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**Annual Report**

**2009**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark One)

**Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the fiscal year ended December 31, 2009

or

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

**100 Ames Pond Drive, Tewksbury, MA**  
(Address of Principal Executive Offices)

**01876**  
(Zip Code)

**(978) 654-7600**

(Registrant's telephone number, including area code)

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

**Securities registered pursuant to Section 12(g) of the Act:**  
**Common Stock, \$0.001 par value**  
Title of class

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  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 this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller Reporting Company

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

The aggregate market value of the common stock held by non-affiliates of the registrant was \$5,705,827 computed by reference to the last reported sale price of the common stock on the OTC Bulletin Board on June 30, 2009.

As of March 31, 2010, 64,904,955 shares of the registrant's common stock were outstanding.

**Documents incorporated by reference:**

**Document Description**

**10-K Part**

Portions of the registrant's Proxy Statement for its Annual Meeting of Stockholders, which will be filed within 120 days after the close of the registrant's fiscal year ended December 31, 2009 ..... Part III

**CAMBRIDGE HEART, INC.**  
**2009 FORM 10-K ANNUAL REPORT**  
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## PART I

### Item 1. Business

#### Company Overview

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

Published clinical data in a broad range of patients with heart disease has shown that patients with symptoms of, or at risk of, life threatening arrhythmias who test positive for MTWA are at an increased risk for subsequent sudden cardiac events including sudden death, while those who test negative are at minimal risk. Sudden cardiac arrest accounts for approximately one-third of all cardiac deaths, or over 400,000 deaths, in the U.S. each year, and is the leading cause of death in people over the age of 45.

All of our products, including our first generation Heartwave and second generation Heartwave II Systems, CH 2000 Cardiac Stress Test System and Micro-V Alternans Sensors, have received 510(k) clearance from the FDA for sale in the U.S. They have also received the CE mark for sale in Europe, and our first generation Heartwave System and CH 2000 System have been approved for sale by the Japanese Ministry of Health Labor and Welfare. Our 510(k) clearance allows our MTWA Test to be used to test anyone with known, suspected, or at risk of ventricular tachyarrhythmia and/or sudden cardiac arrest, and allows the claim that our MTWA Test is predictive of those events. We have also submitted an application with the FDA for 510(k) clearance on our new MTWA Module, which, if granted, would allow for our MTWA Test to be performed on other manufacturers’ stress system platforms.

In March 2006, the Centers for Medicare and Medicaid Services issued a National Coverage Determination that allows for reimbursement to healthcare providers for MTWA testing of patients at risk of SCD only when a MTWA Test is done using the Analytic Spectral Method, which is our patented and proprietary method of analysis.

Cambridge Heart was incorporated in Delaware in 1990. Our executive offices are located at 100 Ames Pond Drive, Tewksbury, Massachusetts 01876. We maintain a website with the address [www.cambridgeheart.com](http://www.cambridgeheart.com). We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission.

#### Strategy

Our mission is to have our MTWA Test become a standard of care in the diagnostic monitoring regime used to identify and manage the risk of SCA in a broad population of cardiac patients. Historically, the Company’s marketing strategy was focused on providing MTWA testing to those patients at highest risk for SCA and who were likely candidates to receive an implantable defibrillation device (“ICD”). Although MTWA testing has

clearly been demonstrated to be useful in identifying those individuals who could benefit from ICD therapy, clinical experience and a growing body of data suggests that MTWA technology can and should be used in a much broader population of cardiac patients. We estimate that there are approximately 10 to 12 million heart attack and heart failure patients in the U.S. who can benefit from annual MTWA testing.

We intend to achieve this mission by making our technology readily available, in multiple product embodiments, in cardiology and internal medicine physician practices and in hospitals that provide healthcare services to a broad group of at-risk cardiac patients who routinely undergo cardiac evaluations, including stress testing. Our strategy calls for the Company to partner with manufacturers of cardiac stress testing equipment to develop an MTWA OEM (Original Equipment Manufacturer) module ("MTWA Module") that will be integrated into their systems. In addition to being sold to the manufacturers' new stress system customers, the Company expects that the MTWA Module will be marketed as an upgrade to the manufacturers' existing installed base of stress systems users. We believe that this strategy will result in our technology being marketed to a much larger number of cardiologists and internal medicine practitioners. We also believe that the access to a larger and more established distribution network will allow us to place more strategic focus on increasing clinical utilization of our Alternans technology and increasing sales of our proprietary Micro-V Alternans Sensors. In this regard, on June 22, 2009, we entered into a Development, Supply and Distribution Agreement (the "Cardiac Science Agreement") with Cardiac Science Corporation ("Cardiac Science") to develop the MTWA Module that will allow our MTWA Test, using our proprietary Micro-V Alternans Sensors, to be performed on Cardiac Science's Q-Stress test platform. We also intend to continue to leverage our direct sales and marketing efforts in support of our overall strategy.

## **Principal Products and Applications**

### ***The Heartwave II System***

Our Heartwave II System, which has replaced our original Heartwave System, is used to perform a Microvolt T-Wave Alternans or MTWA Test. A MTWA Test requires an elevated heart rate to provide an accurate result. The required heart rate typically achieved utilizing exercise as performed on a treadmill similar to a standard stress test. The heart rate can also be elevated through the use of pharmaceuticals or by pacing during an electrophysiology study or using a pace maker.

In April 2005, we received clearance from the FDA to market our Heartwave II System. Unlike our original Heartwave System, the Heartwave II System eliminates the need for a host stress system. The MTWA Test is typically performed as a stand alone diagnostic procedure. The electrocardiographic signals are captured by the Micro-V Alternans Sensors placed at designated locations on the patient's chest and analyzed by the Heartwave II System using our proprietary Analytic Spectral Method for measuring the microvolt levels of T-Wave Alternans.

In addition to MTWA measurement, our Heartwave II System is a cardiac diagnostic system designed to support a broad range of standard and physician-customized protocols for the conduct of cardiac exercise stress testing. Our Heartwave II System is capable of controlling most medical grade treadmills and bicycle ergometers and is well suited for standard, nuclear or echocardiograph stress testing.

### ***Microvolt T-wave Alternans Module***

In February 2010, we completed the development phase of the MTWA Module, and we submitted a 510(k) application for regulatory approval with the FDA. Once approved, the MTWA Module will be an add-on to cardiac stress test systems, which will enable MTWA testing to be performed on Cardiac Science's Q-Stress System platform using our Micro-V Alternans Sensors.

### ***Micro-V Alternans Sensors***

Our Micro-V Alternans Sensors are single patient use, multi-segment electrodes. They are necessary to obtain accurate results from our MTWA Test as they work to reduce background noise and artifact, allowing the processor to properly and accurately analyze the heart's electrical signal.

### ***The CH2000 Cardiac Stress Test System***

Our CH2000 is a cardiac diagnostic system designed to support a broad range of standard and physician-customized protocols for the conduct and measurement of cardiac exercise stress testing. When properly upgraded, it is also able to perform a MTWA Test. It is capable of controlling most medical grade treadmills and bicycle ergometers and is well suited for standard, nuclear or echocardiograph stress tests. The CH2000 is compatible with standard electrodes for routine stress testing and our Micro-V Alternans Sensors for a MTWA testing.

### **Clinical Studies**

Over the years, various studies have shown that our MTWA Test is an effective diagnostic tool for the identification of patients at increased risk of SCA and life-threatening ventricular arrhythmias. Additionally, a negative result from a MTWA Test has been demonstrated to be a strong indication that the patient is at very low risk of ventricular tachyarrhythmia or SCA, both of which we sometimes refer to as a sudden cardiac event. Clinical studies conducted on several thousand patients in high risk cardiac populations have shown that a positive or indeterminate MTWA Test result is at least as accurate a predictor of a future cardiac event as an invasive electrophysiology study. These studies have also shown that patients testing negative for MTWA are at very low risk of dying suddenly from a cardiac event. These studies have been published in a variety of peer reviewed journals such as the *New England Journal of Medicine*, *Circulation*, *Journal of Cardiovascular Electrophysiology*, *Journal of the American College of Cardiology*, and *The Lancet*.

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

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

according to Dr. Costantini, is that MTWA has a high negative predictive accuracy in both ischemic and non-ischemic patients and that the use of ICD prophylaxis in patients with a normal MTWA test and an ejection fraction of 30% or less may not be necessary.

