**A Serious Public Health Hazard**

Sudden cardiac death (SCD) is the leading cause of death in the United States, claiming more than 300,000 lives each year. SCD can strike any part of the population at any time – adults, adolescents, children, athletes, and apparently healthy people. No one is necessarily immune. In 1995, world-class figure skater Sergei Grinkov finished a practice routine, complained of dizziness, and collapsed. Within an hour, despite extensive resuscitation efforts, the 28-year-old skater died, a victim of SCD.

In response to this serious public health hazard, President Clinton signed the Cardiac Arrest Survival Act (HR 2498) into law in November of 2000. The law directs placing Automated External Defibrillators (AEDs) – portable devices that deliver an electric shock to the heart to halt sudden cardiac arrest – in federal buildings. He also signed a law that authorizes $25 million in federal funds to help rural communities purchase AEDs and train rescue personnel. The hope is that these devices, if employed within the first few minutes of arrest, will help save thousands of lives.

This recent legislation helps focus the public’s attention on the need to develop and employ technologies that can help combat SCD. Cambridge Heart responds to this public health hazard with life-saving technology of its own. The Company’s noninvasive Microvolt T-Wave Alternans™ Test fills a gap in current cardiac disease diagnosis, and helps identify and accelerate preventative treatment for patients at risk of SCD. The power to predict is the power to prevent. With early identification, people are free to undergo drug or electrophysiologic (EP) therapies to help them avoid falling victim to SCD.

Cambridge Heart, Inc., located in Bedford, Massachusetts, was founded in 1992 to develop and market breakthrough technology for the noninvasive diagnosis of cardiac disease. In 1999, the Company received clearance from the U.S. Food and Drug Administration (FDA) to market the Microvolt T-Wave Alternans Test as a predictor of Sudden Cardiac Death. The Microvolt T-Wave Alternans Test, the only commercially available test of its kind in the world, measures microvolt levels of T-Wave Alternans using Cambridge Heart’s proprietary Analytic Spectral Method™ and disposable Micro-V Alternans Sensors™. In 2000, the FDA granted clearance to market the Heartwave™, the Company’s flagship product, as a platform for performing the Alternans Test. Cambridge Heart’s products and technology are marketed through sales and distribution channels in the U.S., Europe, Australia and Japan.

**Financial Performance**

Revenues for 2000 were $1,909,900 compared with revenue of $2,136,000 for 1999, a decrease of 11%. This was the result of the Company’s decision to move away from the standard stress test market, which had accounted for a major portion of revenue in 1999, and focus all of its sales efforts on Alternans technology. Sales of Alternans products in the U.S. increased 74% in 2000. The Company reported a net loss of $0.50 per share for the year compared with $0.61 per share in 1999, an improvement of 17%. In addition, Cambridge Heart ended the year with $11,455,200 in cash and marketable securities, compared to $9,176,300 at the end of 1999. We raised $9,748,000 in net proceeds from the sale of common stock during the year.
To Our Shareholders:

Fiscal 2000 was a pivotal year for Cambridge Heart. We achieved a number of critical developmental, regulatory and clinical milestones that will enable us to begin the transition from a research and development focused company, to one dedicated to accelerating revenue growth and ultimately profitability through the sales and marketing of our Microvolt T-Wave Alternans technology. These efforts culminated in the release of the Heartwave in September 2000. This system enables physicians to identify patients at risk of SCD during a routine stress test using their existing stress test system. We are very excited about the Heartwave, as it is a cost-effective product platform that enables us to provide our technology to a broader segment of the market.

Fiscal 2000 was also marked by the significant strides we have made in our efforts to increase clinical usage of our Alternans technology and to obtain reimbursement for providers performing our Alternans Test. With the publication of three major clinical studies of Microvolt T-Wave Alternans this past year, additional regulatory approvals in hand, our new Heartwave System released and gaining acceptance in the marketplace, important partnerships in place, and critical reimbursement secured, we are ready to accelerate revenue growth through creative marketing programs and expanded distribution.

