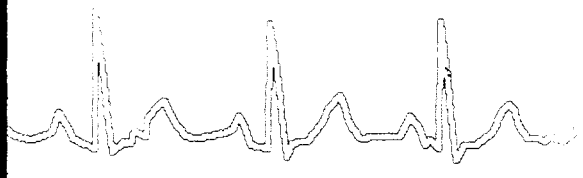
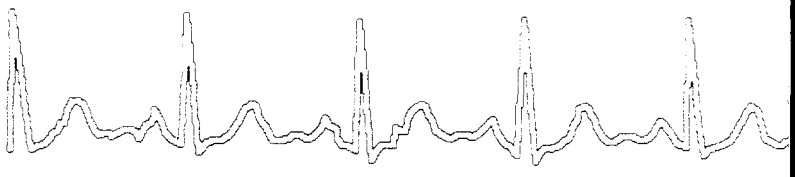
CAMBRIDGE HEART





Beginning Our Ascent

CAMBRIDGE HEART

Cambridge Heart, Inc., located in Bedford, Massachusetts, is engaged in the research, development, and commercialization of products for the noninvasive diagnosis of cardiac disease. The Company's Microvolt T-Wave Alternans Test (MTWA) is the only noninvasive diagnostic tool cleared by the US Food and Drug Administration (FDA) to identify patients at risk for life-threatening arrhythmias and sudden cardiac death (SCD). Cambridge Heart's products - including the Heartwave™ System, CH 2000™ Alternans System, and disposable Micro-V Alternans™ Sensors - are marketed directly in the US and through distributors around the world.

Financial Performance

Revenues increased 63% in 2001 to $3,112,037 compared with revenues of $1,909,883 in 2000. This was primarily the result of strong sales of the Heartwave product in the second half of 2001. The Company reduced its net loss in 2001 to $6,466,433, or $0.37 per share, down from $7,599,373, or $0.50 per share, in 2000. Cambridge Heart ended the year with $8,738,341 of cash and marketable securities, compared to $11,455,242 at the end of 2000. In addition, the Company raised over $3.5 million in equity financing during 2001 and ended the year with three consecutive quarters of record revenues.

Cambridge Heart's Microvolt T-Wave Alternans Test measures extremely subtle beat-to-beat fluctuations in a patient's heartbeat. These minute variations – measured at one-millionth of a volt – are detected at elevated heart rates, often during a typical treadmill stress test. The measurements are captured by proprietary sensors placed on the patient's chest, and analyzed using proprietary algorithms run on our specialized equipment. Extensive clinical research has shown that patients who test positive for Microvolt T-Wave Alternans are at significant risk for sudden cardiac events, while patients who test negative are at minimal risk.

To Our Shareholders:

David A. Chazanovitz
President and CEO

While the year 2001 will be remembered as one that saw both great human tragedy and economic uncertainty, Cambridge Heart achieved a number of milestones that aided us in our efforts to deliver life-saving technology to people at risk of deadly cardiac events. We've made notable progress across a range of strategic objectives, including reimbursement coding and coverage, and publication of additional clinical validation, positioning the Company favorably for 2002 and beyond. With these achievements behind us, we can continue our efforts to drive revenues for our core Microvolt T-Wave Alternans (MTWA) business through the aggressive sales and marketing of our proprietary products throughout the United States.

We are pleased with the progress we made in 2001 toward the increased sales and utilization of our MTWA products in our core US market. The past year saw a 124% increase in MTWA product sales in the US, led by increased sales of our flagship Heartwave product and our disposable Micro-V Alternans Sensors. The significant strides we have made on the clinical and regulatory fronts have proven to be important contributors to our initial Microvolt T-Wave Alternans sales success. Most notable among these accomplishments are the following:

- The publication of two significant studies which provide additional evidence validating the efficacy of our MTWA technology in diverse patient populations
- Obtaining a unique Current Procedural Terminology (CPT) reimbursement code from the American Medical Association
- The adoption of critical Medicare reimbursement policies covering a majority of states
- Achieving ISO 9001 certification and CE marking for all of our products.

These efforts represent a significant step forward for Cambridge Heart and have helped us begin our ascent towards increased market penetration and accelerated revenue growth.

Validation Through Research

Our Microvolt T-Wave Alternans technology is supported by almost a decade of published studies that provide extensive clinical evidence of the effectiveness of MTWA in predicting the risk of cardiac events. In 2001, important research was added to this growing body of medical evidence, which speaks to the efficacy of our technology in a number of critical patient populations.

Post-Myocardial Infarction – An independent multi-center study reported on 834 consecutive post-myocardial infarction (post-MI) patients who were given the MTWA Test and then followed for an average of 25 months. The outcome confirmed the strong results from an initial study of 102 post-MI patients conducted in 1999, and found that MTWA is a strong risk stratifier for sudden cardiac death in these patients. This study is particularly important because these heart attack survivors represent the largest segment of our potential at-risk patient market. Results from the study – the largest ever published on MTWA – appeared in the January 2002 issue of *The American Journal of Cardiology*.

Non-Ischemic Dilated Cardiomyopathy – Another important study, which was presented at the 2001 American Heart Association Meeting held in November, involved patients with Non-Ischemic Dilated Cardiomyopathy (DCM). This condition, marked by an enlarged heart, carries a mortality rate of 25-50% in the first two years after diagnosis. The invasive electrophysiology (EP) study traditionally used to determine the risk of DCM patients has been acknowledged to be a poor predictor in this population. The results demonstrated the predictive value of the MTWA Test. Those who tested positive were shown to have a 30% probability of a cardiac event within 18 months, and those who tested negative were shown to be four times less likely to have a cardiac event. In this study, MTWA was the only noninvasive test to demonstrate statistical significance in predicting cardiac events.

Together, these studies help to further confirm the efficacy of MTWA in diverse, critical cardiac patient populations; increase awareness of our technology within the medical community; and help position Cambridge Heart to penetrate these market segments.

Reimbursement and Clearance

Reimbursement constitutes a major hurdle to the successful promotion of almost all technologies within the healthcare industry. Physicians need easy billing processes and assurance that insurers will cover specific procedures. The American Medical Association's CPT codes enable physicians to bill insurers electronically for approved medical procedures. In Cambridge Heart's case, publication of CPT code 93025 in the Federal Register carries with it an average Medicare payment of $263.53 for our MTWA Test. This compares favorably with standard stress tests, which are reimbursed with an average payment of $99.97.

Cambridge Heart's CPT code – published in the fourth quarter of 2001 and effective as of January 1, 2002 – helps to affirm the MTWA Test's effectiveness, and eliminates the cost and effort involved in manual billing. This achievement removes a significant obstacle in our efforts to increase market penetration and establish broad clinical use of our MTWA technology.

In addition, prompted by our outreach and advocacy efforts, approximately 29 states in the US have either issued or drafted Medicare payment policies for the MTWA Test. We believe that this is an exceptional achievement, given the fact that prior to January 2002 we did not yet possess a unique CPT code. While we are very satisfied with our success in this area to date, we will continue working to bring more states on board and to advocate for the broadest payment policies possible in each state.

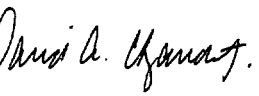
While the major strategic focus of our sales and marketing efforts is the large US market, we continue to work with independent overseas distributors to expand the use of our MTWA technology around the world. In support of these efforts, we received ISO 9001 certification in 2001 that enables us to apply the CE mark to all our products, and ship more easily into the countries in the European Economic Community. The CE mark also aids our efforts to ship products into other areas of the world, as it certifies that the products have been manufactured under appropriate quality systems and are approved in countries that closely examine quality and effectiveness.

On Board

Cambridge Heart is pleased to announce the appointment of Daniel M. Mulvena as Chairman of the Board of Directors effective as of March 2002, replacing Jeffrey M. Arnold, who announced his resignation earlier in March. A Cambridge Heart board member since 1999, Mr. Mulvena is a founding partner of Commodore Associates, a medical device and service consulting company. At the same time, the board voted to elect Robert P. Khederian as a new member of the Company's board. Mr. Khederian is the Chairman of Belmont Capital, a venture capital firm he founded in 1996. Both individuals bring a wealth of public company experience and an in-depth understanding of the medical marketplace to their positions.

A Clear Path

The events of September 11 have only deepened our commitment to preserving lives through the use of noninvasive diagnostic technology. With each passing year, we reaffirm our belief in the importance and value of our revolutionary Microvolt T-Wave Alternans technology – and its ability to help save lives. Through our efforts and achievements in 2001 and past years, we have laid the groundwork to aggressively focus on penetrating the marketplace and growing our core MTWA business. As we begin our ascent toward widespread market acceptance, we are confident that we are well positioned to achieve our long-term goals for the Company. In recognition of these achievements, I would like to extend a personal note of thanks to our employees, customers, partners, and shareholders for their continued loyalty and support.



David A. Chazanovitz
President and Chief Executive Officer

Reaching Our Target

Having obtained a unique CPT code and secured appreciable issuance of Medicare payment policies, Cambridge Heart has eliminated a major obstacle to pursuing its core market: clinical cardiologists. This audience represents the largest group of direct caregivers treating individuals with an elevated risk of sudden cardiac death (SCD) from numerous types of cardiac disease. Because clinical cardiologists are responsible for determining which of their patients may be at the greatest risk of cardiac events and then recommending appropriate treatment, they are the group in greatest need of our noninvasive diagnostic tools. There are approximately 23,000 clinical cardiologists in the US, who see more than 10 million at-risk patients. These physicians and their patients represent the primary market opportunity for Cambridge Heart's MTWA technology and noninvasive products.

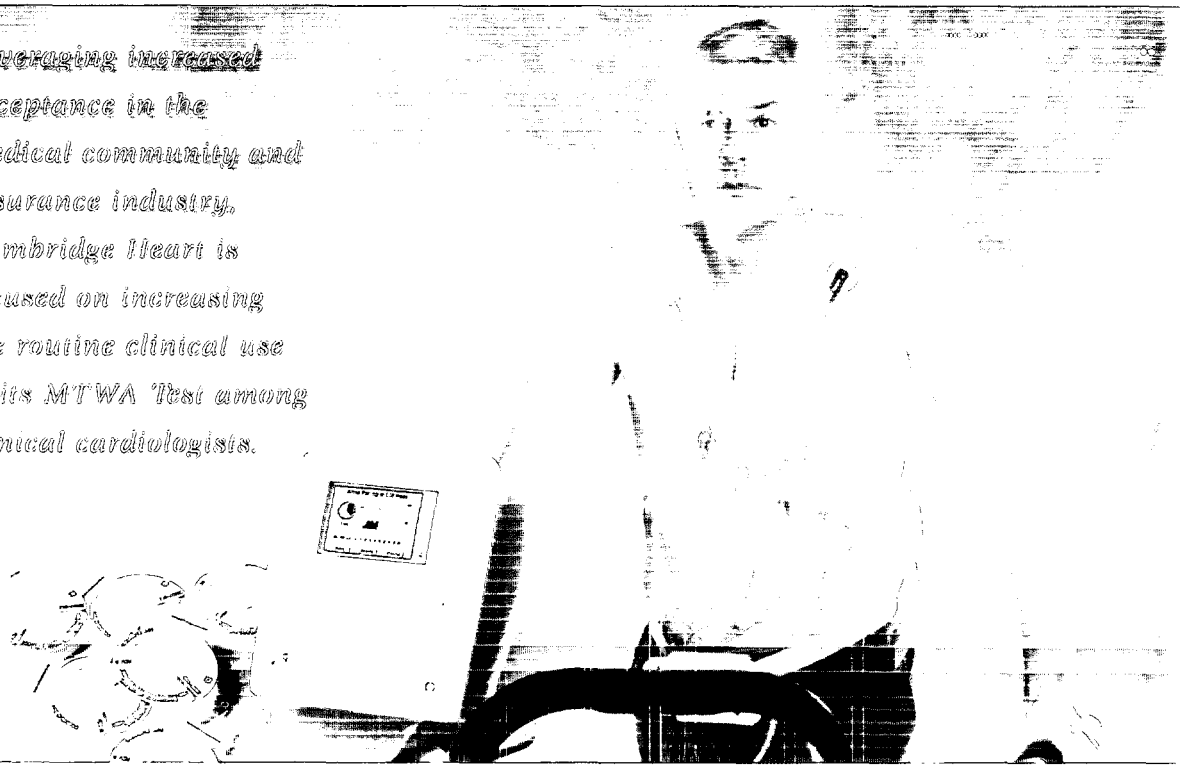
The electrophysiology study has historically been viewed as the gold standard for determining patients at risk of SCD. However, as it is both invasive and expensive, clinical cardiologists are cautious about recommending their patients to an electrophysiologist for evaluation. We believe, and research has confirmed, that the MTWA Test fills a gap in current cardiac diagnosis by providing clinical cardiologists with a much-needed, cost-effective, and noninvasive diagnostic tool for accurately identifying which of their high-risk patients can most benefit from further EP evaluation and possible implantable cardioverter defibrillator (ICD) implantation.

