, 2004 have been restated to give effect to the changes described above. The impact of the adjustments related to the classification of the fair value of our Series B warrants, and periodic changes thereto on our statement of operations for the year ended December 31, 2004 is summarized below:

**STATEMENT OF OPERATIONS**  
(in thousands except share and per share data)

	Year Ended December 31, 2004		
	As Previously Reported	Adjustment	As Restated
Gross profit .....	\$ 2,766		\$ 2,766
Costs and expenses:			
Research and development .....	774		774
Selling, general and administrative .....	5,752		5,752
Loss from operations .....	(3,760)	0	(3,760)
Interest income .....	58		58
Interest expense .....	(1)		(1)
Change in valuation of Series B warrants .....	—	(44)(1)	(44)
Net loss .....	\$ (3,703)	\$(44)	\$ (3,747)
Beneficial conversion feature (Note 8) .....	(2,604)	67(2)	(2,538)
Net loss attributable to common stockholders .....	\$ (6,307)	\$ 23	\$ (6,285)
Net loss per common share-basic and diluted .....	\$ (0.21)		\$ (0.21)
Weighted average common shares outstanding-basic and diluted .....	29,622,673		29,622,673

(1) Change due to reduction in fair value of Series B warrant liability not previously recorded.

(2) Change in beneficial conversion feature resulting from the classification of Series B warrants as current liabilities.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

***Balance Sheet Impact of Restatement***

In addition to the effects on our 2004 statement of operations presented above, the restatement impacted our balance sheet as of December 31, 2004. The following table sets forth the effects of the restatement adjustments on our balance sheet as of December 31, 2004:

**BALANCE SHEET**  
(in thousands)

	Year Ended December 31, 2004		
	As Previously Reported	Adjustment	As Restated
<b>Assets:</b>			
Current assets .....	\$ 9,275		\$ 9,275
Fixed assets, net .....	208		208
Other assets .....	167		167
Total Assets .....	\$ 9,650	\$ —	\$ 9,650
<b>Liabilities and Stockholders' Equity</b>			
Other current liabilities .....	991		991
Series B warrant liability .....	—	1,747(1)	1,747
Total current liabilities .....	991	1,747	2,738
Capital lease obligation, net of current portion .....	2	—	2
Total liabilities .....	993	1,747	2,740
Convertible Preferred Stock .....	3,702	(66)(2)	3,636
Warrants to acquire Convertible Preferred Stock .....	2,526	(1,637)(1)	889
	6,228	(1,703)	4,525
Common Stock .....	35		35
Additional paid-in capital .....	58,567		58,567
Accumulated deficit .....	(56,115)	(44)(3)	(56,159)
Less: deferred compensation .....	(58)		(58)
Total stockholders' equity .....	2,429	(44)	2,385
Total Liabilities and Stockholders' Equity .....	\$ 9,650	\$ —	\$ 9,650

- (1) Change due to recording a liability for Series B warrants determined to be derivatives.
- (2) Change in beneficial conversion feature resulting from the classification of Series B warrants as current liabilities.
- (3) Change due to increase in fair value of Series B warrant liability not previously recorded.

**3. Inventory**

Inventories consisted of the following at December 31, 2004 and 2005, respectively:

	December 31,	
	2004	2005
Raw materials .....	\$466,172	\$408,801
Work in process .....	2,777	11,137
Finished goods .....	22,327	—
	\$491,276	\$419,938

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**4. Fixed Assets**

Fixed assets consist of the following:

	Estimated useful lives (years)	December 31,	
		2004	2005
Computer equipment .....	3-5	\$ 704,678	\$ 704,678
Manufacturing equipment .....	5	418,158	418,158
Office furniture .....	7	87,028	87,028
Sales demonstration and clinical equipment .....	3	1,086,857	1,070,469
		<u>2,296,721</u>	<u>2,280,333</u>
Less-accumulated depreciation .....		<u>2,088,960</u>	<u>2,194,562</u>
		<u>\$ 207,761</u>	<u>\$ 85,771</u>

The Company recorded depreciation expense of \$238,382, \$168,689 and \$117,173 for the years ended December 31, 2003, 2004 and 2005, respectively.

**5. Other Assets**

Other assets consist of the following:

	Estimated useful lives (years)	December 31,	
		2004	2005
Capitalized software development costs .....	3	\$1,482,728	\$1,482,728
Patents .....	5	228,548	228,548
Other assets .....		8,557	8,557
		<u>1,719,833</u>	<u>1,719,833</u>
Less-accumulated amortization .....		<u>1,553,294</u>	<u>1,607,651</u>
		<u>\$ 166,539</u>	<u>\$ 112,182</u>

The Company recorded amortization expense of \$266,630, \$146,801 and \$54,357 for the years ended December 31, 2003, 2004 and 2005, respectively.