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

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

In March 2006, Dr. Paul Chan from the VA Center for Practice Management and Outcomes Research, and the University of Michigan, Ann Arbor gave a presentation at The American College of Cardiology regarding the cost effectiveness of ICD therapy. The objective of the study was to evaluate the cost effectiveness of ICD therapy in MADIT II eligible patients with and without risk stratification using our MTWA Test. The study resulted in an Incremental Cost Effectiveness Ratio (ICER) of \$88,700 per Quality Adjusted Life Year in the ICDs FOR ALL strategies as compared to the use of MTWA risk stratification. The use of MTWA in risk stratifying the population resulted in a \$48,800 Incremental Cost Effectiveness Ratio as compared to medical management. This study was published in *The Journal of the American College of Cardiology* in June 2006.

In May 2006, the *Journal of the American College of Cardiology* published a new clinical study titled, “Prognostic Utility of Microvolt T-Wave Alternans in Risk Stratification of Patients with Ischemic Cardiomyopathy.” Dr. Theodore Chow from the Lindner Center was the Principal Investigator of the study. The study enrolled 768 consecutive patients with ischemic cardiomyopathy and an ejection fraction less than or equal to 35%. The authors studied MTWA to discern if MTWA was an independent predictor of mortality and could, therefore, identify which of the individuals would be at the highest risk of death and most likely to benefit from ICD therapy. After a mean follow-up period of 18 months, the MTWA non-negative, or abnormal, group of patients was associated with a significantly higher risk for all cause and arrhythmic mortality. In the group of patients that were not treated with implantable defibrillator therapy, the arrhythmic death rate for MTWA negative patients was approximately 2% per year while the MTWA non-negative patients’ death rate was more than three times higher.

In August 2006, the “Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death” was jointly released by the American College of Cardiology (ACC), The American Heart Association (AHA) and the European Society of Cardiology (ESC). In this new guideline, collaborated on with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association, MTWA received a Class IIa guideline under the section, “Electrocardiographic Techniques and Measurements.” The consensus guideline stated, “It is reasonable to use T-Wave Alternans for improving the diagnosis and risk stratification of patients with ventricular arrhythmias or who are at risk for developing life-threatening ventricular arrhythmias. (Level of Evidence: A).”

In November 2006, the clinical results from the Alternans Before Cardioverter Defibrillator (ABCD) trial were presented at the American Heart Association's 2006 Scientific Sessions conference. The Primary Investigators of the study, Dr. Otto Costantini, M.D. and David S. Rosenbaum, M.D., presented the results. The study, sponsored by St. Jude Medical, Inc. ("St. Jude Medical"), found that the predictive value of our non-invasive MTWA test was comparable to the invasive electrophysiology (EP) tests in patients with a history of ischemic heart disease at high risk for SCD. The study was published in the fall in the *Journal of American College of Cardiology* in February 2009.

In March 2007, Dr. Gaetano M. De Ferrari, Head of the Intensive Care Unit in the department of cardiology at San Matteo Hospital in Pavia, Italy and a member of the ALPHA Steering Committee, presented the results of a multi-center, prospective study during the Late-Breaking Clinical Trials session of the American College of Cardiology Scientific meeting assessing the utility, using the CH2000 or Heartwave System, in predicting risk of sudden death among patients with non-ischemic cardiomyopathy. The ALPHA study (Prognostic Value of T-Wave Alternans in Patients with Heart Failure Due to Non-ischemic Cardiomyopathy) enrolled 446 consecutive patients with NYHA Class II or III non-ischemic cardiomyopathy and left ventricular ejection fraction (LVEF) less than or equal to 40%. On the primary endpoint (cardiac death and life-threatening arrhythmias), an abnormal MTWA Test had a Hazard Ratio of 4.01 ( $p=0.002$ ), or four times the risk of a normal MTWA test. The 12-month negative predictive value of the test was reported to be 98.7%, indicating that patients with a negative test result are at very low risk of SCD. For patients with LVEF less than 35%, the Hazard Ratio and negative predictive value were 4.28 ( $p=0.004$ ) and 99%, respectively. The study was published in full in the *Journal of the American College of Cardiology* in November 2007.

In November 2007, the results of the MASTER I (Microvolt T-Wave Alternans Testing for Risk Stratification of Post MI Patients) clinical trial, sponsored by Medtronic, Inc., were presented in a Late Breaking Clinical Trial session at the American Heart Association (AHA) Scientific Session. The purpose of this 654 patient, multi-center clinical trial study was to show that MADIT II type patients with a normal MTWA Test result are at very low risk of dying suddenly versus those that test abnormal and, therefore, may not require ICD therapy. Each of the 654 patients met MADIT II criteria, meaning that they had all experienced a heart attack and had an ejection fraction of 30% or less. All of the patients received a currently available Medtronic ICD as prophylactic therapy.

The results of the MASTER I study showed that while the incidence of the primary endpoint (life-threatening ventricular tachyarrhythmic events) was lower in patients with MTWA negative results than patients in the non-negative group (10% vs. 13%), this difference was not adequate to achieve statistical significance. MTWA was, however, found to be a statistically significant predictor of total mortality ( $HR = 2.04$ ,  $p=0.02$ ). The majority of end point events in the MASTER I trial were appropriate ICD shocks. In addition, the event rate in the study was relatively low. Lastly, approximately 20% of patients in the MASTER I trial received a Cardiac Resynchronization Therapy and Defibrillator (CRT-D) device. The study was published in the fall in the *Journal of American College of Cardiology*. An additional 1,200 patients with slightly better pumping function (ejection fraction of 30% to 40%) were planned to be evaluated in a related registry according to the study protocol. The results for 303 patients enrolled in the MASTER II trial was presented as a poster presentation at American College of Cardiology meeting in March 2008. Results show that 7 events occurred in patients with a positive MTWA test, while 4 occurred in MTWA negative patients. The authors concluded that the ability to detect a statistical difference may have been affected by the low event rate. The company understands that the enrollment for MASTER II trial was terminated prematurely due to low event rates.

In May 2008, a meta-analysis, conducted by a group led by Stefan Hohnloser, MD, FHRS, of the JW Goethe University Division of Cardiology in Frankfurt, Germany, assessed 13 MTWA clinical studies involving approximately 6,000 cardiac patients. This analysis was then published in a supplement to the March 2009 issue of the *Heart Rhythm* journal. One of the key conclusions from this work was that in clinical trials, appropriate ICD shocks are an unreliable surrogate endpoint for Sudden Cardiac Arrest (SCA) and can skew results of risk stratification studies.



In November 2009, the results of the PREVENT-SCD trial were presented at the American Heart Association Scientific Sessions in Orlando, Florida. PREVENT-SCD (Prospective Evaluation of Ventricular Tachyarrhythmic Events and Sudden Cardiac Death in Patients with Left Ventricular Dysfunction) was a prospective multi-center study of patients with cardiomyopathy and ejection fraction of 40% or lower that enrolled a total of 453 patients from 38 institutions in Japan. Two hundred eighty (280) patients underwent non-invasive MTWA testing using the analytic spectral method and were followed for up to three years. At a median follow-up time of 36 months, patients with an abnormal MTWA test were 4.4 times more likely to experience a life-threatening arrhythmia or SCD than those with a normal test. The three-year negative predictive value was reported to be 97.0%, indicating that patients with a normal or negative MTWA test were at low risk for experiencing sudden death.

In February 2010, the results of a clinical study were presented at the 29th Annual Scientific Meeting of the Belgian Society of Cardiology in Brussels, Belgium. The study, conducted at Jolimont Hospital in Haine Saint Paul, Belgium, prospectively evaluated MTWA in 73 consecutive patients who met criteria for implantable cardioverter defibrillator implantation for primary prevention of SCD. At a mean follow-up time of 39 months, the incidence of arrhythmic events in patients with an abnormal MTWA test was 7.6 times that for patients who tested negative. Sudden cardiac death was 4.8 times more common in those with an abnormal MTWA result.

## **Reimbursement**

Reimbursement to healthcare providers by Medicare/Medicaid and third party insurers is critical to the long-term success of our efforts to make the MTWA Test a standard of care for patients at risk of ventricular tachyarrhythmia or sudden death. In January 2002, Current Procedural Terminology Code 93025, known as a CPT code, became available for use by healthcare providers for filing for reimbursement for the performance of a MTWA Test. This code may be used alone, or in conjunction with, other diagnostic cardiovascular tests. This unique CPT code provides a uniform language used by healthcare providers to describe medical services but does not guarantee payment for the test. Coding is used to communicate to third party insurers about services that have been performed for billing purposes and can affect both the coverage decision and amount paid by third party insurers. In November 2006, CMS issued a ruling that changed the methodology used to calculate all physician reimbursement codes. This ruling includes reductions in all categories of reimbursement levels through 2010. Effective January 1, 2009, CMS reduced the Medicare payment amount for the CPT code for a MTWA Test from a national average of \$252 in 2008 to \$214 in 2009.