In addition, published clinical data validates that MTWA is not only an equivalent or better predictor of patients at risk of sudden cardiac events than an EP study, but is also significantly more accurate in identifying patients with minimal risk of such events. The strong negative predictive value of the MTWA Test can assist in controlling treatment costs by helping clinical cardiologists determine which of their patients need further evaluation and possible referral for ICD implantation – and which patients can be sent home with assurances that they are at minimal risk.

At-Risk Patient Populations	Number	Clinical Validation
Post-Myocardial Infarction	7.3 million	Yes
Congestive Heart Failure	4.7 million	Yes
Syncope	500,000	Yes
Non-Ischemic Dilated Cardiomyopathy	50,000	Yes

The total at-risk patient population exceeds 10 million. Reaching even a small percentage of this market represents a considerable revenue opportunity for Cambridge Heart's MTWA products.

Leveraging increased acceptance in the medical community and insurance industry, Cambridge Heart is focused on increasing the routine clinical use of its MTWA Test among clinical cardiologists.



Strengthening Our Partnerships

Over the past several years, Cambridge Heart has formed strategic partnerships with a number of ICD providers and cardiac monitoring/stress test companies. These relationships are very important to our field-based sales efforts in that they provide both increased visibility within the medical community and additional revenue streams. In 2001, Cambridge Heart established a number of programs and agreements to help cement these relationships.

ICD companies

Among the most beneficial partner programs we have established are a series of educational symposia hosted jointly by local Cambridge Heart sales representatives and their counterparts at ICD companies. These meetings have led to an increased understanding by both parties of the important role MTWA testing plays in referring appropriate patients for ICD therapy. As a result, a steadily growing number of ICD companies have been added to the chorus of voices promoting the value of MTWA technology. These endorsements have led to increased visibility and credibility within the medical community, and have helped our sales force open the doors to many clinical cardiology practices.

The US healthcare system can benefit from a cost-effective, easy-to-conduct test for patients with potentially life-threatening heart conditions. We believe MTWA is that test, and we are engaging in a number of joint clinical studies that we are confident will confirm our belief. During 2001, St. Jude Medical and Cambridge Heart began enrollment in a jointly sponsored Alternans Before Cardioverter Defibrillator (ABCD) trial. This trial will determine the effectiveness of the noninvasive MTWA Test compared to the current gold standard invasive EP study in directing ICD therapy. The trial hopes to identify more patients at risk of life-threatening arrhythmias and to allow certain patients to proceed directly from a positive MTWA Test to ICD therapy without an intervening invasive test. If the trial proves successful, it could lead to the MTWA Test playing a more important role in directing therapy and to more patients being tested – and treated when appropriate.

Monitoring/stress test companies

Philips Medical (which acquired our distribution partner Agilent Healthcare Solutions last year) is Cambridge Heart's exclusive distributor of the CH 2000 stress test system in the US, and a non-exclusive distributor outside Western Europe and Japan. This partnership has enabled Cambridge Heart's US sales force to focus its energies on selling the Heartwave System, the core Alternans product that the Company believes offers the most favorable revenue opportunities in the US market. We continue to support Philips Medical's sales efforts, as demonstrated by the full product upgrade we completed for the CH 2000 in 2001, as well as the software upgrades that we developed to aid this valuable partner.

In 2001, our partner Spacelabs Medical received 510(k) clearance from the US Food and Drug Administration (FDA) to integrate Cambridge Heart's Microvolt T-Wave Alternans technology for use within its Burdick™ Quest™ exercise stress system. Spacelabs is in the early stages of marketing the jointly developed system, which will provide additional revenue for Cambridge Heart through the sale of Alternans-enabled stress test systems and disposable Micro-V Alternans Sensors.

Theodore Chow, MD *Ohio Heart Health Center, Cincinnati, OH*

"Sudden cardiac death is the most common cause of death, yet most people are asymptomatic until it's too late. We've been using the Microvolt T-Wave Alternans Test for almost a year to help us identify patients at risk for SCD who otherwise would have escaped medical attention."

Ernst A. Raeder, MD *Stony Brook University Hospital, Stony Brook, NY*

"Patients with a history of cardiomyopathy are at high risk of sudden cardiac death. ICDs are an effective treatment, but they're far too costly to warrant giving one to every patient. We need to find sub-groups of patients at the greatest risk for SCD, who can most benefit from ICD treatment. MTWA helps us do that."

Thomas P. Wharton, Jr., MD *Exeter Hospital, Exeter, NH*

"To me, using the MTWA Test instead of the standard EP method is a no-brainer, because it can be done quickly and easily without risk of morbidity to my patients. Most importantly, it's as effective a predictor of sudden cardiac death as an EP study—possibly even better."

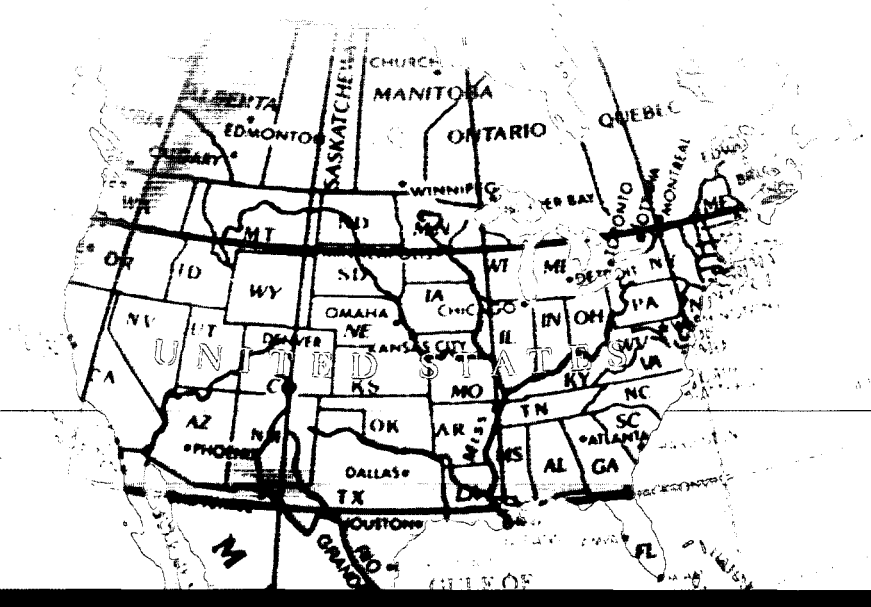
Investing in Our Sales Organization

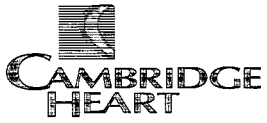
Last year, the Company continued its commitment to expanding its sales organization by extending its US coverage to include 13 sales territories at the end of 2001. Additional hiring is slated to occur incrementally throughout the coming year. We anticipate increasing the sales force by up to 50%. This effort will be supported by the $3.5 million in equity financing that the Company raised during the fourth quarter of 2001.

Our US sales force is currently focused on increasing awareness of our MTWA Test within each of its regions, and on aggressively placing Heartwave systems in cardiology practices. We continue to invest in extensive clinical and technical training for the entire sales force. We feel strongly that focusing our direct sales efforts and the majority of our resources on our proprietary MTWA technology will provide the highest returns for the Company.

There is ample evidence that these investments are bearing fruit. Driven by strong sales of the Heartwave in the second half of the year, the Company ended fiscal 2001 with three consecutive quarters of record revenues. In addition, the selling cycle for the Heartwave decreased from an average of six months or more to as little as three to four months, with some sales being closed in one week. This reduction in our sales cycle is the result of better product positioning; a receptive, responsive target audience; the issuance of our CPT code; and the many inroads and introductions our ICD and monitoring partners have made on our behalf.

Cambridge Heart has made significant investments toward expanding the breadth and knowledge base of its US sales force.





10-K annual report 2001

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

For Annual and Transition Reports
Pursuant to Sections 13 or 15(d) of the
Securities Exchange Act of 1934

(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, 2001

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)	**13-3679946** (I.R.S. Employer Identification No.)
1 Oak Park Drive, Bedford, MA (Address of Principal Executive Offices)	**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 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. ☐

The aggregate market value of voting common stock held by non-affiliates of the registrant was $32,291,037 based on the last reported sale price of the common stock on the Nasdaq National Market on March 15, 2002.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 19,415,681 shares of $0.001 par value common stock as of March 15, 2002.

Documents incorporated by reference:

Document Description	10-K Part
Portions of the Registrant's Proxy Statement for the Annual Meeting of Shareholders to be held June 4, 2002	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 such key problems in cardiac diagnosis as the identification of those at risk of sudden cardiac arrest. Our products incorporate our proprietary technology, Microvolt T-Wave Alternans, and are the only diagnostic tools cleared by the U.S. Food and Drug Administration to non-invasively measure Microvolt levels of T-Wave Alternans, an extremely subtle beat-to-beat fluctuation in a patient's heartbeat. The use of our products and technology in the performance of a Microvolt T-Wave Alternans Test can detect these tiny heartbeat variations, measured at one millionth of a volt, in patients whose heart rate has been elevated by exercise, pharmacologic agents and pacing through the use of our proprietary sensors which are placed on the patient's chest. Published clinical data in a broad range of patients 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. This data has consistently shown that our Microvolt T-Wave Alternans technology is the only non-invasive test comparable or superior to the invasive "gold standard" electrophysiology study in the prediction of sudden death. Sudden cardiac arrest accounts for approximately one-third of all cardiac deaths due to heart attack, or over 300,000, in the United States each year, and is the leading cause of death in people over the ages of 45.

All of our products, including our CH 2000, Heartwave and Micro-V Alternans Sensors, have received 510(k) clearance from the FDA for sale in the United States and all have received the CE mark for sale in Europe. Our CH 2000 and Micro-V Alternans Sensors have been approved for sale by the Ministry of Health in Japan. Our 510(k) clearance includes the claim that our products 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 or sudden death.

Cambridge Heart was incorporated in Delaware in 1990. Our executive offices are located at 1 Oak Park Drive, Bedford, Massachusetts 01730.

Principal Products and Applications

The Heartwave

Our Heartwave System is used to perform a Microvolt T-Wave Alternans Test and is designed to operate seamlessly with all current manufacturers stress test systems during the performance of a standard stress test. Our Heartwave System can also be used as a stand-alone device to test for Microvolt T-Wave Alternans. The EP model of our Heartwave System, performs a Microvolt T-Wave Alternans Test during the conduct of an electrophysiology test. Both models require elevation of the patients heart rate to produce an accurate result. They collect and process Microvolt T-Wave Alternans data using our proprietary Micro-V Alternans Sensors placed on the patient's chest and our Analytic Spectral Method of measuring microvolt levels of alternans.

The Heartwave System is portable and includes:

- a Pentium processor that provides real-time alternans computations and storage of the 10 most recent tests;
- an LCD touch screen that displays key test parameters and means of entering patient information;

- a digital ECG amplifier that, working in concert with our Micro-V Alternans Sensors, makes alternans measurements possible to levels below one microvolt;
- a desk jet printer capable of providing printed trend reports with guided interpretation for quick, accurate analysis.

The CH 2000

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 stress tests. When properly upgraded to activate our Microvolt T-Wave Alternans technology, it is also able to perform a Microvolt T-Wave Alternans Test. It is capable of controlling both treadmill and bicycle ergometers and is well suited for standard, nuclear or echocardiogram stress tests. The CH 2000 is compatible with standard electrodes for routine stress tests and our Micro-V Alternans Sensors for a Microvolt T-Wave Alternans Test.

Microvolt T-Wave Alternans and Ventricular Arrhythmias: Clinical Studies

The association between ventricular arrhythmia and the presence of extremely low levels of Microvolt T-Wave Alternans not detectable by visual inspection of the ECG was unknown until the early 1980s. Research conducted in Dr. Richard Cohen's laboratory at The Massachusetts Institute of Technology indicated that the presence of microvolt (one-millionth of a volt) levels of alternans was predictive of vulnerability to ventricular arrhythmias responsible for sudden cardiac arrest. Dr. Cohen, a founder, director and consultant to us, and his associates developed the technology to quantify this electrical conduction pattern which we exclusively licensed and which forms the basis of our proprietary technology.