**6. Accrued Expenses**

Accrued expenses consist of the following:

	December 31,	
	2004	2005
Accrued employee compensation .....	\$168,451	\$169,140
Deferred revenue .....	162,575	71,518
Accrued consulting costs .....	27,995	50,975
Accrued product warranty costs .....	28,235	43,615
Accrued professional fees .....	94,750	122,550
Accrued other .....	161,425	71,138
	<u>\$643,431</u>	<u>\$528,936</u>

For the years ended December 31, 2003, 2004 and 2005, the Company incurred product warranty expenses of \$26,144, \$62,973, and \$32,616, respectively.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**7. Line of Credit**

On October 30, 2003, the Company paid the remaining \$83,462 due under its Loan and Security Agreement with Silicon Valley Bank, which expired on November 9, 2003. The agreement provided a borrowing base of 80% of eligible accounts receivable as defined in the Loan and Security agreement, up to a maximum borrowing of \$1,200,000, payable on demand. 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 sale of Series A Convertible Preferred Stock, 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 Company incurred interest expense of \$13,300 in fiscal 2003. As of December 31, 2005 and 2004, the Company did not have any credit facilities in place.

**8. Convertible Preferred Stock**

The Company's authorized capital stock includes 2,000,000 shares of \$0.001 par value preferred stock. The preferred stock may be issued at the discretion of our Board of Directors (without further 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, liquidation, redemption, conversion, voting or other rights, which may be more expansive than the rights of the holders of the common stock.

Total shares of Convertible Preferred Stock issued and outstanding at December 31, 2004 and 2005, respectively, are as follows:

	December 31,	
	2004	2005
<i>Series A Convertible Preferred</i>		
Shares issued and outstanding .....	384,612	45,248
Liquidation preference and redemption value .....	\$1,699,985	\$ 199,996
<i>Series B Convertible Preferred</i>		
Shares issued and outstanding .....	5,000	2,173
Liquidation preference and redemption value .....	\$5,000,000	\$2,173,000
<i>Total Convertible Preferred</i>		
Shares issued and outstanding .....	389,612	47,421
Liquidation preference and redemption value .....	<u>\$6,699,985</u>	<u>\$2,372,996</u>

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 reserved to the stockholders of the Company for their action at any meeting of the stockholders of the corporation.

*Series A Convertible Preferred Stock*

On May 12, 2003, the Company entered into an agreement for the sale of \$6.5 million of Series A Convertible Preferred Stock (the "Series A stock") to Medtronic, Inc. and a group of private investors, pursuant to which, the Company sold 696,825 shares of its Series A stock at a purchase price of \$4.42 per share providing gross proceeds of \$3,079,966. Each share of Series A stock is convertible into 13 shares of the Company's common stock.

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

In connection with the sale of the Series A stock, the Company issued warrants for the purchase of an additional 773,724 shares at a purchase price of \$4.42 per share with monthly expiration dates beginning September 1, 2003 and ending February 1, 2004. During fiscal 2003, investors purchased 663,999 shares of Series A stock through the exercise of these warrants providing additional proceeds of \$2,934,876. During fiscal 2004, investors exercised the remaining warrants for the purchase of 109,725 shares of Series A stock providing the Company with gross proceeds of \$484,985.

As part of the financing, the Company also issued to both Medtronic and the private investors warrants exercisable for 471,703 shares of our Series A stock. The exercise price of Medtronic's warrant is \$4.42 and the exercise price per share of the warrants issued to the other investors is \$5.525. These warrants expire on January 1, 2009.

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 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 was recorded as of the original transaction date as the consideration allocated to the convertible security, divided by the number of common shares into which the security converts, was below the fair value of the common stock at the convertible instruments issuance. The value of the beneficial conversion feature recorded related to the Series A stock financing was \$1,533,280. The amount of the beneficial conversion feature was immediately accreted and the accretion resulted in a deemed dividend as the Series A stock is convertible immediately. The deemed dividend was reflected as an adjustment to net loss applicable to common stockholders on the Company's Statement of Operations for the year ended December 31, 2003. The issuance of additional shares of Series A stock or warrants under this financing may result in an additional beneficial conversion feature being recorded.

During 2004 and 2005, investors exercised their rights to convert 1,006,755 and 369,406 shares of Series A stock into 13,087,814 and 4,802,278 shares of the Company's Common Stock. The Company had 384,612 and 45,248 shares of Series A stock and warrants for the purchase of an additional 471,703 and 403,830 shares of Series A stock outstanding at December 31, 2004 and 2005, respectively. During the quarter ended March 31, 2005, Medtronic executed a cashless exercise of their warrant for 67,873 shares of Series A stock.

From January 1, 2006 to March 30, 2006, investors exercised their right to convert 45,248 shares of Series A stock into 588,224 shares of common stock. In addition, during this period, investors exercised outstanding warrants to purchase 149,310 shares of Series A stock and convert them into 1,941,030 shares of common stock. At March 30, 2006, the Company had no shares of Series A stock and warrants for the purchase of 254,520 shares of Series A stock outstanding.