In July 2009, CMS released its proposed 2010 Medicare Physician Fee Schedule (MPFS). MPFS rates are updated annually and have resulted in negative updates since 2002. In November 2009, CMS issued its final ruling on MPFS effective January 1, 2010. This ruling sets forth a reduction in Relative Value Unit (RVU) for nearly all cardiovascular services to be phased in over a four-year period. The final rule also includes an additional 21% reduction in the conversion factor. In past proposals, however, Congress has enacted legislation to sustain the conversion factor component of the reimbursement calculations. Therefore, the impact of this ruling on reimbursement will be determined once the conversion factor is final. In January 2010, CMS temporarily maintained the conversion factor at the 2009 level through the end of March 2010, which set the national average Medicare payment amount for a MTWA test during that period at \$196.71. Any reduction in reimbursement, material change in indication or reversal of private payer coverage for our MTWA Test may affect the demand for, price of, or utilization of our Heartwave II System and Micro-V Alternans Sensors, which may in turn have a material adverse effect on our business.

Prior to March 2006, local Medicare carriers have provided coverage for the Microvolt T-Wave Alternans Test. However, actual reimbursement has been inconsistent and in many instances administratively burdensome to physicians making it difficult to obtain. In addition to Medicare reimbursement at a local level, CMS issues National Coverage Determinations (NCDs) which represent approximately 10% of total Medicare coverage policies. In 2005, we applied to CMS for a NCD in order to gain broader and more uniform reimbursement coverage for our MTWA Test. After a nine-month application process, which included two public comment

periods, CMS released a draft of its NCD on December 21, 2005, which became final on March 21, 2006. This broad coverage policy allows for payment for MTWA testing of patients at risk of SCD only when a MTWA Test is performed using the Analytic Spectral Method, which is our patented and proprietary method of analysis.

We estimate that approximately one-half of the U.S. patient population that we believe are most likely to benefit from our MTWA Test are at least 65 years old and, therefore, eligible for reimbursement via Medicare. We believe the remaining 50% are covered by private insurers such as BlueCross/BlueShield, Aetna, Cigna, Kaiser and United Healthcare. In 2005, we received positive reimbursement decisions from Horizon Blue Cross/Blue Shield units in New Jersey, and had payment policies from Blue Cross/Blue Shield in New York, Iowa, Maryland, Washington DC, Delaware, Michigan and South Dakota. In 2006, we received favorable reimbursement decisions from Aetna and Humana, which included the use of our patented algorithm. Additionally, in 2006, we received positive reimbursement decisions from other large private payers including CIGNA Healthcare, Healthcare Service Corporation (HCSC) and WellPoint. In 2008, Premera Blue Cross and Blue Cross Blue Shield of Arizona revised their policies to make Microvolt T-Wave Alternans testing a covered benefit. In February 2009, Harvard Pilgrim Health Care initiated reimbursement for the MTWA test. In April 2009, WellPoint revised its coverage policy on MTWA testing from a covered service to a non-covered service. We estimate that approximately 6 million high-risk cardiac patients are currently covered for MTWA testing by either Medicare or other commercial health plans in the United States. Typically, private reimbursement coverage for our MTWA Test is available only to those patients who are otherwise indicated for ICD therapy. In 2010, we will continue to work toward securing favorable reimbursement policies from the remaining large private insurance not currently providing MTWA test reimbursement.

## **Marketing and Sales**

Our technology and products are directed towards identifying individuals at risk of SCA, thus providing the physician with additional information on which to base a therapy decision. Typically our target patient populations include those individuals with underlying cardiac disease. In the U.S., those populations include more than 7 million patients who have suffered a myocardial infarction (heart attack), 5 million patients suffering from congestive heart failure (poor pumping function), and more than one million other patients suffering from conditions including syncope (fainting and dizziness) and non-ischemic dilated cardiomyopathy (damaged and enlarged heart). Therefore, we believe that the aggregate at-risk patient population in the U.S. that could benefit from our MTWA Test exceeds 10-12 million. MADIT II and Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) type patients are relatively small, but highly visible and important subsets of this at-risk patient population.

The main target customer for our Heartwave II System, MTWA Module and Micro-V Alternans Sensors is the clinical cardiologist. Clinical cardiologists see the vast majority of patients with existing cardiac conditions. They also prescribe and administer most diagnostic tests either in their office or as an outpatient procedure at the hospital. Our MTWA Test is a non-invasive tool that can be used to identify which of their patients are at the highest risk of sudden cardiac arrest and, therefore, should be considered for more extensive testing and therapy. Conversely, our MTWA Test identifies patients at low risk who may be treated more conservatively, typically through drug therapy.

At December 31, 2009, we had five direct sales representatives who sell our products in the United States. In addition, we had 10 clinical application specialists to install systems, train customers and enhance sensor utilization. In March 2009, in order to reduce cash expenditures, the Company implemented an expense reduction initiative. This initiative included a reduction 33% in headcount. The reduction in headcount, which impacted all of the Company's operational areas, included a restructuring of the direct sales organization to improve cost effectiveness. Refer to the Employee section under Part I, Item 1. Business for details regarding our headcount.

On June 22, 2009, we entered into a Development, Supply and Distribution Agreement, with Cardiac Science as part of our strategy to increase the sales and use of our proprietary MTWA technology. Pursuant to the Cardiac Science Agreement, we developed the MTWA Module that will allow our MTWA Test, using our proprietary Micro-V Alternans Sensors, to be performed on Cardiac Science's Q-Stress test platform via customized software and patient interface. Cardiac Science will market the MTWA Module as an upgrade to its existing installed base of Q-Stress Systems and as an optional feature to new stress customers.

Under the Cardiac Science Agreement, we will sell and deliver to Cardiac Science the MTWA Module and our Micro-V Alternans Sensors (together, the "Products") under purchase orders submitted by Cardiac Science. Cardiac Science will resell the Products for use with their Q-Stress test platform through its direct sales force and through its network of distributors and sub-distributors. Cardiac Science's right to resell the Products is non-exclusive. We may continue to sell, distribute and license our MTWA Test and sensors to other distributors and customers in both generic and customized versions. Cardiac Science will have primary responsibility for preparing sales and marketing materials and for training its sales and service personnel regarding the Products. We will provide clinical and technical training and support to Cardiac Science. In addition, we will provide installation training service to each purchaser of a MTWA Module for use on Cardiac Science's Q-Stress test platform. We also will have customary warranty obligations with respect to the Products sold under the Cardiac Science Agreement.

The initial term of the Cardiac Science Agreement expires on June 22, 2014. The term of the Cardiac Science Agreement will automatically renew for a one year period unless either party notifies the other of its intention to terminate at least 90 days prior to the expiration of the initial or renewal term. We expect that the launch of the MTWA Module for Cardiac Science's Q-Stress test platform will occur in the third quarter of 2010 based on development and regulatory approval timelines. The Cardiac Science Agreement may be terminated by us if the MTWA Module has not been launched by September 30, 2010. The Cardiac Science Agreement also may be terminated by either party in the event that the other party has committed a material breach of its obligations under the Cardiac Science Agreement that has not been cured within 60 days' written notice from the terminating party, upon the bankruptcy of either party, and upon 12 months prior written notice to the other party.

In 2009, approximately 14% of our total revenue came from sales of our products outside the U.S. which are sold through a network of country specific distributors in Europe, Asia and the Middle East.

## **Manufacturing**

The in-house manufacturing process for our Heartwave II System and CH 2000 consists primarily of incoming inspection and final assembly of purchased components. Additionally, our operations group tests, inspects, packages and ships the products. Components and sub-assemblies are purchased according to our specifications and are subject to inspection and testing. We rely on outside vendors to manufacture major components, a number of which are currently supplied by sole source vendors. We purchase components through purchase orders rather than long-term supply agreements. We purchase our Micro-V Alternans Sensors fully assembled and packaged from a third-party supplier. The manufacturing process for the MTWA Module will be consistent with the process for our other products.

In February 2008, we relocated to a new facility in Tewksbury, Massachusetts. We believe that our new facility will be adequate to meet our production requirements through the foreseeable future.

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 March 2009. We passed the inspection with no observations. We are ISO 13485 certified allowing us to apply the CE Mark to all of our products. We are subject to annual audits by our designated notified body, British Standards Institution, to maintain our ISO 13485 certification.

## **Research and Development**

A substantial portion of our research and development investment is focused on our continuing efforts to develop functionality enhancements to our MTWA products, and on supporting clinical research work. During 2009, we focused our development efforts on our Heartwave II System, developing additional features intended to make our MTWA Test easier to perform and more beneficial for our customers, as well as the design and the development of our MTWA Module.