Over the years, studies have shown Microvolt T-Wave Alternans to be an effective diagnostic tool for the identification of patients at risk of sudden death and life-threatening ventricular arrhythmias. Clinical studies conducted on over 4,000 patients in most of the major high risk cardiac populations have shown that a positive result from a Microvolt T-Wave Alternans Test is at least as accurate a predictor of a future cardiac event as an invasive electrophysiology study. These studies have also shown that a negative result from a Microvolt T-Wave Alternans Test is superior as a predictor of future cardiac events than an invasive electrophysiology study. These studies have been published in a variety of peer reviewed journals such as the *New England Journal of Medicine, Journal of Cardiovascular Electrophysiology, Journal of the American College of Cardiology*, and *The Lancet.*

An independent study, conducted at several Japanese medical centers, of 834 consecutive recent heart attack patients with follow-up for an average of 25 months conducted by Dr. Takanori Ikeda of Toho University, and various associates, was published in the *American Journal of Cardiology* in January 2002. The study concluded that Microvolt T-Wave Altenans is a strong risk stratifier for sudden cardiac death after myocardial infarction. Patients testing positive for Microvolt T-Wave Altenans were 11.4 times more likely to have a cardiac arrest or become a victim of sudden cardiac death than patients who had a negative test. This study is the largest single study ever conducted and published on Microvolt T-Wave Alternans. According to American Heart Association statistics, approximately 7.3 million Americans are heart attack survivors and approximately 1.5 Americans sustain a heart attack each year.

In November 2001, at the annual meeting of the American Heart Association, Dr. Thomas Klingenheben of JW Goethe University Hospital in Frankfurt, Germany, presented the results of a study of 133 patients with Non-Ischemic Dilated Cardiomyopathy, which we call DCM, with follow-up for an average of 12 months. The study reported that patients testing positive for Microvolt T-Wave Altenans had a 30% probability of having a cardiac event and patients testing negative were four times less likely to have a cardiac event, within 18 months. Microvolt T-Wave Alternans was the only non-invasive test able to achieve statistical significance in predicting events in this patient population.

Invasive electrophysiology study is known to be an inaccurate predictor in these patients and therefore physicians have been without a reliable risk stratifier. The mortality rate for DCM patients is 25% to 50% in the first two years after diagnosis and approximately one-half of these deaths are sudden cardiac deaths.

Marketing and Sales

Our technology and products are directed towards identifying individuals at risk of sudden cardiac death. Typically our target patient populations include those individuals with underlying cardiac disease. In the U.S., those populations include 7.3 million patients who have suffered a myocardial infarction, which we call heart attack, 4.7 million patients suffering from congestive heart failure, 500,000 syncope patients and over 50,000 patients with non-ischemic dilated cardiomyopathy. Therefore, the aggregate at-risk patient population exceeds 10 million.

We began marketing our Heartwave System following 510(k) clearance by the FDA at the end of 2000. The Heartwave is available in two similar configurations. One is used in the electrophysiology laboratory where the physician inserts a small catheter in the patient's heart in order to elevate the rate at which it beats. The other configuration, our Heartwave Stress System, uses exercise to elevate the heart rate. The Heartwave Stress System accounts for the majority of our Heartwave system sales.

In fiscal 2001, we expanded our direct sales force from 8 to 13 representatives in the U.S. The sales force is trained on the features, benefits and clinical use of our products and our Microvolt T Wave Alternans technology. Our sales and marketing efforts are primarily directed towards the clinical cardiologists, as they are the physicians diagnosing and treating the majority of patients with existing cardiac pathologies. Clinical cardiologists prescribe and often administer most diagnostic tests, including our Microvolt T-Wave Alternans Test, in their office or as an outpatient procedure in the hospital. Both the office and hospital environments represent realistic sales opportunities for our sales representatives.

A sale usually includes a small piece of capital equipment, the Heartwave, and our single use proprietary Micro-V Alternans Sensors. Customers can purchase the hardware and disposable sensors under usual and customary direct purchasing terms. We also make the services of a third party leasing company available to all customers who want to acquire the products without having to pay the full purchase price upfront. In 2001, approximately 50% of our Heartwave Systems were sold through leasing arrangements.

The presentation and publication of the results of clinical studies conducted under controlled study protocols is very important to the overall success of our business as they provide independent evidence of the benefit of Microvolt T-Wave Alternans testing to the medical community. Recently, there have been a number of important presentations and publications such as the studies done by Dr. Ikeda and Dr. Klingenheben, which have substantiated the importance of our technology in identifying patients at risk of ventricular tachycardia and/or sudden cardiac death. These study results are important to our sales and marketing efforts since recent heart attack patients make up the largest patient group at risk of sudden cardiac death.

In addition to our direct sales efforts in the U.S., we have established partnerships and distribution agreements with third party organizations to expand our sales efforts both in the U.S. and around the world.

The most significant agreement, in terms of its effect on Fiscal 2001 revenue, is our distribution agreement with Philips Medical Systems, formerly known as Agilent Healthcare Solutions. Philips Medical Systems is the exclusive U.S. distributor for our CH 2000 Stress Test System and a non exclusive distributor for our CH 2000 Stress Test System in selected markets outside of the U.S. This arrangement allows us to concentrate our direct sales and marketing efforts on our Heartwave and Microvolt T-Wave Alternans technology.

Previously, we entered into a strategic marketing agreement with Spacelabs Medical, Inc, a leading provider of integrated cardiology, monitoring and clinical information systems. The agreement was for the development of software and hardware that allows our Microvolt T-Wave Alternans technology to run on Spacelabs' Burdick® Quest® exercise stress system. In the 4th quarter of 2001, Spacelabs received 510(k) clearance from the FDA allowing them to begin marketing this new product.

In addition to Philips, we utilize a number of independent distributors to market our products outside the U.S. During the years ending December 31, 1999, 2000 and 2001, sales to these international customers accounted for 49%, 40% and 30% of our business, respectively. We anticipate that this percentage will continue to decrease due to our focusing a majority of our sales and marketing resources on penetrating the U.S. market for Microvolt T-Wave Alternans testing with our Heartwave System. The U.S. market represents our largest business opportunity and therefore, the majority of our sales and marketing efforts will be directed towards this market.

Manufacturing

The manufacturing process for our Heartwave, CH 2000, and Micro-V Alternans Sensors consists primarily of final assembly of purchased components, testing operations and packaging. Components 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 perform a limited amount of final assembly of hardware and software components, and testing of our CH 2000 and Heartwave products at our corporate headquarters in Bedford, Massachusetts. We believe that this facility will be adequate to meet our requirements through the term of our current lease agreement. We are required to meet and adhere to the requirements of U.S. and international regulatory agencies, including Good Manufacturing Practices and Quality System Regulation requirements. Our manufacturing facilities are subject to periodic inspection by both U.S. and international regulatory agencies.

We last underwent a Quality System Regulation audit, conducted by the FDA, in August 2001. We passed the inspection with no observations. In September 2001, we received ISO 9001 certification allowing us to apply the CE Mark to all of our products.

Research and Development

A substantial portion of our research and development investment is focused on our efforts in the areas of clinical research and the development of enhancements to our Microvolt T-Wave Alternans technology. Our clinical research is focused on gathering substantial clinical data demonstrating the efficacy of our Microvolt T-Wave Alternans technology and its results as a predictor of patient risk of ventricular tachyarrhythmia or sudden cardiac death in various patient groups.

During Fiscal 2001, the first patients were enrolled in the Alternans Before Cardioverter Difibrillator clinical trial, which we refer to as the ABCD Trial, that we are sponsoring along with St. Jude Medical. This study is intended to evaluate the effectiveness of our Microvolt T-Wave Alternans Test as compared to invasive electrophysiology study in identifying candidates suitable for implantable cardioverter defibrillator therapy.

We filed and received 510(k) clearance for our Automatic Report Classifier, which is an added feature to our Microvolt T-Wave Alternans technology providing a physician performing our Microvolt T-Wave Alternans Test with a clinical interpretation of the test's results. In addition, we developed and received 510(k) clearance for the Microsoft Windows 2000® version of our CH 2000 stress test software for use in our CH 2000 stress test system distributed by Philips in the U.S. We also released a

version of our proprietary Microvolt T-Wave Alternans software for use with the Burdick® Quest® exercise stress system marketed by Spacelabs Medical.

We expect total research and development costs in 2002 to be comparable to 2001. As of December 31, 2001, the Company had four full time employees engaged in research and development activities along with several independent research and engineering consultants.

Patents, Trade Secrets and Proprietary Rights

The computer algorithms that allow the Heartwave and the CH 2000 to measure Microvolt T-Wave Alternans are covered by U.S. patents issued to The Massachusetts Institute of Technology. MIT licenses these patents to us exclusively, and we hold a U.S. patent covering the use of exercise or any other non-invasive means in the measurement of Microvolt T-Wave Alternans. During 1998, we were issued a U.S. patent covering additional proprietary signal processing algorithms and our Micro-V Alternans Sensors for use in the measurement of Microvolt T-Wave Alternans. Corresponding foreign patents are pending with respect to each. The failure to obtain such patents could have a material adverse effect on our business, financial condition and results of operations. We own or are the exclusive licensee of 18 issued or allowed and 5 patents pending in the United States, with 23 corresponding foreign patents issued or pending with respect to our technology.

We have entered into three license agreements with MIT, pursuant to which we are the exclusive licensee of certain technologies upon which our current and potential future products are based. Two of the MIT license agreements that cover the Microvolt T-Wave Alternans measurement technology incorporated in our Heartwave and CH 2000 products are of material importance to us. These licenses are exclusive until 2007, after which each license will convert to a nonexclusive license for the remaining term of the applicable patents, unless MIT agrees to an extension of exclusivity. These license agreements impose various commercialization, sublicensing, insurance, royalty, product liability indemnification and other obligations on us. Our failure to comply with these requirements could result in conversion of the licenses from being exclusive to nonexclusive in nature or, in some cases, termination of the license. The loss of our exclusive rights to the Microvolt T-Wave Alternans technology, licensed under the MIT license agreements or the termination of such agreements could have a material adverse effect on our business, financial condition and results of operations.

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

Reimbursement

Reimbursement to healthcare providers by third party insurers is critical to the long-term success of our efforts to make the Microvolt T-Wave Alternans Test the standard of care for patients with known, suspected or at risk of ventricular tachyarrhythmia or sudden death. In November 2001, the Centers for Medicare and Medicade Services published a unique Current Procedural Terminology code, which we refer to as a CPT code, along with a specific Medicare payment amount of $263.53 for Microvolt T-Wave Alternans testing in the Federal Register. This code may be used alone or in conjunction with other diagnostic cardiovascular tests. Effective January 1, 2002, healthcare providers are able to file for reimbursement for the performance of a Microvolt T-Wave Alternans Test using code 93025. 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.

An insurer's coverage policy addresses whether or not a product or service is offered, and therefore payment will be made, to the healthcare provider for delivery of an insured benefit to the plan enrollees. Third party insurers can deny coverage, or limit coverage to specific patient populations or healthcare providers. As of the end of Fiscal 2001, third party insurers covering Medicare claims in approximately 29 states in the U.S. have issued or drafted policies for issue, defining coverage of our Microvolt T-Wave Alternans Test. Medicare patients represent approximately 50% of the total number of patients with indications that identify them as those that could possibly benefit from a Microvolt T-Wave Alternans Test. In addition, healthcare providers in the United States have received reimbursement from some of the largest third party insurers for the performance of our Microvolt T-Wave Alternans Test on their non-Medicare patients. We expect that this coverage will continue and expand now that the CPT code has simplified the claims filing process. We will continue our efforts to expand coverage for both Medicare and non-Medicare patients to all 50 states, as well as broaden the indications for use included in some policies.

Competition

The cardiac diagnostic medical device market is characterized by intensive development efforts and 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. We cannot assure that we will be successful in identifying, developing and marketing new products or enhancing our existing products. In addition, we cannot assure that new products or alternative diagnostic techniques will not be developed that will render our current products obsolete or inferior. Rapid technological development by competitors may result in our products becoming obsolete before we recover a significant portion of our research and development, and commercialization expenses incurred with respect to such products. Alternative technologies exist today in each of the areas being addressed by us, including electrocardiograms, Holter monitors, ultrasound tests and systems for measuring cardiac late potentials. However, our CH 2000, Heartwave and Micro-V Alternans Sensors are currently the only FDA cleared systems for the non-invasive measurement of Microvolt T-Wave Alternans and prediction of ventricular tachycardias and sudden cardiac death.

Competition from medical devices which help to diagnose cardiac disease is intense and likely to increase. Our potential competitors include manufacturers of stress test equipment, including major multinational companies. Many of our competitors and potential competitors have substantially greater capital resources, name recognition, research and development experience and regulatory, manufacturing and marketing capabilities than us. Many of these competitors offer well-established, broad product lines and ancillary services not offered by us. Some of our competitors have long-term or preferential supply arrangements with hospitals that may act as a barrier to market entry. Other large health care companies may enter the non-invasive cardiac diagnostic product market in the future. Competing companies may succeed in developing products that are more efficacious or less costly than any that we may develop, and such companies also may be more successful than us in producing and marketing such products. We may not be able to compete successfully with existing or new competitors.