#### *Series B Convertible Preferred Stock*

On December 6, 2004, the Company entered into an agreement for the sale of \$5 million of Series B Convertible Preferred Stock (the "Series B stock") to certain institutional and other private investors. Under the terms of the financing, the Company issued and sold 5,000 shares of Series B stock at a purchase price of \$1,000 per share. Each share of Series B stock is convertible into approximately 2,222 shares of the Company's common stock at a conversion price of \$0.45 per share. In the event of the liquidation, dissolution or winding-up of the Company, each share of Series B stock is entitled to receive a liquidation preference equal to \$1,000 per share prior to the payment of any amount to the holders of common stock or the holders of any other class of securities that is junior to the Series B stock but after the payment of the liquidation preference due to the holders of

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

Series A stock. In the event that the Company issues shares of common stock at a purchase price below the conversion price of the Series B stock, the conversion price of the Series B stock will be adjusted to equal such purchase price. In addition, the holders of the Series B stock have certain registration rights with respect to the shares of common stock into which the Series B stock may be converted, which rights obligate the Company to file a Registration Statement with the SEC, and to keep the Registration Statement current until such time as all shares covered by the Registration Statement may be sold pursuant to Rule 144(k) promulgated under the Securities Act of 1933, as amended.

In connection with the sale of the Series B stock, the Company issued warrants (the "Series B warrants") to purchase 2,500 shares of Series B stock. The exercise price of the Series B warrants is \$1,100 per share. In the event of a "Fundamental Transaction" (as defined in the Series B warrants), the holders of Series B warrants are entitled to elect to receive the payment of cash or other consideration in respect of their warrant shares.

The net proceeds from the sale of the securities have been allocated between the Series B stock and the Series B warrants. The fair value of the Series B warrants was calculated at using the Black Scholes valuation model with the following significant assumptions: a) Estimated Warrant Life—15 months, b) Volatility Rate—118%, c) Dividend Rate—0%, and d) Risk Free Rate—3.72%. The final closing price of the Company's common stock as listed on the National Association of Securities Dealers' OTC Bulletin Board on December 6, 2004 was \$0.57 per share and as a result, the Company valued the Series B warrants at \$1,703,008. A beneficial conversion feature was recorded as of the original transaction date as the consideration allocated to the Series B stock, divided by the number of common shares into which the security converts, was below the fair value of the common stock at the time of the convertible instruments issuance. The value of the beneficial conversion feature recorded related to the Series B stock financing was \$2,537,000. The amount of the beneficial conversion feature was immediately accreted and the accretion resulted in a deemed dividend as the Series B stock was convertible immediately. The deemed dividend was reflected as an adjustment to net loss applicable to common stockholders on the Company's Statement of Operations for the year ended December 31, 2004 (See Note 3—*Summary of Restatement of Financial Statements to Reflect Derivative Accounting*).

In connection with the sale of the Company's Series B stock, the Company also issued to the placement agent for the transaction a warrant exercisable for a total of 953,333 shares of the Company's common stock. The warrant expires on December 6, 2009. The exercise price of the this warrant is \$.495 per share of common stock. The Company has valued the warrants using the Black Scholes model as of its date of issue and has recorded \$457,409 as a non-cash issuance cost associated with the sale of the Series B stock.

During 2005, investors exercised their rights to convert 2,952 shares of our Series B stock into 6,559,999 shares of our common stock. There were 5,000 and 2,173 shares of Series B stock and warrants to purchase an additional 2,500 and 2,375 shares of Series B stock outstanding at December 31, 2004 and 2005, respectively.

From January 1, 2006 to March 30, 2006, investors exercised their right to convert 2,143 shares of Series B stock into 4,762,222 shares of common stock. In addition, during this period, investors exercised outstanding warrants to purchase 2,360 shares of Series B stock and convert them into 5,244,444 shares of common stock. At March 30, 2006, the Company had 30 shares of Series B stock and warrants to purchase an additional 15 shares of Series B stock outstanding.

#### **9. Stockholders' Equity**

##### ***Common Stock***

The Company's Board of Directors has authorized 150,000,000 shares of the Company's \$0.001 par value common stock. At December 31, 2005, the Company had 46,300,869 common shares outstanding. As of March 28, 2006, the Company had 60,229,690 common shares outstanding.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**Warrants**

A roll-forward of outstanding warrants for the purchase of common stock of the Company for the years ended December 31, 2003, 2004 and 2005 are summarized as follows:

	December 31, 2003		December 31, 2004		December 31, 2005	
	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 . . . . .	1,370,400	\$2.94	1,319,695	\$1.71	2,102,532	\$1.13
Issued . . . . .	119,515	0.64	953,333	0.50	—	—
Exercised . . . . .			(82,500)	0.34	—	—
Canceled . . . . .	(170,220)	3.43	(87,996)	3.59	(480,000)	3.50
Outstanding at end of year . . . . .	<u>1,319,695</u>	<u>\$1.71</u>	<u>2,102,532</u>	<u>\$1.13</u>	<u>1,622,532</u>	<u>\$0.43</u>

Total warrants for the purchase of common stock outstanding at December 31, 2005 by expiration date were as follows:

	Number of Shares	Exercise Price per Share	Expiration Date
Common stock warrants . . . . .	632,184	\$0.285	December 21, 2006
Common stock warrants . . . . .	37,015	\$1.297	September 26, 2007
Common stock warrants . . . . .	953,333	\$0.495	December 6, 2009
	<u>1,622,532</u>		

From January 1, 2006 to March 30, 2006, holders of outstanding warrants to purchase 1,585,517 shares of common stock had exercised their rights to acquire the common shares, generating gross proceeds to the Company of \$652,072.