As of December 31, 2009, we had two full-time employees engaged in research and development activities along with several independent research and engineering consultants whose services are utilized as necessary. Refer to the Employee section under Part I, Item 1. Business for further details regarding our headcount.

## **Patents, Trade Secrets and Proprietary Rights**

Some of the initial methods that we used in the measurement of MTWA were covered by a U.S. patent issued to The Massachusetts Institute of Technology (“MIT”). This patent was acquired through an exclusive license agreement with MIT that expired in the U.S. in 2006. We have been issued an additional 17 U.S. patents that include claims covering substantial changes and modifications to the initial methods covered by the original MIT patent. The Analytic Spectral Method, our core intellectual property, is the subject of domestic and international patents issued in 2004. The expiration dates of remaining patents range from 2013 to 2021.

We continue to maintain our license agreement with MIT outside the U.S., since the patent rights have not expired outside the U.S. This license agreement imposes various commercialization, sublicensing, insurance, royalty, product liability indemnification and other obligations on us. Our failure to comply with these requirements could result in a conversion of the licenses from exclusive to non-exclusive in nature or, in some cases, termination of the license. We believe that we are in compliance with all of these obligations.

In June 2008, we entered into a license agreement with MIT pursuant to which we acquired an exclusive license to United States Patent 7,336,995 “Method and Apparatus for Tachycardia Detection and Treatment.” This broad patent covers the use of implantable devices such as pacemakers and defibrillators to measure T-Wave Alternans from intra-cardiac signals and to initiate subsequent therapy in order to prevent the development of arrhythmias which may lead to sudden cardiac arrest. Implantable defibrillators currently treat such arrhythmias only after they have been initiated, typically with a high-energy shock. A strategy to predict such rhythms before they occur could allow for preventive strategies, potentially avoiding imminent symptomatic episodes with the delivery of painless therapies.

In December 2009, we filed three patent applications with the U.S. Patent Office to further enhance our intellectual property portfolio. These applications cover our intellectual properties in the areas of measuring Alternans from ambulatory electrocardiographic devices, Alternans and cardiac ischemia, and Alternans and pharmacological agents.

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

## **Competition**

We have competition from other risk stratification testing modalities such as electrocardiogram stress tests, invasive electrophysiology testing, Holter monitors, ultrasound tests and the potential for implanting ICDs in broad patient populations without the need for risk stratifying tests such as our MTWA Test.

GE Medical Systems gained FDA 510(k) concurrence during 2003 for their T-Wave Alternans Algorithm for use with their Case 8000 Stress Exercise System and other analysis modalities. In August 2007, based on a publication by Nieminen et al in *European Heart Journal*, GE Medical filed a formal request for reconsideration of the National Coverage Determination (NCD) for Microvolt T-Wave Alternans to include GE's Modified Moving Average (MMA) methodology.

In February 2008, the Centers for Medicare and Medicaid Services (CMS) released a Proposed Decision Memo stating that there is insufficient evidence to conclude that the MMA method of determining MTWA is reasonable and necessary for the evaluation of Medicare beneficiaries at risk for SCD under section 1862(a)(1)(A) of the Social Security Act, and, therefore, CMS proposed to continue national non-coverage for the MMA method of determining MTWA. After careful examination, CMS found that the evidence base supporting the MMA method of measuring MTWA is limited, and though suggestive of benefit, is not yet convincing.

CMS requested public comments on the proposed determination pursuant to Section 1862(1) of the Social Security Act. In particular, CMS was interested in comments that include new evidence that they had not reviewed in past considerations of the NCD. CMS requested public comment on the reported findings of the MASTER I trial, specifically with regard to whether CMS should continue to cover MTWA in general, regardless of the method used. In May 2008, CMS issued a Final Decision Memorandum reaffirming coverage of MTWA using the spectral analysis method and found insufficient evidence for coverage of MTWA using any other method. Following the full publication of the MASTER I trial results in November 2008, the Company submitted an analysis of the results along with other recent publications supporting the use of MTWA in identifying patients at risk of SCD.

## **Government Regulation**

Our Heartwave Systems, CH 2000, and Micro-V Alternans Sensors have received 510(k) clearance from the FDA for sale in the U.S. The 510(k) clearance for the Heartwave Systems and the CH 2000 includes the claim that they can measure MTWA and the presence of MTWA in patients with known, suspected, or at risk of ventricular tachyarrhythmia predicts increased risk of ventricular tachyarrhythmia and sudden death. In February 2010, we completed the development phase of the MTWA Module, and we submitted a 510(k) application for regulatory approval with the FDA.

Any products manufactured or distributed by us are subject to comprehensive and continuing regulation by the FDA, including record keeping requirements, reporting of adverse experience with the use of the device, post-market surveillance, post-market registry and other actions deemed necessary by the FDA. The most recent FDA inspection of our record keeping, reporting and quality documentation system was concluded in March 2009. We passed the inspection with no observations.

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in these countries are similar to those of the FDA. We have obtained the requisite foreign regulatory approvals for sale of our Heartwave Systems, CH 2000 and Micro-V Alternans Sensors in many foreign countries, including most of Western Europe. We believe that foreign regulations relating to the manufacture and sale of medical devices are becoming more stringent. The European Union adopted regulations requiring that medical devices such as our Heartwave System, CH 2000 and Micro-V Alternans Sensors comply with the Medical Device Directives, which establish the requirements for CE marking of all products prior to their importation and sale. In 2001, we received ISO-9001 and CE certification for our

Heartwave, CH 2000 and Micro-V Alternans Sensors. In 2006, we received ISO-13485-2003 for Heartwave II, CH 2000 and Heartwave I Systems. The Japanese Ministry of Health, Labor and Welfare has also approved our original Heartwave System for sale, and an application has been filed for approval of the Heartwave II System. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

## **Employees**

As of December 31, 2009, we had 26 full-time and six part-time employees. None of our employees are represented by a collective bargaining agreement, and we have not experienced work stoppages. We believe that our relations with our employees are good. In March 2009, in order to reduce cash expenditures, the Company implemented an expense reduction initiative. This initiative included a 33% reduction in headcount. At December 31, 2008, we had 39 full-time and five part-time employees. The reduction in headcount, which impacted all of the Company's operational areas, included a restructuring of the direct sales organization to improve cost effectiveness.

## **Item 1A. Risk Factors**

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

### ***Risks Related to our Operations***

**We have never been able to fund our operations from cash generated by sales of our products, and therefore in the future we may have to meet our working capital requirements through the sale of debt or equity securities.**

We have incurred substantial operating losses through December 31, 2009 and may never generate substantial revenue or achieve profitability on a quarterly or annual basis. We have financed our operating losses through the public and private sale of shares of our common stock and preferred stock. If we cannot increase revenue significantly, or obtain additional capital through equity or debt financings, we may not be able to continue as a going concern. For the year ended December 31, 2009, our auditors included a going concern explanatory paragraph in their audit opinion because of our recurring losses, inability to generate cash flows from operations, and liquidity uncertainty. If we are unable to generate adequate cash flow or obtain sufficient additional funding when needed, we may have to significantly cut back our operations, sell some or all of our assets, license potentially valuable technologies to third parties and/or cease some or all of our operations. This may have a material adverse effect on our operations and the market price of our common stock. In the current economic environment, financing for technology and medical device companies has become increasingly difficult to obtain. Any additional financing may not be available in the amount we need or on terms favorable to us, if at all. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of Cambridge Heart by our stockholders would be reduced and the securities issued could have rights, preferences and privileges more favorable than those of our current stockholders. We believe that our existing resources, and currently projected financials results, which include sales of our MTWA Module to Cardiac Science under the Cardiac Science Agreement, are sufficient to fund our operations through December 31, 2010. We will, however, continue to evaluate the need to raise additional capital through public or private financing, collaborative relationships or other arrangements. There can be no assurance that such capital would be available at all, or if available, that the terms of such financing would not be dilutive to other stockholders.

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

We believe that the financial resources available to us, and currently projected financial results, which include sales of our MTWA Module to Cardiac Science, will be sufficient to finance our planned operations through December 31, 2010. If we are unable to achieve positive cash flow, we will need to raise additional funds. We may also need additional financing sooner if:

- we decide to substantially expand our research and development efforts;
- we decide to expand our marketing and sales capabilities;
- we decide to undertake new sales and/or marketing initiatives;
- we are required to defend or enforce our intellectual property rights;
- sales of our products do not meet our expectations in the United States or internationally;
- our MTWA Module does not receive FDA clearance;
- the launch of our MTWA Module with Cardiac Science does not occur at the time planned;
- sales of our MTWA Module do not meet our expectations;
- we need to respond to competitive pressures; or
- we decide to acquire complementary products, businesses or technologies.