Government Regulation

The manufacture and sale of medical devices intended for commercial distribution are subject to extensive governmental regulation in the U.S. Medical devices are regulated by the FDA and generally require pre-market clearance or pre-market approval prior to commercial distribution. In addition, certain material changes or modifications to medical devices also are subject to FDA review and clearance or approval. The FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising and distribution of medical devices in the United States. Noncompliance

with applicable requirements can result in failure of the government to grant pre-market clearance or approval for devices, withdrawal of approval, total or partial suspension of production, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution. We believe we have received all necessary and required regulatory clearances from the FDA to market our products in the U.S. Our Heartwave, CH 2000, and Micro-V Alternans Sensors have received 510(k) clearance from the FDA for sale in the United States. The 510(k) clearance for the Heartwave and the CH 2000 includes the claim that the they can measure Microvolt T-Wave Alternans, and the presence of Microvolt T-Wave Alternans in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of ventricular tachyarrhythmia and sudden death.

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

Medical devices are classified into one of three classes, class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, pre-market notification and adherence to current Good Manufacturing Practices standards). Class II devices are subject to general controls and special controls (e.g., performance standards, post-market surveillance, patient registries and FDA guidelines). Generally, class III devices must receive pre-market approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable or new devices which have not been found to be substantially equivalent to legally marketed devices), and class III devices require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. Our Heartwave System, and our CH 2000 System are each considered Class II devices.

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in these counties are similar to those of the FDA. We have obtained the requisite foreign regulatory approvals for sale of our Heartwave, CH 2000 and Micro-V Alternans Sensors in many foreign countries, including most of Western Europe. We believe that foreign regulations relating to the manufacture and sale of medical devices are becoming more stringent. The European Union adopted regulations requiring that medical devices such as our Heartwave, CH 2000 and Micro-V Alternans Sensors comply with the Medical Device Directives and which CE marked. In 2001, we received ISO-9001 and CE certification for our Heartwave, CH 2000 and Micro-V Alternans Sensors. The CH 2000 and Micro-V Altenans Sensors are currently approved for sale by the Ministry of Health in Japan. 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, 2001, we had 39 full-time employees. None of our employees are represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

Item 2. ***Properties***

Our facilities consist of approximately 11,000 square feet of office, research and manufacturing space located at 1 Oak Park Drive, Bedford, Massachusetts. This facility is under lease through November 30, 2003. 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, 2001.

Executive Officers of the Registrant

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

Name	Age	Position
David A. Chazanovitz	51	Chief Executive Officer, President, and Director
Robert B. Palardy	53	Vice President, Finance and Administration and Chief Financial Officer
Eric Dufford	43	Vice President, Sales and Marketing and Secretary
James Sheppard	42	Vice President, Operations
Kevin S. Librett	36	Vice President, Research and Development

David A. Chazanovitz. Mr. Chazanovitz became our President and Chief Operating Officer and a director in October 2000 and Chief Executive Officer in February 2001. From July 1998 to September 2000 Mr. Chazanovitz served as Divisional President for Nitinol Medical Technologies, Inc., Neuroscience Division. Mr. Chazanovitz was the founder of Innerventions, Inc. in 1995, which he later merged with Nitinol Medical Technologies, Inc., where he held the position of President of the Septal Repair Division until June 1998. Mr. Chazanovitz has held the position of President for several divisions of C.R. Bard, Inc., including Bard Ventures, Bard Electrophysiology Division and USCI Angiography Division. Mr. Chazanovitz holds a B.S. in Biology from City College of New York and an M.B.A. in Marketing from Long Island University.

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

Eric Dufford. Mr. Dufford became our Vice President, Sales and Marketing and Secretary in August 1997. From January 1990 to May 1994, Mr. Dufford was Director of International Sales for St. Jude Medical, Inc. From May 1994 to August 1997, Mr. Dufford was Division President of Quest Medical Inc.'s Cardiovascular Systems Division. Mr. Dufford earned a B.A. in International Business/ Marketing from the University of Colorado and an M.B.A. from Emory University.

James Sheppard. Mr. Sheppard became our Vice President, Operations in August 1999. From 1996 to 1998, Mr. Sheppard was Vice President, Operations for Nitinol Medical Technology, Inc. From 1995 to 1996, Mr. Sheppard served as Director of Manufacturing for Summit Technology and from 1982 to 1994 he served in several senior management positions at C.R. Bard, Inc. Mr. Sheppard holds a BS in Industrial Engineering from Virginia Polytechnic Institute and State University.

Kevin S. Librett. Mr. Librett was promoted to the position of Vice President, Research and Development in April 2000. Mr. Librett joined Cambridge Heart as a Senior Software Engineer in

August 1993. From August 1995 to August 1997, he served as Software Development Manager. From September 1997 to March 2000 he was Director, Research and Development. Mr. Librett is the inventor or co-inventor of five issued U.S. patents and two pending U.S. patents related to the measurement, assessment and display of myocardial electrical stability. Mr. Librett holds a B.S. in Biophysics from the University of Connecticut and an M.S. in Electrical Engineering and Computer Science from The Massachusetts Institute of Technology.

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 Shareholder Matters*

Market Information and Holders

Shares of our common stock have been traded on the Nasdaq National Market under the symbol "CAMH" since August 2, 1996. Prior to August 2, 1996, our shares were not publicly traded. Our common stock is not traded on any market, foreign or domestic, other than the Nasdaq National Market. The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock as reported on the Nasdaq National Market during the two most recent fiscal years.

	Fiscal 2000		Fiscal 2001	
Period	High	Low	High	Low
First Quarter	$7.50	$2.75	$4.50	$2.00
Second Quarter	$5.25	$2.19	$3.37	$1.78
Third Quarter	$5.00	$2.88	$3.47	$1.40
Fourth Quarter	$4.50	$1.81	$3.00	$1.00

The depositary for our common stock is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005. On March 12, 2002, we had approximately 115 holders of Common Stock of record. This number does not include shareholders 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.

Item 6. *Selected Financial Data*

The following data, insofar as it relates to the years 1997, 1998, 1999, 2000 and 2001, have been derived from our audited financial statements. Our balance sheet dated as of December 31, 2000 and 2001 and the related statements of operations dated for each of the three years in the period ended December 31, 2001 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. This data is in thousands, except per share data.

	Year Ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 1,448	$ 2,097	$ 2,136	$ 1,910	$ 3,112
Cost of goods sold	1,386	1,848	2,007	1,879	2,431
Gross profit (loss)	62	249	129	31	681
Costs and expenses:					
Research and development	3,587	3,595	2,850	2,694	1,845
Selling, general and administrative	3,392	3,753	4,945	5,509	5,702
Total costs and expenses	6,979	7,348	7,795	8,203	7,547
Loss from operations	(6,917)	(7,099)	(7,666)	(8,172)	(6,866)
Interest income, net	869	562	331	573	400
Net loss	$ (6,048)	$ (6,537)	$ (7,335)	$ (7,599)	$ (6,466)
Net loss per share—basic and diluted	$ (0.58)	$ (0.61)	$ (0.61)	$ (0.50)	$ (0.37)
Weighted average shares outstanding—basic and diluted(1)	10,451,560	10,746,844	11,933,261	15,331,565	17,340,789

	December 31,				
	1997	1998	1999	2000	2001
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 12,756	$ 6,490	$ 9,176	$ 11,455	$ 8,738
Working capital	13,456	6,761	8,950	11,258	8,669
Long term debt					101
Total assets	14,748	8,715	11,454	13,975	11,900
Total liabilities	527	902	1,404	1,293	1,981
Accumulated deficit	(15,163)	(21,700)	(29,036)	(36,635)	(43,102)
Stockholders' equity	14,221	7,813	10,049	12,682	9,918

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 such key problems in cardiac diagnosis as the identification of those at risk of sudden cardiac arrest. Our proprietary technology and products are the only diagnostic tool cleared by the U.S. Food and Drug Administration to non-invasively measure Microvolt levels of T-Wave Alternans, an extremely subtle beat-to-beat fluctuation in a patient's heartbeat.

During 2001 we completed the transition of our primary focus from research and development of our proprietary Microvolt T-Wave Alternans technology to sales and marketing of our products. Our efforts are targeted on penetration of a new market with our Heartwave and Micro-V Alternans Sensors products distributed through our direct sales organization in the United States. At the end of 2001, 58% of our employees were engaged in field sales, clinical support and the marketing of our

Microvolt T-Wave Alternans technology. Our CH 2000 stress test system is now distributed exclusively in the U.S. and on a non-exclusive basis outside the U.S., by Philips.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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 incentives, product returns, bad debts, inventories, investments, intangible assets, income taxes, financing operations, warranty obligations, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

Our revenues are 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 maintenance contracts and licenses agreements is recorded over the term of the underlying agreement. Payments received in advance of services being performed is recorded as deferred revenue.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Inventory Obsolescence

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

Long-Lived Assets

Property, plant and equipment are stated at cost less accumulated depreciation. Major renewals and improvements are capitalized; minor replacements, maintenance and repairs are charged to current operations. Depreciation is computed by applying the straight-line method over the estimated useful lives of machinery and equipment (three to seven years). Leasehold improvements are amortized over the shorter of the useful life of the improvement or the life of the related lease. We perform reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Intangible Assets

Intangible assets primarily relate to the value of capitalized software. The cost of capitalized software is amortized on a straight-line basis over the estimated lives of up to three years. Intangible

assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Results of Operations

Fiscal 2001 Compared to Fiscal 2000

Total revenue was $3,112,000 during Fiscal 2001, and $1,909,900 during Fiscal 2000, an increase of 63%. The increase during Fiscal 2001 was primarily due to a 64% increase in revenue from the sale of our Alternans products, primarily Heartwave and Micro-V Alternans Sensors. In addition, revenue from the sale of our CH 2000 Stress Test System increased by 69% over Fiscal 2000 as a result of increased orders from our European distributors and sales to our exclusive U.S. distributor, Philips, during 2001.

U.S. revenue was $2,180,000 during Fiscal 2001 and $1,150,100 during Fiscal 2000, an increase of 90%. Revenue from our core business (U.S. sales of Heartwave and Micro-V Alternans Sensors) during Fiscal 2001 increased 124% compared to Fiscal 2000. Sales of our Microvolt T-Wave Alternans equipment increased 116%, while sales of our Micro-V Alternans Sensors increased 162% during Fiscal 2001. U.S. revenue from the sale of our CH 2000 Stress Test system increased 28% in Fiscal 2001 compared to Fiscal 2000. These standard stress products are sold exclusively in the U.S. by Philips.

International revenue was $932,000 during Fiscal 2001 and $760,100 during Fiscal 2000, an increase of 23%. Revenue from the sale of standard stress test systems increased 116% in Fiscal 2001. This is primarily the result of an increase in orders from our European distributor in the United Kingdom that were funded by government resources designated specifically for the upgrade of cardiology equipment in public hospitals. Revenue from the sale of Microvolt T-Wave Alternans systems declined during Fiscal 2001, primarily as a result of a change in emphasis from the higher priced CH 2000 System to the more flexible, lower priced Heartwave System.

Gross profit was 22% of total revenue in Fiscal 2001 compared to 2% for Fiscal 2000. The improvement in the margin percentage to sales reflects the favorable effect of higher sales of our more profitable Heartwave and Micro-V Alternans Sensors by lowering the amount of labor and overhead costs required to manufacture each unit. Additionally, the supplier cost reductions had a favorable effect on overall gross margins.

Research and development costs were $1,845,300 in Fiscal 2001 compared to $2,694,500 in Fiscal 2000, a decrease of 32%. Costs incurred during the first half of 2000 reflected the development efforts associated with our Heartwave stress and EP systems. Both versions of the product were introduced to the market during the second half of 2000. Research and development costs during 2001 were primarily in support of key clinical studies and selected development programs, including the development of a new Microsoft Windows 2000® operating system for our CH 2000 stress test system distributed exclusively in the U.S. by Philips.

Selling, general and administrative expenses were $5,701,800 in Fiscal 2001 compared to $5,508,600 in Fiscal 2000, an increase of 4%. We incurred increased costs associated with the recruitment and hiring of 7 additional direct sales representatives during Fiscal 2001. We anticipate that our costs during Fiscal 2002 will increase, as we expect to continue the expansion of our U.S. sales organization in additional major metropolitan areas.

Interest income was $399,300 in Fiscal 2001 compared to $573,100 in Fiscal 2000, a decrease of 30%. This decrease resulted from a lower level of invested cash during Fiscal 2001 as compared to Fiscal 2000 and the decline in both short and long term interest rates during the last twelve month period.

Fiscal 2000 Compared to Fiscal 1999

Total revenues were $1,909,900 during Fiscal 2000 and $2,136,000 during the twelve month period ended December 31, 1999, which we refer to as Fiscal 1999, a decrease of 11%. The decrease during Fiscal 2000 was led by a 20% decline in sales during the first nine months of 2000 compared to the same period in 1999. This was the result of our decision to focus all of our sales efforts on our Alternans technology and away from the standard stress test market, which had accounted for a major portion of our revenue in Fiscal 1999. However, revenue during the fourth quarter of Fiscal 2000 increased 40% over the average of the three previous quarters of Fiscal 2000. This increase was primarily the result of the introduction of our new Heartwave System during the third quarter of Fiscal 2000.