**10. Stock Plans**

**1993 and 1996 Stock Option Plans**

During 1993, the Company adopted the 1993 Incentive and Non-Qualified Stock Option Plan (the "1993 Plan") and in 1996 the Board of Directors authorized the 1996 Equity Incentive Plan (the "1996 Plan"). The Plans provide for the grant of incentive and non-qualified stock options to management, other key employees, consultants and directors of the Company. No new awards may be made under the 1993 Plan. In 1999, the Board of Directors authorized and the stockholders approved an amendment to the 1996 Plan to increase the total number of shares authorized for issuance under the plan from 1,000,000 to 1,300,000 shares of the Company's common stock. The total shares of common stock that may be issued pursuant to the exercise of options granted under the 1993 and 1996 Plans are 1,155,000. Of this amount, 255,000 are exercisable at December 31, 2005. Under the terms of both plans, 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.

**1996 Director Option Plan**

During 1996, the Board of Directors authorized the issuance of up to 100,000 shares of the Company's common stock pursuant to its 1996 Director Option Plan (the "Director Plan"). Under the Director Plan, outside directors of the Company who are not otherwise affiliated with the Company are entitled to receive options to purchase 10,000 shares of common stock upon their initial election to the Board of Directors.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

**2001 Stock Incentive Plan**

During 2005, 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 5,000,000 to 6,750,000 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 1,000,000 shares. A total of 490,625, 105,875 and 47,100 shares of restricted stock were granted under the 2001 Plan during 2003, 2004 and 2005, respectively, of which restrictions had lapsed with respect to 453,850 shares at December 31, 2005. The total shares of common stock that may be issued pursuant to the exercise of options granted under the 2001 Plan are 4,352,625. Of this amount 966,125 are exercisable at December 31, 2005. 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.

All options granted during 2003, 2004 and 2005 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, 2003, 2004 and 2005 are summarized as follows:

	December 31, 2003		December 31, 2004		December 31, 2005	
	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	3,196,200	\$2.43	4,696,393	\$1.50	5,267,625	\$1.42
Granted	2,557,875	0.65	1,206,000	0.72	4,902,500	0.31
Exercised	(7,500)	0.46	(253,143)	0.22	—	—
Canceled/Forfeited	(1,050,182)	2.20	(381,625)	1.07	(4,662,500)	1.34
Outstanding at end of year	<u>4,696,393</u>	<u>\$1.50</u>	<u>5,267,625</u>	<u>\$1.42</u>	<u>5,507,625</u>	<u>\$0.56</u>
Exercisable at end of year	<u>2,324,222</u>	<u>2.09</u>	<u>2,647,895</u>	<u>1.99</u>	<u>1,221,125</u>	<u>1.51</u>
Weighted average fair value of options granted during the year		\$0.69		\$0.42		\$0.61

The following table summarizes information about stock options outstanding under all of the Company's stock option plans at December 31, 2005:

Range of exercise prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price of Options Exercisable
\$0.20 - \$0.50	4,678,000	9.30	\$0.30	416,500	\$0.35
\$0.51 - \$1.00	353,125	8.06	\$0.66	328,125	\$0.67
\$1.01 - \$2.50	224,000	7.01	\$1.47	224,000	\$1.47
\$2.51 - \$4.00	158,000	4.11	\$2.88	158,000	\$2.88
\$4.01 - \$9.38	94,500	2.22	\$7.31	94,500	\$7.31
	<u>5,507,625</u>	8.86	\$0.56	<u>1,221,125</u>	\$1.51

At December 31, 2005, 5,507,625 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there are 1,907,817 options available for future grant. Outstanding options generally vest on a pro rata basis over a period of three to five years.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

The Company has recorded compensation expense (benefit) related to options granted to non-employee consultants for services rendered, totaling \$137,440 in 2003, \$24,204 in 2004, and \$29,730 in 2005 based on the market price of our common stock.

On August 15, 2005, four Company officers entered into option exchange agreements with the Company whereby an aggregate of 2,686,750 options, issued at varying times and varying prices, were cancelled and replaced with an aggregate 2,975,000 options priced at \$0.29, the last reported price that day. In the fourth quarter of 2005, the Company recorded a compensation expense of \$131,161 relating to the option exchange.

On September 19, 2005, five members of the Board of Directors entered into individual option exchange agreements with the Company whereby an aggregate of 805,000 options, issued at varying times with varying prices, were cancelled and replaced with an aggregate of 805,000 options prices at \$0.30, the last reported price that day. In the fourth quarter of 2005, the Company recorded a compensation expense of \$34,436 relating to the option exchange.

On October 24, 2005, the Company's Board of Directors approved the acceleration of vesting of all unvested, out-of-the-money employee stock options. As a result, options to purchase 230,008 unvested shares of the company's common stock with a weighted average exercise price of \$0.73 and exercise prices ranging from \$0.45 to \$1.30, which would otherwise have vested over the next 38 months, became fully vested. The Company took this action in order to reduce future compensation expense that would otherwise be required to be recorded in the statements of operations in period following the effectiveness of the Financial Accounting Standards Board's new standard, Statement of Financial Accounting Standard No. 123R, "Share-Based Payment" which requires companies to recognize stock-based compensation expense associated with stock options based on the fair value method.