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

**We depend on our MTWA technology for a majority of our revenue, and if it does not achieve broad market acceptance, our ability to execute our business plan and achieve meaningful revenue will be limited.**

We believe that our ability to succeed in the future will depend, in large part, upon the successful market acceptance of our MTWA technology. Market acceptance will depend upon our ability to demonstrate the diagnostic advantages and cost-effectiveness of this technology. The failure of our MTWA technology to achieve broad market acceptance, the failure of the market for our products to grow or to grow at the rate we anticipate, or a decline in the price of our products due to competitive pressures or a decline in the availability of reimbursement, would reduce our revenues and further limit our ability to succeed. This could have a material adverse effect on the market price of our common stock. We can give no assurance that we or our strategic partner(s) will be able to successfully commercialize or achieve market acceptance of our MTWA technology or that our competitors will not develop competing technologies that are perceived to be superior to our technology.

**The economic and financial market downturn and tightening of the credit markets has and may continue to have an adverse impact on our business.**

The deterioration of the economic conditions has had an adverse impact on our existing and target customers. These conditions, in turn, have a significant influence on customers' buying decisions. Given that a significant part of our revenue comes from sales of capital equipment to small to medium sized cardiology with limited financial resources practices, the tightening of credit has and may continue to negatively affect our sales. If the economy continues to decline and credit continues to be difficult to obtain, customers may continue to delay or refrain from purchasing our equipment.

**A critical component of our strategy is to broaden our distribution channels through strategic alliances. If we are unable to establish sufficient distribution partnerships or if the timing is slower than expected, our business plan will be adversely impacted.**

Our strategy is to broaden our distribution channels by establishing alliances with medical device partners and distributors with synergistic attributes. The widespread adoption of our technology may be dependent on establishing and maintaining these strategic relationships. Successfully establishing and managing such relationships may be difficult given the current environment. Furthermore, the financial terms of the relationships will have a direct impact on our operating results. Moreover, when, or if, such partnerships are established, we may have to contend with competing interests of our potential partners and/or distributors. In June 2009, we partnered with Cardiac Science to develop and market the MTWA Module, which will allow our MTWA Test using our proprietary Micro-V Alternans Sensors to be performed on Cardiac Science's Q-Stress test platform. Cardiac Science will market the MTWA Module as an upgrade to its existing installed base of Q-Stress Systems and as an optional feature to new stress customers. However, there can be no assurance that additional relationships are attainable at all or on terms favorable to us.

**Our ability to generate revenue from the sales of our MTWA Module is dependent upon the sales and marketing efforts of third party stress test manufacturers.**

In June 2009, we entered into an agreement with Cardiac Science to market the MTWA Module, which will be integrated with Cardiac Science's Q-Stress Systems. Cardiac Science will market the MTWA Module as an upgrade to their existing installed base of Q-Stress Systems, and as an optional feature to new stress customers. Under the Cardiac Science Agreement, we will sell and deliver to Cardiac Science the MTWA Module and our Micro-V Alternans Sensors. Cardiac Science will resell these products for use with their Q-Stress test platform through its direct sales force and through its network of distributors and sub-distributors. If Cardiac Science is unable to sell the MTWA Module and our Micro-V Alternans Sensors effectively or limits the amount of time and resources that it devotes to marketing these products, it could materially and adversely affect the results of our operations. Furthermore, if our distribution arrangement with Cardiac Science is unsuccessful, we may have to reconsider our sales and marketing strategy, which may also materially and adversely affect the sale of our products and our financial condition. In addition, we are unsure what effect, if any, the sales of our MTWA Module through Cardiac Science will have on our current direct selling efforts.

**We face substantial competition in the market for cardiac diagnostic devices from substantially larger and better financed competition, which may result in others discovering, developing or commercializing competing products more successfully than we do.**

Competition from competitors' medical devices that diagnose cardiac disease is intense and likely to increase. Our success will depend on our ability to develop product enhancements and applications for technologies, as well as our ability to establish and maintain a market for our products. We compete with manufacturers of electrocardiogram stress tests, the conventional method of diagnosing ischemic heart disease, as well as with manufacturers of other invasive and non-invasive tests, including EP testing, electrocardiograms, Holter monitors, ultrasound tests and systems of measuring cardiac late potentials. GE Medical Systems has introduced an analysis system to measure t-wave alternans. GE Medical Systems has received concurrence from the FDA of its 510(k) allowing it to distribute the product in the United States. We believe if GE can secure the reimbursement for its MTWA methodology with Medicare it will pose a significant risk to the success of our business. See further detail under *Competition* in Item 1. "Business".

In addition, many of our current as well as prospective competitors have substantially greater capital resources, name recognition, research and development regulatory, manufacturing and marketing capabilities. Many of these competitors offer broad, well-established product lines and ancillary services not offered by us. Some of our competitors also enjoy long-term or preferential supply arrangements with physicians and hospitals which may act as a barrier to market entry.



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

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

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

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

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

We participate in clinical studies relating to our MTWA technology in order to more firmly establish the predictive value of such technologies. Any clinical study or trial which fails to demonstrate that the measurement of MTWA is at least comparable in accuracy to alternative diagnostic tests, or which otherwise calls 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 obtain critical components and sub-assemblies for the manufacture of our products from a limited group of suppliers, and if our suppliers fail to meet our requirements we may be unable to meet customer demand and our customer relationships would suffer.**

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

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

We can give no assurance that we would be able to identify and qualify additional suppliers of critical components and sub-assemblies in a timely manner. Further, a significant increase in the price of one or more key components or sub-assemblies included in our products could seriously harm our results of operations.

**We may have difficulty responding to changing technology.**

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

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

We market our products internationally through independent distributors. These distributors also distribute competing products under certain circumstances. The loss of a significant international distributor could have a material adverse effect on our business if a new distributor, sales representative or other suitable sales organization cannot be found on a timely basis in the relevant geographic market. Because we rely on distributors for international sales, any revenues we receive in those territories will depend upon the efforts of our distributors. Furthermore, we cannot be sure that a distributor will market our products successfully or that the terms of any future distribution arrangements will be acceptable to us. In 2009, 14% of our revenue came from the sale of product to international distributors.

**If economic conditions or slow market adoption of our MTWA technology cause us to reduce the selling price of our products, our gross margin and operating results will likely worsen.**

The average selling prices of our products are subject to market conditions. Market conditions that may impact our selling prices include:

- changes in reimbursement policies of government and third-party payers;
- physician practices and hospital budgetary constraints;
- the introduction of competing products;
- tightening of credit for customers seeking financing for their purchase of our equipment; and
- delays in purchasing decisions.

If such external factors cause us to offer our products at lower prices and we are unable to mitigate the lower selling prices with lower cost of goods, our gross margins and operating results will likely decline.

*Risks Related to the Market for Cardiac Diagnostic Equipment*

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

Our revenue is primarily derived from sales of our Heartwave II Systems and Micro-V Alternans Sensors. Our ability to successfully commercialize these products depends on our first obtaining, and then maintaining, adequate levels of third-party reimbursement for use of these products by our customers. The amount of reimbursement in the U.S. that is available for clinical use of the MTWA Test varies. In the U.S., the cost of medical care is funded, in substantial part, by government insurance programs, such as Medicare and Medicaid, and private and corporate health insurance plans. Third-party payers will seek to deny reimbursement if they determine that a prescribed device is not used in accordance with cost-effective treatment methods as determined

by the payer, or is experimental, investigations unnecessary or inappropriate. In July 2009, CMS released its proposed 2010 Medicare Physician Fee Schedule (MPFS). MPFS rates are updated annually and have resulted in negative updates since 2002. In November 2009, CMS issued its final ruling on MPFS effective January 1, 2010. This ruling sets forth a reduction of Relative Value Unit (RVU) for nearly all cardiovascular services to be phased in over a four-year period. The final rule also includes an additional 21% reduction in the conversion factor. In past proposals, however, Congress has enacted legislation to sustain the conversion factor component of the reimbursement calculations. Therefore, the impact of this ruling on reimbursement will be determined once the conversion factor is final. In January 2010, CMS temporarily maintained the conversion factor at the 2009 level through the end of March 2010, which set the national average Medicare payment amount for a MTWA Test during that period at \$196.71. Any reduction in reimbursement, material change in indication or reversal of private payer coverage for our MTWA Test may affect the demand for, price of, or utilization of our Heartwave II System and Micro-V Alternans Sensors, which may in turn have a material adverse effect on our business.