Fueling Widespread Clinical Adoption

In June, Cambridge Heart received FDA clearance to market the Heartwave System. The Heartwave helps identify patients at risk of SCD by measuring Microvolt T-Wave Alternans using our proprietary, disposable Micro-V Alternans Sensors and our unique Analytic Spectral Method to measure and collect alternans data at a microvolt level. The Heartwave enables physicians to perform the Alternans Test without having to replace their existing stress test system. With approximately nine million stress tests performed each year in the U.S. alone, the Heartwave allows us to pursue a large market opportunity for both the Heartwave and our disposable Micro-V Alternans Sensors. In September, we initiated shipment of our Heartwave System.

As part of our product strategy, we also developed the Heartwave EP™ System. Electrophysiology (EP) testing is an invasive procedure that is the current gold standard test for identifying patients at risk of SCD. The Heartwave EP model uses our Micro-V Alternans Sensors to measure Microvolt T-Wave Alternans in patients undergoing EP testing. This is an exciting development for Cambridge Heart, as there are approximately 1,500 EP labs in the U.S. that conduct over 100,000 EP studies per year. In the fourth quarter of Fiscal 2000, we shipped the first Heartwave EP units to customers for use in the EP Lab.
At the Helm

After seven years in which he guided Cambridge Heart in their efforts to transform pioneering research in the field of noninvasive cardiac diagnosis into breakthrough clinical products, Jeff Arnold announced his decision to retire as Chief Executive Officer in February 2001. During his tenure, Jeff helped fuel the broad-based clinical and regulatory acceptance of Microvolt T-Wave Alternans as a powerful predictor of SCD, and position Cambridge Heart to achieve long-term commercial success in the medical marketplace. He will continue in his role as Chairman of the Board of Directors, which will enable him to remain an influential force in the future growth of the Company.

In October 2000, Cambridge Heart announced the appointment of David Chazanovitz as President and Chief Operating Officer, at which time he assumed responsibility for the day-to-day operations of Cambridge Heart. In February 2001, David was appointed Chief Executive Officer. Formerly the Divisional President of NMT Medical’s Neurosciences Division, David joined Cambridge Heart with 28 years of experience in sales, marketing and general management of medical products businesses, ranging from early-stage device companies to established organizations. As former President of C. R. Bard’s Electrophysiology division, David has in-depth knowledge of Cambridge Heart’s customers and markets, and brings a wealth of knowledge, vision and leadership experience.
Clinical studies have played a critical role in validating the efficacy of Cambridge Heart’s noninvasive cardiac diagnostic tools and building awareness of our technology within the medical community. This past year saw the publication of three independent studies, involving three critical and diverse patient populations, which were reported in well-respected, peer reviewed journals. All concluded that Microvolt T-Wave Alternans was a highly effective test for identifying patients at risk of SCD.

Proof Positive

- The Journal of the American College of Cardiology reported on a study that concluded that the presence of Microvolt T-Wave Alternans was highly effective in predicting life-threatening arrhythmias in patients who have survived a previous heart attack. This study supports the efficacy of Microvolt T-Wave Alternans in a large, important patient population.

- The results of a company-sponsored, prospective multi-center clinical study published in The Journal of the American College of Cardiology showed that patients with a positive Microvolt T-Wave Alternans test were 13.9 times more likely to have a serious ventricular arrhythmia or to die than patients with a negative test. In comparison, patients with a positive EP test were only 4.7 times more likely to have a serious ventricular arrhythmia or to die than patients with a negative test.

- An article published in the prestigious British medical journal, The Lancet, reported that Microvolt T-Wave Alternans technology is the most effective noninvasive test to identify patients with congestive heart failure who are at risk for developing life-threatening abnormal heart rhythms.

While additional studies remain, there can be little doubt as to the powerful diagnostic capabilities of Microvolt T-Wave Alternans. This body of clinical evidence helps foster widespread acceptance, validation and support for our Alternans technology among the medical community - a critical step toward achieving market penetration.
Obtaining reimbursement for the Alternans Test was a top priority for Fiscal 2000. To assist in these efforts, we employed a two-tiered reimbursement strategy that involved expanding coverage and pursuing coding. We’re pleased with the progress made on both fronts.