**1996 Employee Stock Purchase Plan**

In June 2004, the stockholders voted to increase the number of shares authorized under the 1996 Employee Stock Purchase Plan to eligible employees from 300,000 to 600,000 shares of the Company's common stock. Under the Purchase Plan, the Company is authorized to make one or more offerings during which employees may 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.

Pursuant to the 1996 Employee Stock Purchase Plan, the Company issued 148,076, 71,916 and 177,528 shares of common stock at an average price of \$0.32, \$0.69 and \$0.26 during 2003, 2004 and 2005 respectively. As of September 30, 2005, the Company cancelled its Employee Stock Purchase Plan. At December 31, 2004, the Company had 240,298 shares of common stock reserved for issuance under the Purchase Plan.

**11. Income Taxes**

The income tax benefit consists of the following:

	<b>Year ended December 31,</b>		
	<b>2003</b>	<b>2004</b>	<b>2005</b>
Income tax benefit:			
Federal .....	\$ 1,592,941	\$ 337,727	\$ 1,702,315
State .....	(213,348)	186,604	(19,302)
	\$ 1,379,593	\$ 524,331	\$ 1,683,013
Deferred tax asset valuation allowance .....	(1,379,593)	(524,331)	(1,683,013)
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

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

	Year ended December 31,		
	2003	2004	2005
Net operating loss carryforwards .....	\$ 17,168,246	\$ 17,878,008	\$ 19,843,414
Research and development tax credit carryforwards .....	1,606,446	1,606,292	1,599,564
Capitalized research and development .....	3,668,370	3,618,403	3,311,877
Other .....	211,410	130,095	87,646
Gross deferred tax assets .....	22,654,472	23,232,798	24,872,501
Capitalized software .....	(64,881)	(120,150)	(71,198)
Fixed assets .....	(65,737)	(43,772)	(36,560)
Patent costs .....	(46,272)	(66,962)	(69,810)
Net deferred tax assets .....	\$ 22,477,582	\$ 23,001,914	\$ 24,694,933
Deferred tax asset valuation allowance .....	(22,477,582)	(23,001,914)	(24,694,993)
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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. Based upon the weight of all available evidence, the Company has provided a full valuation allowance for its deferred tax 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 \$1,400,000 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,		
	2003	2004	2005
Statutory U.S. federal tax rate .....	(35.0)%	(35.0)%	(35.0)%
State taxes, net of federal tax benefit .....	(5.6)	(5.9)	(5.9)
Non-deductible expenses .....	2.4	1.8	1.7
Federal research and development credits .....	(0.1)	(0.1)	—
Other .....	10.9	0.6	0.6
Valuation allowance on deferred tax assets .....	27.4	38.6	38.6
	<u>— %</u>	<u>— %</u>	<u>— %</u>

As of December 31, 2005, the Company has approximately \$48,308,000 federal and \$34,809,000 state net operating loss carryforwards and \$1,150,000 and \$691,000 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. The credits and carryforwards expire in various years ranging from 2006 to 2024.

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

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 Convertible Preferred Stock issuance in 1993 and the Series B Convertible 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. Subsequent significant changes in ownership could further affect the limitations in future years.

**12. Savings Plan**

In January 1995, the Company 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 2003, 2004 or 2005.

**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 holds 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, 2004 and 2005.

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 the 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 \$28,235 and \$43,615 of accrued warranties at December 31, 2004 and 2005, respectively.

	December 31,	
	2004	2005
Balance at beginning of period . . . . .	\$ 58,202	\$ 28,235
Provision for warranty for units sold . . . . .	33,006	47,996
Cost of warranty incurred . . . . .	(62,973)	(32,616)
Balance at end of period . . . . .	\$ 28,235	\$ 43,615

**CAMBRIDGE HEART, INC.**

**NOTES TO FINANCIAL STATEMENTS—(Continued)**

***Operating Leases***

The Company has various non-cancelable operating leases for office space and equipment which expire through 2006. Certain of these leases provide the Company with various renewal options. Total rent expense under all operating leases was approximately \$193,029, \$137,886 and \$141,407 for the years ended December 31, 2003, 2004 and 2005, respectively. At December 31, 2005, future minimum rental payments under the non-cancelable leases are \$142,676 and \$8,492 for fiscal 2006 and 2007 and beyond, respectively.

***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 \$20,000 of such minimum license maintenance fees subsequent to December 31, 2005 as the technology is used. License maintenance fees paid during 2003, 2004 and 2005 amounted to \$10,000, \$10,000 and \$10,000, respectively. The future minimum license maintenance fee commitments at December 31, 2005 are approximately as follows:

2006 .....	10,000
2007 .....	<u>10,000</u>
	<u>\$20,000</u>

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 a consulting fee of \$135,000 during fiscal 2002. 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 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 2002 and 2003, a royalty of 1% of net sales of products developed from certain technologies developed by this individual. The amended agreement required that, during fiscal 2003 and 2004, 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 the previous fiscal year and a royalty of 1.5% of net sales of these

## CAMBRIDGE HEART, INC.

### NOTES TO FINANCIAL STATEMENTS—(Continued)

products in excess of the net sales of these products recorded by the Company during the previous fiscal year. This formula for the payment of royalties was in effect through the end of fiscal 2004. Beginning in fiscal 2005, the amended agreement requires 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, 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 \$113,131, \$69,852 and \$72,043 during fiscal 2003, 2004 and 2005, respectively.