U.S. revenue was $1,150,100 during Fiscal 2000 and $1,087,700 during Fiscal 1999, an increase of 6%. Revenue from the sale of all Microvolt T-Wave Alternans products (CH 2000, Heartwave, Micro-V Alternans Sensors) during Fiscal 2000 increased 74% compared to Fiscal 1999. Sales of Microvolt T-Wave Alternans equipment, both our CH 2000 and Heartwave products, increased 64%, while sales of Micro-V Alternans Sensors increased 140% during Fiscal 2000. Revenue from the sale of standard stress test systems declined 53% in Fiscal 2000 compared to Fiscal 1999 reflecting the change in our focus away from the standard stress market.

International revenue was $760,100 during Fiscal 2000, and $1,048,300 during Fiscal 1999, a decrease of 27%. Revenue from the sale of equipment declined 32% in Fiscal 2000. This was primarily the result of our Japanese distributors efforts to reduce its inventory levels of CH 2000 in advance of the introduction of the Heartwave to Japan, in the second half of 2001. Revenue from the sale of Micro-V Alternans Sensors to international distributors in Fiscal 2000 increased 46% over Fiscal 1999.

Our revenue recognition method for license fees has been to recognize income ratably over the term of the license. License fee revenue for Fiscal 2000 and Fiscal 1999 was $50,000 each year.

Gross profit was 2% of total revenue in Fiscal 2000 compared to 6% for Fiscal 1999. The decrease was the result of higher costs incurred on initial Heartwave units shipped during the third and fourth quarters of Fiscal 2000.

Research and development costs were $2,694,500 in Fiscal 2000 compared to $2,850,400 in Fiscal 1999, a decrease of 5%. Costs associated with the design and development of our new Heartwave products accounted for a major portion of the costs incurred during Fiscal 2000. These costs were partially offset by reduced costs associated with lower levels of clinical and regulatory activity during Fiscal 2000 when compared to Fiscal 1999.

Selling, general and administrative expenses were $5,508,600 in Fiscal 2000 compared to $4,945,500 in Fiscal 1999, an increase of 11%. The growth in Fiscal 2000 expenditures include, costs incurred for the promotion of our new Heartwave products, introduced late in Fiscal 2000, and expenses in support of our efforts to gain favorable reimbursement from third-party insurers for healthcare providers for their performance of a Microvolt T-Wave Alternans tests. In addition, we incurred costs associated with the recruitment and hiring of 5 additional direct sales representatives in the second half of Fiscal 2000. General and administrative expenses increased during Fiscal 2000 as a result of costs incurred for the recruitment and hiring of key personnel.

Interest income was $573,100 in Fiscal 2000 compared to $331,100 in Fiscal 1999, an increase of 73%. This increase resulted from a higher level of invested cash resulting from the sale of 2,990,000 shares of our common stock in two private placements completed in January 2000 and September 2000.

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, 2001.

We have not recorded a provision for income taxes for the years 1997, 1998, 1999, 2000 and 2001 because we incurred net losses in each of such years. At December 31, 2001, we had net operating loss carryforwards of $35,610,000 as well as $1,071,000 of federal and $562,000 of state tax credit carryforwards, available to offset future taxable income and income tax liabilities, respectively. These carryforwards generally expire in the years 2007 through 2021 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 ($35,610,000) at December 31, 2001 for our deferred tax assets since, in our opinion, realization of these future benefits is not sufficiently assured (defined as a likelihood of slightly more than 50 percent).

Quarterly Financial Results

The following tables set forth a summary of our unaudited quarterly results of operations for 2001 and 2000. In the opinion of management, this information has been prepared on the same basis as the audited Consolidated 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 Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. The quarterly operating results are not necessarily indicative of future results of operations.

	Three Months Ended (Unaudited)			
	March 31, 2001	June 30, 2001	Sept 30, 2001	Dec 31, 2001
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 678	$ 739	$ 837	$ 858
Cost of goods sold	514	597	659	661
Gross profit (loss)	164	142	178	197
Costs and expenses:				
Research and development	564	461	354	466
Selling, general and administrative	1,498	1,488	1,361	1,355
Total costs and expenses	2,062	1,949	1,715	1,821
Loss from operations	(1,898)	(1,807)	(1,537)	(1,624)
Interest income, net	185	105	76	34
Net loss	$(1,713)	$(1,702)	$(1,461)	$(1,590)
Net loss per share—basic and diluted	$ (0.10)	$ (0.10)	$ (0.09)	$ (0.09)

	Three Months Ended (Unaudited)			
	March 31, 2000	June 30, 2000	Sept 30, 2000	Dec 31, 2000
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$ 413	$ 458	$ 433	$ 607
Cost of goods sold	435	455	424	565
Gross profit (loss)	(22)	3	9	42
Costs and expenses:				
Research and development	924	662	677	431
Selling, general and administrative	1,269	1,350	1,368	1,523
Total costs and expenses	2,193	2,012	2,045	1,954
Loss from operations	(2,215)	(2,009)	(2,036)	(1,912)
Interest income, net	129	120	102	222
Net loss	$(2,086)	$(1,889)	$(1,934)	$(1,690)
Net loss per share—basic and diluted	$ (0.14)	$ (0.13)	$ (0.13)	$ (0.10)

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2001	June 30, 2001	Sept 30, 2001	Dec 31, 2001
Statement of Operations Data:				
Revenue	100%	100%	100%	100%
Cost of goods sold	76%	81%	79%	77%
Gross profit (loss)	24%	19%	21%	23%
Costs and expenses:				
Research and development	83%	62%	42%	54%
Selling, general and administrative	221%	201%	163%	158%
Total costs and expenses	304%	263%	205%	212%
Loss from operations	(280%)	(244%)	(184%)	(189%)
Interest income, net	27%	14%	9%	4%
Net loss	(253%)	(230%)	(175%)	(185%)

	As a Percentage of Total Revenues Three Months Ended (Unaudited)			
	March 31, 2000	June 30, 2000	Sept 30, 2000	Dec 31, 2000
Statement of Operations Data:				
Revenue	100%	100%	100%	100%
Cost of goods sold	105%	99%	98%	93%
Gross profit (loss)	(5%)	1%	2%	7%
Costs and expenses:				
Research and development	224%	145%	156%	71%
Selling, general and administrative	307%	295%	316%	251%
Total costs and expenses	531%	440%	472%	322%
Loss from operations	(536%)	(439%)	(470%)	(315%)
Interest income, net	31%	26%	24%	37%
Net loss	(505%)	(413%)	(447%)	(279%)

Liquidity and Capital Resources

During Fiscal 2001, we raised gross proceeds of $3,558,800 from the sale of common stock. In addition, we used $749,800 of a $1,000,000 line of credit collateralized by the Company's assets at the end of Fiscal 2001. These financing activities offset cash used to fund the increased level of operations, with corresponding increases in most balance sheet accounts. Cash, cash equivalents and marketable securities decreased by $2,716,900 from December 31, 2000 to December 31, 2001, consistent with our net loss for Fiscal 2001 net of total financing activities. Accounts receivable, net, increased by $377,900 during the year, reflecting increase in sales in Fiscal 2001 compared with Fiscal 2000. Inventory increased by $267,570 during the year, resulting from planned inventory builds to support our increase in sales volume, as well as, the postponement of fourth quarter 2001 shipments of Philips CH 2000 stress systems. Fixed asset additions during the year primarily represent increased sales demonstration, clinical research units and additional information systems infrastructure.

The proceeds of our equity offerings have been used primarily to fund the accumulated deficit of $43,101,609 reflecting expenditures to support research, new product development and clinical trials activities, expansion of our sales organization, and to support an administrative infrastructure and the

investment of approximately $2,022,900 in property and equipment through December 31, 2001. As of December 31, 2001, we had cash, cash equivalents and marketable securities of $8,738,300.

Under the terms of various 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 $30,000 per year through 2008. We are committed to pay an aggregate of $210,000 of such minimum license maintenance fees subsequent to December 31, 2001. As part of these agreements, the Company is also committed to meet certain development and sales milestones, including a requirement to spend a minimum of $200,000 in any two-year period for research and development, clinical trials, marketing, sales and/or manufacturing of products related to certain technology covered by the consulting and technology agreements.

We anticipate that our existing capital resources will be adequate to satisfy our capital requirements for at least the next 12 months.

Contractual Obligations and Commercial Commitments

Our major contractual obligations are included in the table below. There are no major commercial commitments as of December 31, 2001.

	Payments Due by Period				
Contractual Obligations	Total	2002	2003	2004	2005 And Beyond
Equipment loan	$249,803	$146,116	$ 92,314	$11,941	$ —
Operating leases	$384,344	$200,486	$179,659	$ 2,642	$ 1,557
License maintenance fees	$210,000	$ 30,000	$ 30,000	$30,000	$90,000
Total Contractual Obligations	$844,147	$376,602	$201,973	$44,583	$91,557

New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires business combinations initiated after June 30, 2001 to be accounted for using the purchase method of accounting. It also specifies the types of acquired intangible assets that are required to be recognized and reported separately from goodwill. SFAS 142 will require that goodwill and certain intangibles no longer be amortized, but instead tested for impairment at least annually. SFAS 142 is required to be applied starting with fiscal years beginning after December 15, 2001, with early applications permitted in certain circumstances. We do not expect that the adoption of FAS 141 and 142 will have a significant impact on our financial statements.

In June 2001, The FASB issued Statement of Financial accounting Standards No. 143 ("SFAS 143"), "Accounting for Asset Retirement Obligations," which is effective January 1, 2003. SFAS addresses the financial accounting and reporting for obligations and retirement costs related to the retirement of tangible long-lived assets. We do not expect that the adoptions of SFAS 143 will have significant impact on our financial statements.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets", which is effective January 1, 2002. SFAS 144 Supersedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions relating to the disposal of long-lived assets. We do not expect that the adoptions of SFAS 144 will have a significant impact on our financial statements.

Factors Which May Affect Future Results

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

Risks Related to our Operations

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

We are engaged primarily in the commercialization, manufacture, research and development of products for the non-invasive diagnosis of heart disease. We have incurred substantial and increasing net losses through December 31, 2001. We may never generate substantial revenues or achieve profitability on a quarterly or annual basis. We expect that our selling, general and administrative expenses will increase significantly in connection with the expansion of our sales and marketing activities. Revenues generated from the sale of our products will depend upon numerous factors, including:

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

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

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

We 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 could not be found on a timely basis in the relevant geographic market. To the extent that we rely on sales in certain territories through distributors, 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.

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 revenues could decline

We believe that our future success will depend, in large part, upon the successful commercialization and market acceptance of our Microvolt T-Wave Alternans technology. Market acceptance will depend upon our ability to demonstrate the diagnostic advantages and cost-effectiveness of this technology. The failure of our Microvolt T-Wave Alternans technology to achieve broad market acceptance, the failure of the market for our products to grow or to grow at the rate we anticipate, or a decline in the price of our products would reduce our revenues. This could have a material adverse effect on the market price of our common stock. We can give no assurance that we will be able to successfully commercialize or achieve market acceptance of our Microvolt T-Wave Alternans technology or that our competitors will not develop competing technologies that are superior to our technology.

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

We have sponsored and are continuing to sponsor clinical studies relating to our Microvolt T-Wave Alternans technology and Micro-V Alternans Sensors to more firmly establish the predictive value of such technology. Although studies on high risk patients to date have indicated that the measurement of Microvolt T-Wave Alternans to predict the vulnerability to ventricular arrhythmia is comparable to electrophysiology testing, we do not know whether the results of such studies, particularly studies involving patients who are not at high risk, will continue to be favorable. Any clinical studies or trials which fail to demonstrate that the measurement of Microvolt T-Wave Alternans is at least comparable in accuracy to alternative diagnostic tests, or which otherwise call into question the cost-effectiveness, efficacy or safety of our technology, would have a material adverse effect on our business, financial condition and results of operations.

We may have difficulty responding to changing technology

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

We depend heavily on a third party, to support the commercialization of our CH 2000 stress test system.

We rely solely on a single third party to commercialize our CH 2000 stress test system in the United States. Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to commercializing our products may not be within our control. The third parties on which we rely may not be able to recruit and retain skilled sales representatives. Furthermore, our interests may differ from those of third parties that commercialize our products. Disagreements that may arise with third parties could limit the commercialization of our products, or result in litigation or arbitration, which would be time-consuming, distracting and expensive. If any third party that supports the commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, such breach, termination or failure could:

- limit the continued commercialization of our CH 2000 product,
- require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the commercialization of this product, or

- result in the termination of the commercialization of this product,

and the resulting disruption of our business could have a material adverse effect on our results of operations.