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

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Although we maintain product liability insurance in the U.S. and in other countries in which we conduct business, including clinical trials and product marketing and sales, such coverage may not be adequate. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of our products, cause a significant financial burden on Cambridge Heart, or both, which in either case could have a material adverse effect on our business and financial condition.

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

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

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

Our success will depend, in part, on our ability to avoid infringing the intellectual property rights of others and/or breaching the licenses upon which our products and technologies are based. We have licensed significant technology and patents from third parties, including patents and technology relating to MTWA licensed from the Massachusetts Institute of Technology. Our license of patents and patent applications impose various commercialization, sublicensing, insurance, royalty and other obligations on our part. If we fail to comply with these requirements, licenses could convert from being exclusive to non-exclusive in nature or could terminate, either of which would adversely affect our business.

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

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

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our facilities consist of 17,639 usable square feet of office, research and manufacturing space located at 100 Ames Pond Drive, Tewksbury, Massachusetts. This facility is under a five-year lease expiring on April 30, 2013 with the option to extend for one additional period of five years.

**Item 3. Legal Proceedings**

We are not party to any material legal proceedings.

**Item 3A. Executive Officers of the Registrant**

*Ali Haghighi-Mood, Ph.D.* Mr. Haghighi-Mood, age 50, has been our President and Chief Executive Officer since December 2007. From December 2006 until December 2007, Dr. Haghighi-Mood served as our Executive Vice President, Chief Operating Officer and Chief Technology Officer. He was the Vice President of Research and Development from July 2003 until December 2006. From January 2002 to July 2003, he served as our Director of Research and has worked in our research and development department since January 1997. Dr. Haghighi-Mood is the holder of several patents covering our Microvolt T-Wave Alternans technology including our proprietary Analytic Spectral Method for the measurement of T-Wave Alternans. Dr. Haghighi-Mood holds a B.S. and an M.S. in Electrical Engineering from the University of Tehran and a Ph.D. in Biomedical Engineering from the University of Sussex in the U.K.

*Vincenzo LiCausi.* Mr. LiCausi, age 36, has been our Chief Financial Officer and Vice President of Finance and Administration since July 2007. From October 2006 to July 2007, Mr. LiCausi was our Controller. Prior to joining Cambridge Heart, from 2004 to 2006, Mr. LiCausi was employed by Bard Electrophysiology, a division of C.R. Bard, serving in various positions including General Accounting Manager. From 2001 to 2004, Mr. LiCausi was Senior Financial Analyst of Planning & Analysis with Tropicana Products, a division of PepsiCo. From 1997 to 2001, Mr. LiCausi was a Senior Auditor for Deloitte & Touche. Mr. LiCausi is a CPA and has a B.S. in Accountancy from Bentley University in Waltham, MA.

*Roderick de Greef.* Mr. de Greef, age 49, has served as our Chairman of the Board since November 2008. During the same period, Mr. de Greef has been employed by the Company to work with the Company's Chief Executive Officer and the Board of Directors to formulate the strategic plan of the Company and to oversee the execution of corporate strategy. Mr. de Greef previously served as the Company's Chief Financial Officer from October 2005 to July 2007 and as the Company's Vice President of Finance and Administration from June 2006 to July 2007. From February 2001 to September 2005, Mr. de Greef was Executive Vice President and Chief Financial Officer of Cardiac Science, Inc., which merged with Quinton Cardiology, Inc. From 1995 to 2001, Mr. de Greef provided independent corporate advisory services to a number of early-stage companies. From 1986

to 1995, Mr. de Greef served as Chief Financial Officer of several publicly held, development stage medical technology companies. Mr. de Greef is also a member of the board of directors of several public companies, including Endologix, Inc., and Bio Life Solutions Inc., both of which are in the life sciences field. Mr. de Greef has a B.A. in Economics and International Relations from California State University at San Francisco and earned his M.B.A. from the University of Oregon.

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

**Item 4. Reserved**

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information and Holders

Shares of our common stock are traded on the OTC Bulletin Board under the symbol "CAMH.OB". The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock as reported on the OTC Bulletin Board during the two most recent fiscal years.

<u>Period</u>	<u>2008</u>		<u>2009</u>	
	<u>High</u>	<u>Low</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$1.45	\$0.75	\$0.18	\$0.07
Second Quarter .....	\$0.95	\$0.40	\$0.17	\$0.09
Third Quarter .....	\$0.52	\$0.12	\$0.12	\$0.06
Fourth Quarter .....	\$0.38	\$0.06	\$0.12	\$0.06

The depository for our common stock is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005. On March 9, 2010, we had approximately 144 holders of common stock of record. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

#### Dividends

We have never declared or paid cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, restrictions imposed by financing arrangements, if any, legal and regulatory restrictions on the payment of dividends, current and anticipated cash needs and other factors the board of directors deems relevant. If we were to pay dividends, such dividends would be paid to holders of our preferred stock, prior to any such distribution to holders of common stock. On December 23, 2009, the holder of shares of our Series C Convertible Preferred Stock (the "Series C Preferred") exchanged all outstanding shares of Series C Preferred for an equal number of shares of our Series C-1 Convertible Preferred Stock (the "Series C-1 Preferred") in connection with our private placement sale of Series D Convertible Preferred Stock. The holders of our Series C-1 Preferred are entitled to receive a cash dividend of \$2.76 million (which is the total dividends deemed to be accrued as of December 23, 2009 when the Series C Preferred was exchanged for shares of Series C-1 Preferred) plus cumulative cash dividends at the rate of eight percent (8%) of the deemed original issue price of the Series C-1 Preferred (which is \$2,500 per share) per year on each outstanding share of Series C-1 Preferred (the "Series C-1 Dividend"), provided, however, that the Series C-1 Dividend is only payable when, as and if declared by the Board of Directors. The Series C-1 Dividend is payable prior and in preference to any declaration or payment of any dividend on common stock, other series of our preferred stock or any other capital stock of the Company.

### Item 6. Selected Financial Data

Not applicable.

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

### **Forward-Looking Statements**

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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”, “estimates”, “could” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements as a result of any number of factors. Factors that may cause or contribute to such differences include failure to achieve broad market acceptance of the Company’s MTWA technology, failure of our sales and marketing organization or partners to market our products effectively, inability to hire and retain qualified clinical applications specialists in the Company’s target markets, failure to obtain or maintain adequate levels of third-party reimbursement for use of the Company’s MTWA test, customer delays in making final buying decisions, decreased demand for the Company’s products, failure to obtain funding necessary to develop or enhance our technology, adverse results in future clinical studies of our technology, failure to obtain or maintain patent protection for our technology, overall economic and market conditions. Many of these factors are more fully discussed, as are other factors, in Item 1A. “Risk Factors”. In addition, any forward-looking statements represent our estimates only as of today and should not be relied upon as representing our estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so except as may be legally necessary, even if our estimates should change.

### **Overview**

We are engaged in the research, development and commercialization of products for the non-invasive diagnosis of cardiac disease. Using innovative technologies, we are addressing a key problem in cardiac diagnosis—the identification of those at risk of sudden cardiac arrest. Our proprietary technology and products are the first diagnostic tools cleared by the FDA to non-invasively measure Microvolt levels of T-Wave Alternans or MTWA, an extremely subtle beat-to-beat fluctuation in the T-Wave portion of a patient’s electrocardiogram. Our MTWA Test is performed using our Heartwave II System in conjunction with our single patient use Micro-V Alternans Sensors.

In March 2007, we entered into a Co-Marketing Agreement with St. Jude Medical granting St. Jude Medical the exclusive right to market and sell our Heartwave II System and other MTWA products to cardiologists and electrophysiologists in North America. In June 2007, the Co-Marketing Agreement was amended, effective March 21, 2007, to enable St. Jude Medical to also market our Heartwave II System and other MTWA products to North American primary care and internal medicine physicians and to enable Cambridge Heart’s sales team to support St. Jude Medical’s field sales force in all physician markets in North America.

In July 2008, we entered into a Restated Co-Marketing Agreement with St. Jude Medical which, effective May 5, 2008, replaced the previous Co-Marketing Agreement. The amendment granted St. Jude Medical the non-exclusive right to market and sell our Heartwave II System and other MTWA products to physicians in North America. Pursuant to the Restated Agreement, we retained full sales responsibility and could approach and deal directly with any account. We agreed to collaborate in the development and implementation of co-marketing programs with respect to marketing our products that may involve co-branding marketing materials, co-sponsoring of educational events and joint presence at industry conventions and trade shows. The Restated Agreement ended on November 5, 2008.