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

One customer accounted for 14%, 7% and 1% of total revenues and 10%, 2% and 0% of the accounts receivable balance as of December 31, 2003, 2004, and 2005, respectively. During the years ended December 31, 2003, 2004 and 2005, international sales accounted for 9%, 14% and 22% of the total revenues, respectively. Company policy does not require collateral on accounts receivable balances.

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

As the Company previously reported in its Current Report on Form 8-K dated November 24, 2004, the Company changed its independent public accounting firm for the fiscal year ending December 31, 2004 from PricewaterhouseCoopers LLP to Vitale, Caturano & Company, Ltd.

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

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, 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 of 1934) as of December 31, 2005.

Disclosure controls and procedures are designed with the objective of ensuring that (i) information required to be disclosed in the Company's reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the principal executive officer and the principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2005, our disclosure controls and procedures were not effective due to the fact that we had misapplied generally accepted accounting principles related to the accounting for derivative liabilities in accordance with EITF 00-19 and SFAS 133. At the time of the December 2004 sale of our Series B stock, the Company failed to determine that the warrants to purchase shares of Series B stock issued to investors in the December 2004 financing were required to be accounted for as liabilities. As a result, we had not classified these warrants as liabilities in our historical financial statements.

We have restated our financial statements for the year ended December 31, 2004 in order to correct the accounting in such financial statements with respect to the warrants to purchase shares of Series B stock in accordance with EITF 00-19 and SFAS 133. Over the course of 2005, we have taken steps to improve our internal controls over financial reporting and disclosure controls and procedures. These steps have included improved training regarding accounting for debt and preferred stock and related warrants.

We believe that our disclosure controls and procedures are effective, as of the date of filing this Annual Report on Form 10-K, to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

***(b) Changes in Internal Controls Over Financial Reporting.***

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934) during the fiscal quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART III**

### **Item 10. Directors And Executive Officers Of The Registrant**

The information required by this Item 10 and not already provided in Item 4A will be contained in our proxy statement for our 2006 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2005, and such information 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](http://www.cambridgeheart.com).

### **Item 11. Executive Compensation**

Information required by this Item 11 will be contained in our proxy statement for our 2006 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2005, and such information is incorporated herein by reference.

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

Information required by this Item 12 will be contained in our proxy statement for our 2006 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2005, and such information is incorporated herein by reference.

### **Item 13. Certain Relationships and Related Transactions**

Information required by this Item 13 will be contained in our proxy statement for our 2006 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2005, and such information is incorporated herein by reference.

### **Item 14. Principal Accountant Fees and Services**

Information required by this Item 14 will be contained in our proxy statement for our 2006 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2005, and such information is incorporated herein by reference.

## PART IV

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

(a) Financial Statements.

For a list of the financial information included herein, see Index to the Financial Statements on page 30 of this Annual Report on Form 10-K.

(b) 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.

(c) 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 31, 2006.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DAVID A. CHAZANOVITZ</u> <b>David A. Chazanovitz</b>	Chairman, President, Chief Executive Officer (Principal Executive Officer)	March 31, 2006
<u>/s/ RODERICK DE GREEF</u> <b>Roderick de Greef</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2006
<u>/s/ RICHARD J. COHEN</u> <b>Richard J. Cohen</b>	Director	March 31, 2006
<u>/s/ KENNETH HACHIKIAN</u> <b>Kenneth Hachikian</b>	Director	March 31, 2006
<u>/s/ ROBERT P. KHEDERIAN</u> <b>Robert P. Khederian</b>	Director	March 31, 2006
<u>/s/ JEFFREY J. LANGAN</u> <b>Jeffrey J. Langan</b>	Director	March 31, 2006
<u>/s/ REED MALLECK</u> <b>Reed Malleck</b>	Director	March 31, 2006