**Coverage**

Expanding coverage involves working with Medicare and private third-party payers to assist them in understanding and accepting the use of Microvolt T-Wave Alternans testing. Since beginning our coverage campaign during the fourth quarter of 1999, we have obtained reimbursement for our Alternans Test for the majority of privately insured patients. To date, health care providers performing our Alternans Test have received payment from some of the largest insurers in the nation, including Aetna, United Healthcare, CIGNA, PacifiCare and various Blue Cross and Blue Shield companies across the country. Having these major payers on board should deliver the critical mass we need to fuel rapid adoption by additional health insurance providers.

In August, Medicare began reimbursing for the Microvolt T-Wave Alternans Test for hospital outpatients under the new Prospective Payment System created by the Health Care Financing Administration (HCFA). This system enables hospitals to bill electronically for the Alternans Test and ensures that they will receive payment for Medicare patients who receive the Alternans Test on an outpatient basis.

**Coding**

The American Medical Association’s (AMA) CPT codes provide a uniform language that providers and payers use to communicate services that have been performed for billing purposes. Coding is critical to our reimbursement efforts as it enables health care providers to bill electronically for the Alternans Test, standardizes reimbursement amounts and facilitates payment. Without a Category 1 CPT code, physicians and hospitals must submit letters of medical necessity along with their claims – resulting in a manual claims review process at the insurance companies. This time-consuming process is a deterrent for many doctors who are looking for assurance of automatic reimbursement. We have received a letter from the AMA stating that they plan to establish a permanent Category 1 CPT code for our Microvolt T-Wave Alternans Test. The new code is due for publication in January of 2002.

**Sales Expansion**

With the introduction of the Heartwave and our increasing success with reimbursement, we intend to aggressively expand our U.S. sales organization during 2001. We will use the proceeds from the sale of common stock during 2000 to increase the size and scope of our U.S. sales force and our marketing programs.

We are pleased with the caliber of professionals we have been able to recruit, all of whom have strong medical sales backgrounds. Our U.S. sales force will focus their efforts primarily on increasing our penetration of the installed base of 23,000 stress systems and 1,500 EP labs with our two new Heartwave models.
We are continuing efforts to establish additional strategic corporate relationships for the sales and distribution of our products and technology. In Fiscal 2000, we signed the first of these agreements with Spacelabs Medical, Inc. to market our Microvolt T-Wave Alternans technology as part of their Quest™ stress test system. We expect Spacelabs to submit a 510(k) to the FDA for approval in the very near future, and anticipate that initial product shipments will begin in the second quarter of 2001. We recently signed an agreement with Agilent Technologies for the exclusive United States distribution rights to our CH 2000™ stress test system. We expect the system to be available through the Agilent sales network in April 2001. We are excited about these partnerships as they create strong, viable distribution channels for our products and technology.

The Road Ahead

We are continuing to pursue efforts that will expand our reimbursement base and validate the powerful predictive accuracy of Microvolt T-Wave Alternans.

Reimbursement - As this annual report goes to press, a “model coverage policy” developed by Medicare’s cardiology working group has been distributed to the approximately 40 local Medicare carriers for review. We expect this model to be the basis for the individual medical review policies the majority of these carriers will develop in 2001. We will also be working with the AMA to determine the dollar valuation assigned to our permanent Category 1 CPT code for the Alternans Test.

Additional research - In 2001, we will partner with St. Jude Medical, Inc. in a multi-center clinical study intended to determine the effectiveness of Microvolt T-Wave Alternans in identifying candidates for implantable cardioverter defibrillator (ICD) therapy. Patients in the Alternans Before Cardioverter Defibrillator (ABCD) study will undergo both a noninvasive Microvolt T-Wave Alternans Test and an EP test, with patients testing positive for either test receiving an ICD. The purpose of this trial is to identify more patients at risk of life-threatening arrhythmias and to allow certain patients to proceed directly from a positive Alternans Test to ICD therapy without requiring an intervening invasive test. The results of this test could lead to the Alternans Test playing a more important role in directing therapy.