In order to position the Company to operate more efficiently, focus its resources to take advantage of strategic opportunities and reduce cash expenditures, at the end of the first quarter of 2009 we implemented an expense reduction initiative. This initiative included a 33% reduction in headcount. The reduction in headcount,

which impacted all of the Company's operational areas, included a restructuring of the direct sales organization to improve cost effectiveness.

In June 2009, we announced a new strategy aimed at increasing the sales and use of our proprietary MTWA technology. The strategy calls for the Company to partner with manufacturers of cardiac stress testing equipment to develop an MTWA Module that would be integrated into their systems and marketed to a much larger number of cardiologists and internal medicine practitioners. Historically, the Company's marketing strategy was focused on providing MTWA testing to those patients at highest risk for SCA and who were likely candidates to receive implantable defibrillation devices (ICDs). Although MTWA testing has clearly been demonstrated to be useful in identifying those individuals who could benefit from ICD therapy, clinical experience and a growing body of data suggests that MTWA technology can and should be used to identify and manage the risk of SCA in a much broader population of cardiac patients. The Company estimates that there are approximately 10 to 12 million heart attack and heart failure patients in the U.S., who can benefit from annual MTWA testing. Furthermore, this new strategy makes our technology more readily accessible, economically attractive and logistically simpler to integrate into the practice of those physicians who are already providing cardiac stress or other non-invasive testing. The MTWA Module would allow an integrated stress and MTWA Test, using the Company's proprietary sensors, to be performed on a partners' stress testing platform via customized software and patient interface. The manufacturer would market the MTWA Module as an upgrade to their existing installed base of Q-Stress Systems, and as an optional feature to new stress customers.

As the first step in the execution of this new strategy, the Company signed a non-exclusive development and distribution agreement with Cardiac Science, a global leader in automated external defibrillator (AED) and diagnostic cardiac monitoring devices, to develop a MTWA Module. Under the Cardiac Science Agreement, we will sell and deliver to Cardiac Science the MTWA Module and our Micro-V Alternans Sensors (together, the "Products") under purchase orders submitted by Cardiac Science. Cardiac Science will resell the Products for use with their Q-Stress test platform through its direct sales force and through its network of distributors and sub-distributors. Cardiac Science's right to resell the Products is non-exclusive. We may continue to sell, distribute and license our MTWA Test and Micro-V Alternans Sensors to other distributors and customers in both generic and customized versions. Cardiac Science will have primary responsibility for preparing sales and marketing materials and for training its sales and service personnel regarding the Products. We will provide clinical and technical training and support to Cardiac Science. In addition, we will provide installation training service to each purchaser of a MTWA Module for use on Cardiac Science's Q-Stress test platform. We also will have customary warranty obligations with respect to the Products sold under the Cardiac Science Agreement.

The initial term of the Cardiac Science Agreement expires on June 22, 2014. The term of the Cardiac Science Agreement will automatically renew for a one year period unless either party notifies the other of its intention to terminate at least 90 days prior to the expiration of the initial or renewal term. The Cardiac Science Agreement may be terminated by us if the MTWA Module has not been launched by September 30, 2010. The Cardiac Science Agreement also may be terminated by either party in the event that the other party has committed a material breach of its obligations under the Cardiac Science Agreement that has not been cured within 60 days' written notice from the terminating party, upon the bankruptcy of either party, and upon 12 months prior written notice to the other party.

In November of 2009, we completed the prototype development of our MTWA Module and later, in February 2010, we completed the product development phase of the MTWA Module. Also in February 2010, we submitted a 510(k) application for regulatory approval of the MTWA Module with the U.S. Food and Drug Administration. We expect that the product will be launched in the third quarter of 2010.

In July 2009, CMS released its proposed 2010 Medicare Physician Fee Schedule (MPFS). MPFS rates are updated annually and have resulted in negative updates since 2002. In November 2009, CMS issued its final ruling on MPFS effective January 1, 2010. This ruling sets forth reduction in Relative Value Unit (RVU) for nearly all cardiovascular services to be phased in over a four-year period. The final rule also includes an



additional 21% reduction in conversion factor. In past proposals, however, Congress has enacted legislation to sustain the conversion factor component of the reimbursement calculations. Therefore, the impact of this ruling on reimbursement will be determined once the conversion factor is final. In January 2010, CMS temporarily maintained the conversion factor at the 2009 level through the end of March 2010, which set the national average Medicare payment amount for a MTWA test during that period at \$196.71. Any reduction in reimbursement, material change in indication or reversal of private payer coverage for our MTWA Test may affect the demand for, price of, or utilization of our Heartwave II System and Micro-V Alternans Sensors, which may in turn have a material adverse effect on our business. See further discussion regarding reimbursement in Item 1A. "Risk Factors".

In December 2009, we filed three patent applications with the U.S. Patent Office to further enhance our intellectual property portfolio. These applications cover our intellectual property in the areas of measuring Alternans from ambulatory electrocardiographic devices (i.e. Holter monitoring equipment), Alternans and cardiac ischemia, and Alternans and pharmacological agents.

On December 23, 2009, we completed a private placement of Series D Convertible Preferred Stock ("Series D Preferred"), raising proceeds of approximately \$1.8 million, net of issuance costs. Under the terms of the financing, the Company issued and sold 1,852 shares of Series D Preferred, which have a senior liquidation preference, at a purchase price of \$1,000 per share. Each share of Series D Preferred is convertible into shares of the Company's common stock at a conversion price of \$0.082 per common share, representing a 15% premium to the 20-day trailing average of the Company's closing common stock price as of December 21, 2009 (the "Closing Price"). The total number of shares of common stock initially issuable upon conversion of the Series D Preferred issued in the financing is 22,585,366. In addition to the Series D Preferred, the Company issued a short-term warrant and a long-term warrant to each investor. The short-term warrant entitles the investor, for a period of one year, to purchase a number of shares of common stock equal to 50 percent of the number of shares of common stock into which the Series D Preferred purchased by each investor is convertible. The exercise price of the short-term warrant is \$0.107 per share, or a 50% premium to the Closing Price. If the short-term warrants are exercised, an additional \$1.2 million in capital would be raised in 2010. The long-term warrant entitles the investor, for a period of up to five years, to purchase a number of shares of common stock equal to 30 percent of the number of shares of common stock into which the Series D Preferred purchased by each investor is convertible. The exercise price of the long-term warrant is \$0.142 per share, or a 100% premium to the Closing Price. If at anytime during the five-year term, the Company's common stock trades at \$0.284 per share or higher for a period of 20 consecutive trading days, the Company can require the investors to exercise all remaining warrants, which would generate additional capital of approximately \$900,000. The Series D Preferred financing was provided by institutional and individual investors, including existing shareholders. Three members of our Board of Directors also participated in the financing and provided approximately 20% of the total capital raised.

In December 2009, we reduced the size of our Board of Directors from seven members to five in order to reduce expenses and streamline our decision making process. As part of the reduction, Kenneth Hachikian, Reed Malleck and Dr. Richard Cohen resigned as directors of the Company effective December 30, 2009. Dr. Cohen continues to work with the Company as a consultant and as Chairman of the Company's Scientific Advisory Board, in which capacities he will interact with the Board of Directors on a regular basis. On December 30, 2009, Paul McCormick, Executive Chairman of Cardiogenesis, Inc., a member of the board of directors of Endologix, Inc. and Cianna Medical, Inc. and former President and Chief Executive Officer of Endologix, Inc., joined our Board of Directors.

In 2010, we intend to continue to broaden our distribution channels through strategic alliances with medical device companies that offer synergistic opportunities and offer large established distribution networks, as well as explore opportunities for new applications of our technology. This will enable us to focus our resources on enhancing utilization of our MTWA Test and increasing awareness of our technology in the medical community through marketing initiatives and education programs. We also will continue to seek additional third party payer reimbursement from other third party insurers that currently do not cover MTWA testing.