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of the Registrant is incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant is incorporated herein by reference to Exhibit 3.2 to the Registrant's Form 10-K for the fiscal year ended December 31, 2001 (File No. 0-20991).
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant is incorporated by reference to Exhibit 3.3 to the Registrant's Form 10-K for the fiscal year ended December 31, 2003 (File No. 0-20991).
3.4	Certificate of Designations of the Preferred Stock of the Registrant to be Designated Series A Convertible Preferred Stock, dated as of May 12, 2003 is incorporated herein by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, dated as of December 6, 2004 is incorporated herein by reference to Exhibit 3.5 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.
3.7	By-Laws of the Registrant, as amended is incorporated herein by reference to Exhibit 3.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
4.1	Specimen Certificate for shares of Common Stock, \$.001 par value, of the Registrant is incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
4.2	See Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 for provisions of the Registrant's certificate of incorporation, certificate of designations and by-laws defining the rights of holders of common stock.
10.1#	1993 Incentive and Non-Qualified Stock Option Plan, as amended is incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.2#	1996 Equity Incentive Plan, as amended is incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.3#	1996 Employee Stock Purchase Plan is incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.4#	Amendment No. 3 to 1996 Employee Stock Purchase Plan is incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement as filed on April 29, 2004.
10.5#	1996 Director Stock Option Plan is incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.6#	2001 Stock Incentive Plan is incorporated herein by reference to Exhibit 10.5 to Appendix A to the Registrant's Definitive Proxy Statement as filed on May 9, 2005.
10.7#	Summary of Amendments to Certain of the Registrant's Equity Plans is incorporated herein by reference to Exhibit 10.7 to the Registrant's Form 10-K for the fiscal year ended December 31, 2004 (File No. 0-20991).
10.8#	Form of Exchange Agreement between the Registrant and Certain Executive Officers dated August 15, 2005.

<u>Exhibit No.</u>	<u>Description</u>
10.9#	Form of Exchange Agreement between the Registrant and Certain Non-Employee Directors dated September 19, 2005.
10.10#	Consulting and Technology Agreement between the Registrant and Dr. Richard J. Cohen, dated February 8, 1993 is incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.11#	License Agreement By and Between the Registrant and Dr. Richard J. Cohen, dated February 8, 1993 is incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.12	License Agreement by and between the Registrant and the Massachusetts Institute of Technology, dated September 28, 1993, relating to the technology of "Assessing Myocardial Electrical Stability" is incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 0-20991).
10.13#	Agreement to Extend the Consulting and Technology Agreement between the Registrant and Dr. Richard J. Cohen, dated January 28, 2003 is incorporated herein by reference to Exhibit 10.9 to the Registrant's Form 10-K for the fiscal year ended December 31, 2002 (File No. 0-20991).
10.14	First Amendment to the License Agreement by and between the Registrant and the Massachusetts Institute of Technology dated May 21, 1998, relating to the technology of "Assessing Myocardial Electrical Stability" is incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-20991).
10.15+	Distributor Agreement, dated as of April 1, 1998, by and between the Registrant and Reynolds Medical Ltd. is incorporated herein by reference to Exhibit 10.6 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-20991).
10.16#	Severance Agreement dated November 18, 1999 between the Registrant and James Sheppard is incorporated herein by reference to Exhibit 10.34 to the Registrant's Form 10-K for the fiscal year ended December 31, 1999 (File No. 0-20991).
10.17+	Distribution and License Agreement dated August 1, 2003 between the Registrant and Burdick, Inc. a subsidiary of Quinton Cardiology Systems, Inc. is incorporated herein by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2003 (File No. 0-20991).
10.18#	Severance Agreement dated September 27, 2000 between the Registrant and David Chazanovitz is incorporated herein by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended September 30, 2000 (File No. 0-20991).
10.19#	Amendment dated January 1, 2005 to the Severance Agreement dated September 27, 2000 between the Company and David Chazanovitz is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated February 23, 2005 (File No. 0-20991).
10.20#	Severance Agreement dated January 30, 2003 between the Registrant and Robert LaRoche is incorporated herein by reference to Exhibit 10.27 to the Registrant's Form 10-K for the fiscal year ended December 31, 2002 (File No. 0-20991).
10.21#	Severance Agreement dated September 17, 2003 between the Registrant and Ali Haghghi-Mood is incorporated herein by reference to Exhibit 10.20 to the Registrant's Form 10-K for the fiscal year ended December 31, 2004 (File No. 0-20991).
10.22#	Offer Letter dated September 8, 2005 between Cambridge Heart, Inc. and Roderick de Greef is incorporated herein by reference to Exhibit 10.01 of the Company's Form 8-K filed on October 5, 2005 (File No. 0-20991).
10.23#	Severance Agreement dated October 3, 2005 between Cambridge Heart, Inc. and Roderick de Greef is incorporated by reference to Exhibit 10.02 of the Company's Form 8-K filed on October 5, 2005 (File No. 0-20991).