Positioned to Perform

While establishing broad-based acceptance of new clinical methods is a complex process, we believe that Cambridge Heart is well-positioned to achieve long-term commercial success. Our positive outlook is based on the size of the potential market for our products; the strength of our products; the outstanding results of our clinical studies; the strategic alliances we have established; and the strides we have taken towards complete reimbursement coverage. In closing, we wish to thank our shareholders, employees and customers who supported us in our pursuit of these important goals during 2000.

Jeffrey M. Arnold
Chairman of the Board

David A. Chazanovitz
President and Chief Executive Officer
The Next Wave of Growth

The successes of the past year have put Cambridge Heart in a good position to take advantage of the significant market opportunity for our products. We are now ready to capitalize on our investments and penetrate the substantial market for our technology.

Our sales and marketing strategy leverages direct and indirect sales channels in an effort to fuel widespread clinical usage of Alternans – and drive our growth. During the next two years, we will focus on getting Heartwave systems up and running in doctors’ offices and labs across the country so that we stimulate increased demand for our disposable Micro-V Alternans Sensors. Down the road, we expect strong revenue from the sales of our disposable sensors as health care providers begin repeatedly performing Alternans Tests.

Our direct sales efforts will be enhanced by the expansion of our sales organization and our marketing and reimbursement efforts. To facilitate this growth, we’ve restructured our U.S. sales organization into two distinct regions and expanded our training efforts. In addition, our marketing group has begun launching advertising, telemarketing and direct mail campaigns targeted at cardiologists and electrophysiologists in an effort to stimulate demand for the Microvolt T-Wave Alternans Test.
Our strategic partnerships will help us penetrate the stress test market. Our arrangement with Spacelabs marks the first critical distribution agreement with a leading stress test manufacturer. As part of this strategic alliance, we will conduct joint sales and marketing efforts to expand the potential market for Alternans testing into the stress test market. Today, Spacelabs has approximately 30% of the U.S. market share – and provides us with a valuable foothold into a mature market.

Under our latest agreement, Agilent Technologies will take over the sales and distribution of our CH 2000 stress test system to the U.S. stress test market. We expect that the CH 2000 will become available through the Agilent sales network in April 2001 and enable us to gain further market penetration. Through Agilent Technologies’ extensive sales network, the CH 2000 should capitalize on the benefits associated with a larger sales and marketing organization. This agreement enables our direct sales force to concentrate all of their efforts on the sales and marketing of our patented Microvolt T-Wave Alternans technology via the Heartwave System.
**BOARD OF DIRECTORS**

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Maren D. Anderson  
Former Vice President of Covance, Inc.  
Harris A. Berman  
Chief Executive Officer, Tufts Health Plan  
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  
Jeffrey J. Langan  
President and Chief Executive Officer, Nexxient, Inc.  
Daniel M. Mulvena  
Founding Partner, Commodore Associates

**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

**SCIENTIFIC ADVISORY BOARD**

Richard J. Cohen, M.D., Ph.D.  
Harvard-Massachusetts Institute of Technology  
Division of Health Sciences and Technology  
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

**SHAREHOLDER INFORMATION**

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

**COMPANY INFORMATION**

Additional copies of the Annual Report, including the Annual Report to the Securities and Exchange Commission on Form 10-K, may be obtained without charge by contacting:  
Investor Relations  
Cambridge Heart, Inc.  
1 Oak Park Drive  
Bedford, Massachusetts 01730  
888.226.9283  
www.cambridgeheart.com

**ANNUAL MEETING**

The annual meeting for shareholders will be held on May 31, 2001, at 10:00 am at:  
Hale and Dorr LLP  
60 State Street  
Boston, Massachusetts 02109

**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

**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 Form 10-K filed with the Commission for the end of the year ended December 31, 2000.

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