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

Competition from competitors' medical devices that diagnose cardiac disease is intense and likely to increase. Our success will depend on our ability to develop products and apply our technology and our ability to establish and maintain a market for our products. We compete with manufacturers of electrocardiogram stress tests, the conventional method of diagnosing ischemic heart disease, as well as with manufacturers of other invasive and non-invasive tests, including EP testing, electrocardiograms, Holter monitors, ultrasound tests and systems of measuring cardiac late potentials. Many of our competitors and prospective competitors have substantially greater capital resources, name recognition, research and development experience and regulatory, manufacturing and marketing capabilities. Many of these competitors offer broad, well-established product lines and ancillary services not offered by Cambridge Heart. Some of our competitors have long-term or preferential supply arrangements with physicians and hospitals which may act as a barrier to market entry.

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

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

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

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

Risks Related to the Market for Cardiac Diagnostic Equipment

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

The testing, manufacture, marketing and sale of medical devices entails the inherent risk of liability claims or product recalls. Although we maintain product liability insurance in the United States and in other countries in which we conduct business, including clinical trials and product marketing and sales, such coverage may not be adequate. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or product recall could inhibit or prevent commercialization of the CH 2000 and the Heartwave systems, or cause a significant

financial burden on Cambridge Heart, or both, and could have a material adverse effect on our business, financial condition, and ability to market the both systems as currently contemplated.

We may not be able to maintain adequate levels of third-party reimbursement

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

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

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

Others could claim that we infringe their intellectual property rights

Our commercial success will depend in part on our neither infringing patents issued to others nor breaching the licenses upon which our products might be based. We have licensed significant technology and patents from third parties, including patents and technology relating to Microvolt T-Wave Alternans and cardiac electrical imaging licensed from The Massachusetts Institute of Technology. Our licenses of patents and patent applications impose various commercialization, sublicensing, insurance, royalty and other obligations on our part. If we fail to comply with these requirements, licenses could convert from being exclusive to nonexclusive in nature or could terminate.

We could become involved in litigation over intellectual property rights

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Litigation, which would likely result in substantial cost to us, may be

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

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

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

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

We own financial instruments that are sensitive to market risk as part of our investment portfolio. The investment portfolio is 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. These investments are evaluated 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 Financial Statements for a description of our other financial instruments. We carry the amounts reflected in the balance sheet of cash and cash equivalents, trade receivables, trade payables, and line of credit at fair value at December 31, 2001 due to the short maturities of these instruments.

Item 8. *Financial Statements and Supplementary Data*

CAMBRIDGE HEART, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the accompanying balance sheets and the related statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Cambridge Heart, Inc. at December 31, 2000 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Boston, Massachusetts
January 24, 2002

CAMBRIDGE HEART, INC.
BALANCE SHEET

	December 31, 2000	December 31, 2001
Assets		
Current assets:		
Cash and cash equivalents	$ 1,305,845	$ 2,162,304
Marketable securities	10,149,397	6,576,036
Accounts receivable, net of allowance for doubtful accounts of $54,807 and $36,610 at December 31, 2000 and 2001, respectively	617,619	995,476
Inventory	406,096	673,666
Prepaid expenses and other current assets	72,058	141,268
Total current assets	12,551,015	10,548,750
Fixed assets, net	827,211	662,024
Other assets	596,782	688,775
	$13,975,008	$11,899,549
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 578,050	$ 574,409
Accrued expenses	507,751	657,079
Short term debt	206,958	648,322
Total current liabilities	1,292,759	1,879,810
Long term debt	—	101,481
Total liabilities	1,292,759	1,981,291
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 2,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2000 and 2001	—	—
Common Stock, $0.001 par value; 50,000,000 shares authorized; 17,052,597 and 19,266,751 shares issued and outstanding at December 31, 2000 and 2001, respectively	17,053	19,267
Additional paid-in capital	49,326,663	53,010,063
Accumulated deficit	(36,635,176)	(43,101,609)
	12,708,540	9,927,721
Less: deferred compensation	(26,291)	(9,463)
	12,682,249	9,918,258
	$13,975,008	$11,899,549

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

CAMBRIDGE HEART, INC.

STATEMENT OF OPERATIONS

	Year Ended December 31,		
	1999	2000	2001
Revenue	$ 2,135,981	$ 1,909,883	$ 3,112,037
Cost of goods sold	2,006,557	1,879,246	2,430,646
Gross Profit	129,424	30,637	681,391
Costs and expenses:			
Research and development	2,850,423	2,694,483	1,845,331
Selling general and administrative	4,945,499	5,508,596	5,701,802
Loss from operations	(7,666,498)	(8,172,442)	(6,865,742)
Interest income	331,084	573,069	399,309
Net loss	$(7,335,414)	$(7,599,373)	$(6,466,433)
Net loss per share—basic and diluted	$ (0.61)	$ (0.50)	$ (0.37)
Weighted average shares outstanding—basic and diluted	11,933,261	15,331,565	17,340,789

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

CAMBRIDGE HEART

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional paid-in capital	Accumulated deficit	Deferred compensation	Total stockholders' equity
	Number of Shares	Par value				
Balance at December 31, 1998	10,906,174	$10,906	$29,603,435	$(21,700,389)	$(101,010)	$ 7,812,942
Issuance of common stock through exercise of stock options, and employee stock purchase plan	16,707	17	56,770			56,787
Compensation related to non-employee stock options granted			20,428			20,428
Amortization of deferred compensation			(29,800)		51,574	21,774
Sale of common stock through a private placement net of fees	2,998,476	2,998	9,469,772			9,472,770
Net loss				(7,335,414)		(7,335,414)
Balance at December 31, 1999	13,921,357	$13,921	$39,120,605	$(29,035,803)	$ (49,436)	$10,049,287
Issuance of common stock through exercise of stock options, warrants and employee stock purchase plan	96,080	96	350,350			350,446
Compensation related to non-employee stock options granted			118,342			118,342
Amortization of deferred compensation			(7,655)		23,145	15,490
Sale of common stock through a private placement net of fees	3,035,160	3,036	9,745,021			9,748,057
Net loss				(7,599,373)		(7,599,373)
Balance at December 31, 2000	17,052,597	$17,053	$49,326,663	$(36,635,176)	$ (26,291)	$12,682,249
Issuance of common stock through exercise of stock options, warrants and employee stock purchase plan	633,695	634	873,466			874,100
Compensation related to non-employee stock options granted			67,525			67,525
Amortization of deferred compensation			(3,208)		16,828	13,620
Sale of common stock through a private placement net of fees	1,580,459	1,580	2,745,617			2,747,197
Net loss				(6,466,433)		(6,466,433)
Balance at December 31, 2001	19,266,751	$19,267	$53,010,063	$(43,101,609)	$ (9,463)	$ 9,918,258

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

CAMBRIDGE HEART, INC.

STATEMENT OF CASH FLOWS

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

	Year ended December 31,		
	1999	2000	2001
Cash flows from operating activities:			
Net loss	$(7,335,414)	$(7,599,373)	$(6,466,433)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	573,518	595,487	617,886
Loss on disposal of fixed assets	9,518	18,398	
Compensation expense on stock options	42,202	133,832	81,145
Changes in operating assets and liabilities:			
Accounts receivable	(21,165)	(40,463)	(377,857)
Inventory	(34,424)	54,817	(267,570)
Prepaid expenses and other current assets	50,470	68,139	(69,210)
Other assets	2,037	(30,332)	(31,884)
Accounts payable and accrued expenses	295,804	(111,795)	145,687
Net cash used for operating activities	(6,417,454)	(6,911,290)	(6,368,236)
Cash flows from investing activities:			
Purchases of fixed assets	(376,659)	(507,932)	(185,898)
Capitalization of software development costs	(256,208)	(400,586)	(326,910)
Purchases of marketable securities	(2,454,603)	(3,630,473)	—
Liquidation of marketable securities	—	—	3,573,361
Net cash (used in) provided by investing activities	(3,087,470)	(4,538,991)	3,060,553
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	9,529,557	10,098,503	3,621,297
Proceeds from utilization of bank credit line	206,727	231	542,845
Net cash provided by financing activities	9,736,284	10,098,734	4,164,142
Net increase (decrease) in cash and cash equivalents	231,360	(1,351,547)	856,459
Cash and cash equivalents, beginning of year	2,426,032	2,657,392	1,305,845
Cash and cash equivalents, end of year	$ 2,657,392	$ 1,305,845	$ 2,162,304

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

Supplemental Disclosure of Cash Flow Information

During 1999, 2000 and 2001 the Company paid $0, $12,056 and $13,244, respectively, in interest expense.

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 anticipates that its existing capital resources will be adequate to satisfy its capital requirements through December 2002. Thereafter, the Company may require additional funds to support its operating requirements or for other purposes and may seek to raise such additional funds through public or private equity financing or from other sources. There can be no assurance that additional financing will be available at all or that, if available, such financing would be obtainable on acceptable terms to the Company.

2. Summary of Significant Accounting Policies

Significant accounting policies followed by the Company are as follows:

Cash Equivalents and Marketable Securities

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. Marketable Securities consist of money market accounts, short-term securities of state government agencies, and short-term corporate bonds and commercial paper of companies with strong credit ratings and in diversified industries. The short-term securities of state government agencies are redeemable at their face value, and bear interest at variable rates which are adjusted on a frequent basis. Accordingly, these investments are subject to minimal credit and market risk. The short-term corporate bonds and short-term securities of state government agencies with maturities greater than three months from date of purchase, totaling $10,149,397 and $6,576,036 at December 31, 2000 and 2001, respectively, are classified as held to maturity, and mature within one year. The short-term commercial paper, short-term securities of state government agencies with maturities less than three months from date of purchase and money market securities, totaling $1,112,857 and $1,586,246 at December 31, 2000 and 2001, respectively, are classified as cash equivalents. All of these investments have been recorded at amortized cost, which approximates fair market value. No realized or unrealized gains or losses have been recognized.

Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, accounts receivable, accounts payable, and accrued expenses approximate their fair values at December 31, 2000 and 2001.

Inventories

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

2. Summary of Significant Accounting Policies (Continued)

Fixed Assets

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

Segment

Management uses consolidated financial information in determining how to allocate resources and assess performance. For this reason, the Company has determined that it is engaged principally in one industry segment. See Note 12 with respect to significant customers and with respect to sales in other geographic areas.

Revenue Recognition

The Company generally recognizes product revenue upon shipment of goods provided that risk of loss has passed to the customer, all obligations of the Company have been fulfilled, persuasive evidence of an arrangement exists, the fee is fixed or determinable, and collectibility is probable. Revenue from maintenance contracts and licenses is recorded over the term of the underlying agreement. Payments received in advance of services being performed is recorded as deferred revenue.

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 requires 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.

The Company amortizes software development costs on a straight-line basis over the estimated economic life of the product generally 3 years.

Costs capitalized at December 31, 2001, which are included in other assets in the accompanying balance sheet, totaled $620,000 ($540,000 at December 31, 2000), net of $786,000 of accumulated amortization ($539,000 at December 31, 2000).

Licensing Fees and Patent Costs

The Company has entered into licensing agreements which give 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 these licensing agreements 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

2. Summary of Significant Accounting Policies (Continued)

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. Amounts capitalized at December 31, 2001 totaled $61,000 ($57,000 at December 31, 2000), net of $109,000 of accumulated amortization ($89,000 at December 31, 2000), which are included in other assets in the accompanying balance sheet.

Stock-Based Compensation

The Company accounts for employee awards under its stock plans in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. The Company adopted Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), for disclosure purposes only (Note 7). All stock based awards to non-employees are accounted for at their fair value as prescribed by SFAS 123 and EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in conjunction with Selling, Goods or Services".

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingencies and the reported amounts of revenues and expenses. Amounts subject to these estimates include Revenue recognition reserves for doubtful accounts, inventory valuation, and estimated liabilities. Actual results could differ from these estimates.

Net Loss Per Share

We report earnings per share in accordance with Statement of Financial Accounting Standards No. 128 ("SFAS 128"), "Earnings per Share". Basic earnings per share excludes dilution and is computed by dividing income available to common stockholders by the weighted-average number of common shares outstanding for the period. Options to purchase 1,705,450, 1,979,250 and 2,954,000 shares of common stock were not included in the 1999, 2000 and 2001 computation of diluted loss per share, respectively, because inclusion of such options would have had an anti-dilutive effect on the net loss per share.

As a result of the Company's net loss both basic and diluted earnings per share are computed by dividing the net loss available to common shareholders by the weighted average number of shares of common stock outstanding.

Comprehensive Income

Comprehensive income is comprised of two components, net income and other comprehensive income. For the years ended December 31, 2001, 2000 and 1999, the Company had no other comprehensive income.