<u>Exhibit No.</u>	<u>Description</u>
10.24	Lease Agreement By and Between the Registrant and R.W. Connelly, dated November 30, 2003 is incorporated by reference to Exhibit 10.16 to the Registrant's form 10-K for the fiscal year ended December 31, 2003 (File No. 0-20991).
10.25	Securities Purchase Agreement among the Registrant and The Tail Wind Fund, Ltd. and Robert P. Khederian dated December 21, 2001 is incorporated herein by reference to Exhibit 10.31 to the Registrant's Form 10-K for the fiscal year ended December 31, 2001 (File No. 0-20991).
10.26	Amendment to Registration Rights Agreement and Waiver, dated May 12, 2003, by and among the Registrant, The Tail Wind Fund, Ltd. and Robert P. Khederian is incorporated herein by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended March 31, 2003 (File No. 0-20991).
10.27	Amendment No. 1, dated May 12, 2003, to the Warrant issued as of September 14, 2000 to the Tail Wind Fund Ltd. by and between the Registrant and the Tail Wind Fund Ltd. is incorporated herein by reference to Exhibit 10.3 to the Registrant's Form 10-Q for the quarter ended March 31, 2003 (File No. 0-20991).
10.28	Warrant to Purchase Stock issued to Silicon Valley Bank on September 26, 2002 is incorporated herein by reference to Exhibit 4.2 to the Registrant's Form 10-Q for the quarter ended September 30, 2002 (File No. 0-20991).
10.29	Securities Purchase Agreement among the Registrant and the Purchasers dated May 12, 2003 is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.30	Registration Rights Agreement, dated as of May 12, 2003, by and among the Registrant and the signatories thereto is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.31	Form of Long-Term Warrant to purchase shares of Series A Preferred Convertible Stock of the Registrant issued on May 12, 2003 in connection with the sale of the Series A Convertible Preferred Stock is incorporated herein by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.32	Warrant to purchase shares of Series A Preferred Convertible Stock of the Registrant issued on May 12, 2003 to Medtronic, Inc. in connection with the sale of the Series A Convertible Preferred Stock is incorporated herein by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.33	Amendment to Consulting and Technology Agreement between the Registrant and Dr. Richard Cohen, dated May 7, 2003 is incorporated by reference to Exhibit 10.28 to the Registrant's Form 10-K for the fiscal year ended December 31, 2003 (File No. 0-20991).
10.34	Securities Purchase Agreement, dated as of December 6, 2004 by and among the Registrant and the signatories thereto is incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
10.35	Registration Rights Agreement, dated as of December 6, 2004 by and among the Registrant and the signatories thereto is incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
10.36	Form of Warrant to purchase shares of Series B Convertible Preferred Stock of the Registrant, dated as of December 6, 2004 and issued in connection with the sale of shares of Series B Convertible Preferred Stock is incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).

<u>Exhibit No.</u>	<u>Description</u>
10.37	Form of Warrant to purchase shares of common stock, dated as of December 6, 2004 issued to placement agent in connection with the sale of shares of Series B Convertible Preferred Stock is incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-2, as amended (File No. 333-121915).
14.1	Code of Business Conduct and Ethics is incorporated by reference to Exhibit 14.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (File No. 0-20991).
23.1	Consent of Vitale, Caturano & Company Ltd.
23.2	Consent of PricewaterhouseCoopers LLP
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

# Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Items 15(a) and 15(b) of Form 10-K.

+ Confidential treatment has been requested as to certain portions of this Exhibit. Such portions have been omitted and filed separately with the Securities and Exchange Commission.

## **BOARD OF DIRECTORS**

David A. Chazanovitz  
Chairman of the Board, President and  
Chief Executive Officer,  
Cambridge Heart, Inc.

Richard J. Cohen, M.D., Ph.D.  
Whitaker Professor of Biomedical Engineering,  
Massachusetts Institute of Technology in the Harvard  
and MIT Division of Health Sciences and Technology

Kenneth Hachikian  
Principal and Partner,  
Stonegate Group, Ltd.

Robert P. Khederian  
Chairman,  
Belmont Capital Partners, LLC

Jeffrey J. Langan  
Independent Consultant with  
Maine Point Associates

Reed Malleck  
Vice President, Operations  
Healthwyse, LLC

## **EXECUTIVE OFFICERS**

David A. Chazanovitz  
Chairman of the Board, President and  
Chief Executive Officer

Roderick de Greef  
Chief Financial Officer

Ali Haghghi-Mood  
Vice President, Operations, Research and Development

Robert LaRoche  
Vice President, Sales and Marketing

## **ANNUAL MEETING**

The annual meeting of stockholders will be held on  
June 6, 2006 at 10:00 a.m. at the offices of  
Nutter, McClennen & Fish, LLP, 155 Seaport Blvd.,  
Boston, Massachusetts 02210

## **INDEPENDENT REGISTERED ACCOUNTANTS**

Vitale, Caturano & Company, Ltd.  
80 City Square  
Boston, Massachusetts 02129

## **LEGAL COUNSEL**

Nutter, McClennen & Fish, LLP  
155 Seaport Blvd.  
Boston, Massachusetts 02210

## **CORPORATE INFORMATION**

Additional copies of this Annual Report, including  
the Company's Annual Report on Form 10-K, may  
be obtained without charge by contacting:

Investor Relations  
Cambridge Heart, Inc.  
1 Oak Park Drive  
Bedford, Massachusetts 01730  
(888) 226-9283  
[www.cambridgeheart.com](http://www.cambridgeheart.com)

## **TRANSFER AGENT & REGISTRAR**

The transfer agent is responsible for shareholder  
records and issuance of stock certificates.  
Shareholder requests concerning these matters are  
most efficiently answered by corresponding  
directly with American Stock Transfer & Trust  
Company at the following address:

American Stock Transfer & Trust Company  
59 Maiden Lane  
New York, New York 10038  
(800) 937-5449

## **SHAREHOLDER INFORMATION**

Stock Listing  
The Company's common stock is quoted on the  
National Association Of Securities Dealers'  
OTC Bulletin Board  
Symbol: CAMH.OB