New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires business combinations initiated after June 30, 2001 to

2. Summary of Significant Accounting Policies (Continued)

be accounted for using the purchase method of accounting. It also specifies the types of acquired intangible assets that are required to be recognized and reported separately from goodwill. SFAS 142 will require that goodwill and certain intangibles no longer be amortized, but instead tested for impairment at least annually. SFAS 142 is required to be applied starting with fiscal years beginning after December 15, 2001, with early applications permitted in certain circumstances. We do not expect that the adoption of FAS 141 and 142 will have a significant impact on our financial statements.

In June 2001, The FASB issued Statement of Financial accounting Standards No. 143 ("SFAS 143"), "Accounting for Asset Retirement Obligations," which is effective January 1, 2003. SFAS addresses the financial accounting and reporting for obligations and retirement costs related to the retirement of tangible long-lived assets. We do not expect that the adoptions of SFAS 143 will have significant impact on our financial statements.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets", which is effective January 1, 2002. SFAS 144 Supersedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions relating to the disposal of long-lived assets. We do not expect that the adoptions of SFAS 144 will have a significant impact on our financial statements.

3. Fixed Assets

Fixed assets consist of the following:

	Estimated useful lives (years)	December 31, 2000	December 31, 2001
Computer equipment	3–5	$ 579,721	$ 623,816
Manufacturing equipment	5	380,568	409,745
Office furniture	7	85,552	85,552
Sales demonstration and clinical equipment	3	791,125	903,751
		1,836,966	2,022,864
Less—accumulated depreciation		1,009,755	1,360,840
		$ 827,211	$ 662,024

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2000	2001
Accrued employee compensation	$239,111	$325,734
Accrued clinical trial costs	48,000	78,400
Accrued professional fees	54,558	44,700
Accrued other	166,082	208,245
	$507,751	$657,079

5. Line of Credit

The Company has a working capital line in place which provides a borrowing base of 75% of eligible accounts receivable as defined in the agreement, up to a maximum borrowing of $500,000, payable on demand. Interest is payable monthly in arrears at the bank's prime rate plus .5% (5.25% at December 31, 2001). This working capital line is scheduled to expire on May 31, 2002. In addition, the Company utilizes a $500,000 equipment line available for financing the purchase of eligible capital equipment, including computer hardware and manufacturing molds and tooling as defined in the agreement. Interest is payable monthly in arrears at the bank's prime rate plus 1.5% (6.25% at December 31, 2001). The equipment line of credit matures on various dates between June 2003 and September 2004. The amount outstanding on both lines of credit at December 31, 2001 is $749,803 of which $148,843 is scheduled for repayment in 2002, $89,019 in 2003 and $11,941 in 2004. Both credit lines are collateralized by all of the Company's assets as defined in the agreement. The Company has incurred interest expense related to both line of credits of $13,244 in 2001, $12,056 in 2000, and $0 in 1999.

6. Stockholders' Equity

Preferred Stock

The Company's Board of Directors has authorized 2,000,000 shares of the Company's $0.001 par value preferred stock. The preferred stock may be issued at the discretion of the Board of Directors of the Company (without stockholder approval) with such designations, rights and preferences as the Board of Directors may determine from time to time. This preferred stock may have dividend, liquidation, redemption, conversion, voting or other rights which may be more expansive than the rights of the holders of the common stock.

Common Stock

In a private placement transaction completed in December 2001, the Company raised gross proceeds totaling $2,750,000 from the sale of 1,580,459 shares of Common Stock at $1.74 per share. Offering expenses for this placement approximate $80,000.

Warrants

During 2001, the Company entered into agreements with holders of previously issued warrants for the purchase of 737,832 shares of common stock. Pursuant to these agreements, the exercise price per

6. Stockholders' Equity (Continued)

share of each warrant was reduced to $1.50 in exchange for a shortened exercise period and the requirement that the warrants be exercised for cash. Of these amended warrants, warrants for the purchase 539,203 shares of common stock were exercised in 2001. Total warrants for the purchase of an aggregate of 198,979 shares of common stock with amended terms were outstanding at December 31, 2001.

During 2001, warrants to purchase a total of 632,184 shares of common stock with an exercise price of $2.80 per share were issued in connections with the sale of 1,580,459 shares of commons stock.

Total warrants outstanding at December 31, 2001 were as follows:

	Number of Shares	Exercise Price Per Share	Expiration Date
Common stock	198,979	$1.500	May 5, 2002
Common stock	66,667	$3.710	June 9, 2003
Common stock	76,414	$3.500	October 6, 2004
Common stock	11,582	$4.200	December 9, 2004
Common stock	562,500	$3.500	September 14, 2005
Common stock	632,184	$2.280	December 21, 2006

7. 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 provided for the granting of incentive and non-qualified stock options to management, other key employees, consultants and directors of the Company. The total number of shares of common stock made available for issuance pursuant to the exercise of options granted under the plans was 2,962,663. No additional shares are eligible for grant under either of the plans. Under the terms of both plans, incentive stock options could 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. The total number of shares of common stock that were issued pursuant to the exercise of options granted under the 1996 Director Plan were 40,000. Of this amount 40,000 remain unexercised at December 31, 2001.

7. Stock Plans (Continued)

2001 Stock Incentive Plan

During 2001, the Board of Directors authorized the 2001 Stock Incentive Plan providing for the issuance of up to 1,700,000 shares of the Company's common stock to eligible employees, officers, directors, consultants and advisors. The total number of shares of common stock that may be issued pursuant to the exercise of options granted under the 2001 Plan are 1,123,500. 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 1999, 2000 and 2001 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, 1999, 2000 and 2001 are summarized as follows:

	December 31, 1999		December 31, 2000		December 31, 2001	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at beginning of year	1,341,500	$3.55	1,705,450	$3.53	1,979,250	$2.79
Granted	617,950	3.47	552,500	3.18	1,140,000	2.45
Exercised	(1,750)	1.20	(6,250)	1.68	(60,000)	0.20
Canceled	(252,250)	6.22	(272,450)	5.57	(105,250)	4.52
Outstanding at end of year	1,705,450	$3.53	1,979,250	$2.79	2,954,000	$2.63
Exercisable at end of year	785,128	$2.07	971,725	$2.27	1,434,067	$2.49
Weighted average fair value of options granted during the year		$0.96		$1.27		$0.45

The following table summarizes information about stock options outstanding under all of the Company's stock option plans at December 31, 2002:

Range of exercise prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number of Options Exercisable	Weighed Average Exercise Price of Options Exercisable
$.020–$2.49	809,500	6.13	$0.80	566,500	$0.59
$2.50–$3.05	1,516,500	8.53	2.71	528,167	2.71
$3.06–$9.38	628,000	7.69	4.59	339,400	5.29
	2,954,000	7.31	$2.63	1,434,067	$2.49

At December 31, 2001, 2,954,000 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there are 626,500 options available for future grant. Outstanding options generally vest on a pro rata basis over a period of three to five years.

The Company has recorded compensation expense related to options granted to non-employee consultants for services rendered, as well as options to employees repriced in 1998, totaling $20,428 in 1999, $118,342 in 2000, and $67,525 in 2001.

7. Stock Plans (Continued)

1996 Employee Stock Purchase Plan

During 1996, the Board of Directors authorized the 1996 Employee Stock Purchase Plan (the "Purchase Plan"). The Purchase Plan provides for the issuance of up to 100,000 shares of the Company's common stock to eligible employees. Under the Purchase Plan, the Company is authorized to make one or more offerings during which employees may purchase shares of common stock through payroll deductions made over the term of the offering. The term of individual offerings, which are set by the Board of Directors, may be for periods of twelve months or less and may be different for each offering. The per-share purchase price at the end of each offering is equal to 85% of the fair market value of the common stock at the beginning or end of the offering period (as defined by the Purchase Plan), whichever is lower. The Company issued 14,857, 14,961 and 34,200 shares of common stock at an average price of $3.68, $3.01 and $1.56 during 1999, 2000 and 2001 respectively. At December 31, 2001, the Company had 13,250 shares of common stock reserved for issuance under the Purchase Plan.

Fair Value Disclosures

As discussed in Note 2, the Company has elected to adopt SFAS 123 for options granted to employees for disclosure only. Had compensation cost for the Company's option plans and employee stock purchase plan been determined based on the fair value of the options at the grant dates, as prescribed in SFAS 123, for options granted in 1999, 2000 and 2001 the Company's net loss and net loss per share would have been as follows:

	Year ended December 31,		
	1999	2000	2001
Net loss:			
As reported	$7,335,414	$7,599,373	$6,466,433
Pro forma	$7,537,124	$7,869,246	$7,293,625
Net loss per share:			
As reported—basic and diluted	$ 0.61	$ 0.50	$ 0.37
Pro forma—basic and diluted	$ 0.63	$ 0.51	$ 0.42

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 1999, 2000 and 2001, respectively: (i) dividend yield of 0% for all periods; (ii) expected volatility of 0%-50%, 60%, and 50%; (iii) risk free interest rates of 6.1%-6.9%, 4.58% and 4.56%; and (iv) expected option terms of 4 years for 1999, 2000 and 2001. SFAS 123 requires that volatility be considered in the calculation of the fair value of an option grant only for grants made when an entity has publicly traded securities or has filed a registration statement to do so. Accordingly, a volatility of 0% was utilized for options granted by the Company prior to the initial filing of its Registration Statement on Form S-1 in 1996.

The above pro forma disclosures reflect options granted during 1999, 2000 and 2001 only. Because additional option grants are expected to be made each year and options vest over several years, the above pro forma disclosures are not necessarily representative of the pro forma effects of reported net income (loss) for future years.

8. Income Taxes

The income tax benefit consists of the following:

	Year ended December 31,		
	1999	2000	2001
Income tax benefit:			
Federal	$ 2,272,772	$ 2,375,768	$ 2,324,271
State	796,063	470,107	387,456
	3,068,835	2,845,875	2,711,727
Deferred tax asset valuation allowance	(3,068,835)	(2,845,875)	(2,711,727)
	$ —	$ —	$ —

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

	December 31,		
	1999	2000	2001
Net operating loss carryforwards	$ 12,307,604	$ 15,049,459	$ 14,313,684
Research and development tax credit carryforwards	1,451,927	1,525,425	1,465,918
Capitalized research and development	—	—	3,430,042
Other	58,292	77,403	187,893
Gross deferred tax assets	13,817,823	16,652,287	19,397,537
Capitalized software	(138,142)	(158,893)	(331,305)
Fixed assets	(46,261)	(14,829)	(63,695)
Patent costs	(24,453)	(23,723)	(38,017)
Net deferred tax assets	13,608,967	16,454,842	18,964,520
Deferred tax asset valuation allowance	(13,608,967)	(16,454,842)	(18,964,520)
	$ —	$ —	$ —

The Company has generated taxable losses from operations since inception and, accordingly, has no taxable income available to offset the carryback of net operating losses. In addition, although management's operating plans anticipate taxable income in future periods, such plans provide for taxable losses over the near term and make significant assumptions which cannot be reasonably assured including approval of the Company's products and labeling claims by the U.S. Food and Drug Administration and market acceptance of the Company's products by customers. Based upon the weight of all available evidence, the Company has provided a full valuation allowance for its deferred tax assets since, in the opinion of management, realization of these future benefits is not sufficiently assured (defined as a likelihood of slightly more than 50 percent).

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

8. Income Taxes (Continued)

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,		
	1999	2000	2001
Statutory U.S. federal tax rate	(35.0)%	(35.0)%	(35.0)%
State taxes, net of federal tax benefit	(10.85)	(6.2)	(6.0)
Non-deductible expenses	0.24	1.5	0.7
Federal research and development credits	(3.37)	(.6)	(2.2)
Other	0.94	(1.6)	0.5
Valuation allowance on deferred tax assets	48.04	37.5	42.0
	—%	—%	—%

As of December 31, 2001, the Company has approximately $35,610,000 of net operating loss carryforwards and $1,071,000 and $562,000 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 2007 to 2021.

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

9. Savings Plan

In January 1995, Cambridge Heart adopted a retirement savings plan for all employees pursuant to Section 401(k) of the Internal Revenue Code. Employees become eligible to participate on the first day of the calendar quarter following their hire date. Employees may contribute any whole percentage of their salary, up to a maximum annual statutory limit. The Company is not required to contribute to this plan. The Company made no contributions to this plan in 1999, 2000 or 2001.

10. Commitments

Operating Leases

The Company has various non-cancelable operating leases for office space and computer hardware and software which expire through 2004. Certain of these leases provide the Company with various renewal options. Total rent expense under all operating leases was approximately $202,500, $231,043 and $226,441 for the years ended December 31, 1999, 2000 and 2001, respectively.

At December 31, 2001, future minimum rental payments under the non-cancelable leases are as follows:

2002	$200,486
2003	179,659
2004	2,642
2005 and thereafter	1,557
	$384,344

License Maintenance Fees

Under the terms of various license, consulting and technology agreements, the Company is required to pay royalties on sales of its products. Minimum license maintenance fees under these license agreements, which are creditable against royalties otherwise payable for each year, range from $10,000 to $30,000 per year through 2008. The Company is so required to meet certain development and sales milestones as specified in the agreements. Should the Company fail to meet such milestones, the license arrangements may be terminated at the sole option of the licensor. License maintenance fees paid during 1999 and 2000 amounted to $20,000 and $40,000, respectively, in each year. License maintenance paid during 2001 totaled $30,000. The future minimum license maintenance fee commitments at December 31, 2001 are approximately as follows:

2002	$ 30,000
2003	30,000
2004	30,000
2005	30,000
Thereafter	90,000
	$210,000

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

11. Related Party Transactions, Including Royalty Obligations

License Agreement/Consulting and Technology Agreement

In February 1993, the Company entered into 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 and a faculty member at the institution with which the Company has entered

11. Related Party Transactions, Including Royalty Obligations (Continued)

into certain other license agreements. This agreement required the Company to pay a monthly consulting fee of $10,833 during Fiscal 2001. The agreement has been extended to December 31, 2002. In February 2000, the Company modified this consulting agreement for additional consulting services, requiring the Company to pay an additional consulting fee of $8,333 per month. This modification expired in January 2001. Total payments made on both agreements during 1999, 2000 and 2001 were approximately $121,300, $217,494 and $135,329 respectively, and are included in research and development expense. The Company is also required to remit to this individual a royalty of 1% of net sales of products developed from certain other technology licensed from the institution described above. If the Company chooses to sublicense such products to an unrelated party, the royalty will be based on 7% of the gross revenue received from the unrelated party for products developed from such technology. The Company granted options to this individual to purchase 45,000 shares vesting annually over a 3 year period and granted an additional option to purchase 20,000 shares vesting annually over a 4 year period in Fiscal 2000 and 35,000 shares vesting annually over a 4 year period during Fiscal 2001.

Operations through December 31, 2001 did not result in the recognition of any material royalty expense in connection with these agreements.

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

Revenues from two customers accounted for 6%, 24% and 42% of total revenues during 1999, 2000 and 2001, respectively. These customers accounted for 4%, 38%, and 50% of the accounts receivable balance at December 31, 1999, 2000 and 2001, respectively. During the years ended December 31, 1999, 2000 and 2001, export sales accounted for 49%, 40% and 30% of 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*

Not applicable.

PART III

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

The response to this item is contained in part under the caption "EXECUTIVE OFFICERS OF THE REGISTRANT" in Part I hereof, and the remainder is contained in the Company's Proxy Statement for the Annual Meeting of Stockholders to be held on June 4, 2002 (the "2002 Proxy Statement") under the caption "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference.

Item 11. *Executive Compensation*

The response to this item is contained in the 2002 Proxy Statement under the captions "Compensation of Directors," "Executive Compensation," and "Severance and Other Agreements," and is incorporated herein by reference.

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

The response to this item is contained in the 2002 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions*

The response to this item is contained in the 2002 Proxy Statement under the caption "Transactions with Directors," and is incorporated herein by reference.

PART IV

Item 14. *Exhibits, Financial Statement Schedules, and Reports on Form 8-K*

(a) 1. *Financial Statements*

Our financial statements listed in the Index to Financial Statements in Item 8 hereof are filed as part of this Annual Report on Form 10-K.

(a) 2. *Financial Statement Schedules*

All applicable information is readily determinable from the notes to our financial statements.

(a) 3. *Listing of Exhibits*

Exhibit No.	Description
(1)3.1	Restated Certificate of Incorporation of the Registrant.
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant.
(1)3.3	By-Laws of the Registrant, as amended.
(1)4.1	Specimen Certificate for shares of Common Stock, $.001 par value, of the Registrant.
(1)10.1#	1993 Incentive and Non-Qualified Stock Option Plan, as amended.
(1)10.2#	1996 Equity Incentive Plan, as amended.
(1)10.3#	1996 Employee Stock Purchase Plan.
(1)10.4#	1996 Director Stock Option Plan.
10.5#	2001 Stock Incentive Plan.
(1)10.6#	Consulting and Technology Agreement between the Registrant and Dr. Richard J. Cohen, dated February 8, 1993.
(1)10.7#	Employment Agreement between the Registrant and Jeffrey M. Arnold, dated September 1, 1993, as amended.
(1)10.8#	License Agreement By and Between the Registrant and Dr. Richard J. Cohen, dated February 8, 1993.
(1)10.9	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".
(1)10.10	License Agreement by and between the Registrants and the Massachusetts Institute of Technology, dated September 28, 1993, relating to the technology of "Cardiac Electrical Imaging".
(2)10.11#	Agreement to Extend the Consulting and Technology Agreement between the Registrant and Dr. Richard J. Cohen, dated January 23, 1998.
(3)10.12	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 "Cardiac Electrical Imaging".
(3)10.13	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".
(9)10.14	OEM Purchase Agreement by and between the Registrant and Agilent Technologies, Inc. dated March 16, 2001.
(10)10.15	OEM Purchase Agreement Addendum by and between the Registrant and Philips Medical Systems dated October 5, 2001.
(3)10.16	Distributor Agreement, dated as of April 1, 1998, by and between the Registrant and Reynolds Medical Ltd.
(3)10.17	Distributor Agreement, dated as of March 1, 1998, by and between the Registrant and Image. Monitoring, Inc.
(4)10.18	Registration Rights Agreement among the Registrant, The Tail Wind Fund Ltd., Special Situations Private Equity Fund, L.P., Special Situations Fund III, L.P. and Geoffrey H. Galley dated June 8, 1999.
(5)10.19#	Amendment dated September 8, 1999 to the Employment Agreement between the Registrant and Jeffrey M. Arnold dated September 1, 1993.
(5)10.20#	Amendment dated October 25, 1999 to the Employment Agreement between the Registrant and Jeffrey Arnold dated September 1, 1993.
(5)10.21#	Severance Agreement dated November 18, 1999 between the Registrant and Robert Palardy.
(5)10.22#	Severance Agreement dated November 18, 1999 between the Registrant and Eric Dufford.

Exhibit No.	Description
(5)10.23#	Severance Agreement dated November 18, 1999 between the Registrant and James Sheppard.
10.24#	Severance Agreement dated November 18, 1999 between the Registrant and Kevin Librett.
(6)10.25	Distribution and License Agreement dated May 10, 2000 between the Registrant and SMI Medical, Inc.
(7)10.27	Sensor Usage Agreement Remarketing Agreement dated September 8, 2000 between Registrant and Americorp Financial, Inc.
(7)10.28#	Severance Agreement dated September 27, 2000 between the Registrant and David Chazanovitz.
(7)10.29#	Agreement dated June 19,2000 between Registrant and Jeffrey M. Arnold modifying the Employment Agreement of Jeffrey M. Arnold.
10.30	Lease Agreement By and Between the Registrant and R.W. Connelly, dated June 5, 2000.
10.31	Securities Purchase Agreement among the Registrant and The Tail Wind Fund, Ltd. and Robert P. Khederian dated December 21, 2001.
10.32	Registration Rights Agreement among the Registrant and The Tail Wind Fund, Ltd. and Robert P. Khederian dated December 21, 2001.
23.1	Consent of PricewaterhouseCoopers LLP.

(1) Incorporated herein by reference to the Company's Registration Statement on Form S-1, as amended (File No. 333-04879).

(2) Incorporated herein by reference to the Company's Form 10-K, as amended, for the fiscal year ended December 31, 1997.

(3) Incorporated herein by reference to the Company's Form 10-Q, as amended, for the quarter ended June 30, 1998.

(4) Incorporated herein by reference to the Registrant's Form 10-Q, as amended, for the quarter ended June 30, 1999.

(5) Incorporated herein by reference to the Registrant's Form 10-K, as amended, for the fiscal year ended December 31, 1999.

(6) Incorporated herein by reference to the Registrant's Form 10-Q, as amended, for the quarter ended June 30, 2000.

(7) Incorporated herein by reference to the Registrant's Form 10-Q, as amended, for the quarter ended September 30, 2000.

(8) Incorporated herein by reference to the Registrant's Form 10-K for the fiscal year ended December 31, 2000.

(9) Incorporated herein by reference to the Registrant's Form 10-Q, as amended, for the quarter ended March 31, 2001.

(10) Incorporated herein by reference to the Registrant's Form 10-Q, as amended, for the quarter ended September 30, 2001.

Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Items 14(a) and 14(c) of Form 10-K.

(b) No Current Reports on Form 8-K were filed by the Company during the last quarter of the period covered by this report.

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 xx, 2002.

CAMBRIDGE HEART, INC.

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

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

Signature	Title	Date
/s/ DAVID A. CHAZANOVITZ David A. Chazanovitz	President, Chief Executive Officer and Director (Principal Executive Officer)	March xx, 2002
/s/ ROBERT B. PALARDY Robert B. Palardy	Chief Financial Officer (Principal Financial and Accounting Officer)	March xx, 2002
/s/ DANIEL M. MULVENA Daniel M. Mulvena	Chairman of the Board of Directors	March xx, 2002
/s/ MAREN D. ANDERSON Maren D. Anderson	Director	March xx, 2002
/s/ RICHARD J. COHEN Richard J. Cohen	Director	March xx, 2002
/s/ ROBERT P. KHEDERIAN Robert P. Khederian	Director	March xx, 2002
/s/ JEFFREY J. LANGAN Jeffrey J. Langan	Director	March xx, 2002

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Board of Directors

Daniel M. Mulvena, Chairman
Founding Partner, Commodore Associates

Maren D. Anderson
Former Vice President of Covance, Inc.

David A. Chazanovitz
President and Chief Executive Officer, Cambridge Heart, Inc.

Richard J. Cohen, M.D., Ph.D.
Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology and NASA Center for Quantitative Cardiovascular Physiology, Modeling, and Data Analysis

Robert P. Khederian
Chairman, Belmont Capital

Jeffrey J. Langan
President, Maine Point Associates

Scientific Advisory Board

Richard J. Cohen, M.D., Ph.D.
Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology and NASA Center for Quantitative Cardiovascular Physiology, Modeling, and Data Analysis

Jeremy N. Ruskin, M.D.
Massachusetts General Hospital

Myron L. Weisfeldt, M.D.
Columbia Presbyterian Medical Center

Douglas P. Zipes, M.D.
Indiana University School of Medicine

Dividend Policy

The Company has never declared or paid cash dividends on its capital stock. Payment of dividends will rest within the discretion of the Board of Directors and will depend upon, among other factors, earnings, capital requirements, and financial condition.

Transfer Agent and Common Stock 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
Shareholder Services Department
6201 15th Avenue
Brooklyn, NY 11219
718.921.8380

Officers

David A. Chazanovitz
President and Chief Executive Officer

Eric Dufford
Vice President of Sales and Marketing and Secretary

Kevin S. Librett
Vice President of Research and Development

Robert B. Palardy
Vice President of Finance and Administration and Chief Financial Officer

James W. Sheppard
Vice President of Operations

Shareholder Information

Stock Listing
The Company's common stock is quoted on the NASDAQ National Market, Symbol: CAMH

Company 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.CAM.WAVE (226.9283)
www.cambridgeheart.com

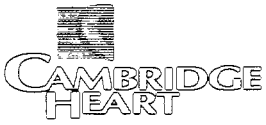
Annual Meeting
The annual meeting for stockholders will be held on June 4, 2002, at 10:00 am at:
Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109

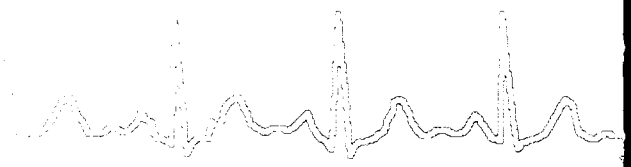
Legal Counsel
Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109

Auditors
PricewaterhouseCoopers LLP
160 Federal Street
Boston, Massachusetts 02110

This document includes forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that statements in this report which are not strictly historical statements, including, without limitation, statements regarding management's plans and objectives for future operations, product plans and performance, potential savings to the health-care system, management's assessment of market factors, as well as statements regarding the strategy and plans of the Company, constitute forward-looking statements. In some cases, we use words such as "believes," "expects," "anticipates," "plans," "estimates" and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements involve risk and uncertainties of the Company, including without limitation, failure to obtain funding necessary to develop or enhance the Company's technology, adverse results in future clinical studies of our technology, failure to obtain or maintain patent protection for our technology, failure to obtain or maintain adequate levels of third-party reimbursement for use of our products, and other risks detailed in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed with the Commission for the year ended December 31, 2001.

P/N 30-0026-004 Rev A





Cambridge Heart, Inc.

1 Oak Park Drive Bedford, MA 01730 888.226.9283 www.cambridgeheart.com