At December 31, 2009, we had 26 full time and six part time employees, of which 14 full time and two part time employees were engaged in sales, marketing and clinical support activities, three full time and one part time employee involved in manufacturing and operations, two full time employees engaged in research and development, and seven full time and three part time employees dedicated to administrative support. Refer to the Employee section under Part I, Item 1. Business for further details regarding our headcount.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Management's discussion and analysis of the financial condition and results of operations is based upon the financial statements which have been prepared in accordance with accounting principles generally accepted in the United States. Note 2 of the notes to the financial statements contained in this Annual Report on Form 10-K includes a summary of our significant accounting policies and methods used in the preparation of our financial statements. The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to the fair value of preferred stock and warrants, revenue recognition, incentive compensation, product warranties, bad debt allowances and inventory valuation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

### ***Revenue Recognition***

Revenue from the sale of product to all of the Company's customers is recognized upon shipment of goods provided that risk of loss has passed to the customer, all of the Company's obligations have been fulfilled, persuasive evidence of an arrangement exists, the fee is fixed or determinable, and collectability is probable. Revenue from the sale of product to all of our third-party distributors is subject to the same recognition criteria. These distributors provide all direct repair and support services to their customers. The Company also sells maintenance agreements with the HearTwave System. Revenue from maintenance contracts is recognized separately based on amounts charged when sold on a stand-alone basis and is recorded over the term of the underlying agreement. Payments of \$302,573 at December 31, 2009 (\$362,938 at December 31, 2008) received in advance of services being performed is recorded as deferred revenue and included in current liabilities in the accompanying balance sheet. The Company offers usage agreements under its Technology Placement Program ("TPP") whereby customers have use of the HearTwave System and a pre-set level of Micro-V Alternans Sensors for a 90-day period. Under the TPP, the Company retains title to the HearTwave System. The revenue from the TPP is recognized over the term of the usage agreement, which is generally three months.

### ***Allowance for Doubtful Accounts***

We maintain an allowance for doubtful accounts for estimated losses resulting from the non-payment of outstanding amounts due to us from our customers. We determine the amount of the allowance by evaluating the customer's credit history, current financial condition and payment history. We make a judgment as to the likelihood we will experience a loss of all or some portion of the outstanding balance.

As of December 31, 2009, our allowance for doubtful accounts was \$171,515. We believe we have an adequate allowance; however, additional write-offs could occur if future results significantly differ from our expectations.

### ***Inventory Valuation***

We regularly assess the value of our inventory for estimated obsolescence or unmarketable inventory. If necessary, we write-down our inventory value to the estimated fair market value based upon assumptions about

future demand and market conditions. In December 2009, we had a reserve of \$967,148, mostly related to the inventory that was built up in order to satisfy our contractual obligations to St. Jude Medical. The reserve is due to the uncertainty of realizing the value of excess inventory. We do not believe that the inventory is exposed to obsolescence risk. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required from time to time that could adversely affect our operating results for the fiscal period in which such write-downs are affected.

### ***Stock-Based Compensation***

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the statement of operations over the requisite service period.

The Company uses the Black-Scholes option pricing model which requires extensive use of financial estimates and accounting judgment, including the expected volatility of the Company's common stock over the estimated term of the options granted, estimates of the expected time period that employees will retain their vested stock options prior to exercising them, and the number of shares that are expected to be forfeited before the options are vested. The use of alternative assumptions could produce significantly different estimates of the fair value of the stock-based compensation and, as a result, provide significantly different amounts recognized in the Company's statement of operations.

### ***Product Warranty***

The Company warrants all of its non-disposable products as to compliance with their specifications and that the products are free from defects in material and workmanship for a period of 13 months from the date of delivery. The Company maintains a reserve for the estimated cost of potential future repair of its products during this warranty period. The amount of the reserve is based on the Company's actual return and repair cost experience. If the rate and cost of future warranty activities materially differs from the Company's historical experience, additional costs would have to be reserved that could materially affect the Company's operating results.

### ***Preferred Stock and Warrants***

The Company initially account for convertible preferred stock and associated warrants by allocating the proceeds received net of transaction costs based on the relative fair value of the convertible preferred stock and the warrants issued to the investors, and then to any beneficial conversion features contained in the convertible preferred securities. The Company determined the initial value of the convertible preferred stock and warrants using valuation models the Company considered to be appropriate.

### **Results of Operations**

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

	<u>2008</u>	<u>% of Total</u>	<u>2009</u>	<u>% of Total</u>	<u>% Inc/(Dec) 2009 vs 2008</u>
<b>Alternans Products:</b>					
U.S. ....	\$2,847,509	67%	\$1,988,416	62%	-30%
Rest of World .....	287,865	7%	293,041	9%	2%
Total .....	<u>3,135,374</u>	74%	<u>2,281,457</u>	71%	-27%
<b>Non-Alternans Products:</b>					
U.S. ....	721,319	17%	781,737	24%	8%
Rest of World .....	382,050	9%	168,715	5%	-56%
Total .....	<u>1,103,369</u>	26%	<u>950,452</u>	29%	-14%
Total Revenues .....	<u>\$4,238,743</u>	100%	<u>\$3,231,909</u>	100%	-24%

## 2009 Compared to 2008

### REVENUE

Total revenue for 2009 and 2008 was \$3,231,909 and \$4,238,743, respectively, a decrease of 24%. Revenue from the sale of our MTWA product line, which we call our Alternans Products, was \$2,281,457 during 2009 compared to \$3,135,374 during 2008, a decrease of 27%. Alternans Products accounted for 71% and 74% of total revenue for 2009 and 2008, respectively. System placements in 2009 were 51 compared to 70 in 2008. In 2009, we sold fewer Heartwave II Systems compared to 2008, due to a number of factors including weak economic conditions and uncertainty in healthcare and reimbursement, which had a significant adverse impact on medical capital equipment sales in 2009 as a whole.

In addition to the general economic weakness in the medical capital equipment market, we continued to face a number of other challenges including the historical marketing strategy of the technology, practice integration issues and a lack of a distribution network. We believe that our new strategy will help us overcome these obstacles. By making our technology available in multiple product embodiments and by partnering with manufacturers of cardiac testing equipment, we can reach a much larger number of cardiologists and internal medicine practitioners that provide healthcare services to a broad group of at-risk cardiac patients who routinely undergo cardiac evaluations. This new strategy makes our technology more readily accessible, economically attractive and logistically simpler to integrate into the practice of those physicians who are already providing cardiac stress or other non-invasive testing. We also believe that the access to a larger and more established distribution network will allow us to place more strategic focus on increasing clinical utilization of our Alternans technology and increasing sales of our proprietary Micro-V Alternans Sensors.

### GROSS PROFIT

Gross profit was 43% of total revenue in 2009 compared to 25% of total revenue in 2008. This increase in gross margin is primarily due to the \$920,787 provision, recorded in 2008, reducing the excess inventory purchased to fulfill expected sales and satisfy our contractual obligations under the arrangement with St. Jude Medical. The provision is based on the uncertainty of realizing the value of the excess inventory. We do not believe that the inventory is exposed to obsolescence risk. We anticipate that overall gross profit will improve in 2010 to a small to moderate degree as we launch the lower cost MTWA Module in the third quarter of 2010.

### OPERATING EXPENSES

The following table presents, for the periods indicated, our operating expenses. This information has been derived from our statement of operations included elsewhere in this Annual Report on Form 10-K. Our operating expenses for any period are not necessarily indicative of future trends.

	<u>2008</u>	<u>% of Total Revenue</u>	<u>2009</u>	<u>% of Total Revenue</u>	<u>% Inc/(Dec) 2009 vs 2008</u>
Operating Expenses:					
Research and development . . . . .	\$ 542,102	13%	\$ 380,840	12%	-30%
Selling, general and administrative . . . . .	<u>10,861,678</u>	<u>256%</u>	<u>8,380,199</u>	<u>259%</u>	<u>-23%</u>
Total . . . . .	\$11,403,780	269%	\$8,761,039	271%	-23%

### RESEARCH AND DEVELOPMENT

Research and development (R&D) expenses were \$380,840 in 2009 compared to \$542,102 in 2008, a decrease of 30%. The decrease is primarily attributable to one-time patent related costs incurred in 2008, as well as recruiting fees. We expect R&D costs to increase in 2010 as a result of the development of the MTWA Module.

### *SELLING, GENERAL AND ADMINISTRATIVE*

Selling, general and administrative (SG&A) expenses were \$8,380,199 in 2009 compared to \$10,861,678 in 2008, a decrease of 23%. Selling and marketing costs, which accounted for 42% of total SG&A in 2009, decreased 32% from 2008. The decrease in selling expense from 2008 was driven by the reduction in headcount in March 2009 and lower variable selling expenses as a result of lower sales of commissionable products in the U.S. Refer to the Employee section under Item 1. "Business" for further details regarding headcount. Administrative costs accounted for 58% of total SG&A compared to 52% in 2008. SG&A costs for 2009 included \$1,990,834 in non-cash stock-based compensation expense, compared to \$2,418,122 in 2008. We anticipate that SG&A expenses will decrease in 2010 as we continue to eliminate or scale back on consultative and overhead costs.

### *INTEREST INCOME/INTEREST EXPENSE*

Interest income was \$29,556 in 2009 compared to \$356,941 in 2008, a decrease of 92%. The decrease is primarily the result of lower amounts of invested cash and declining short-term interest rates. Interest expense was \$6,926 in 2009 compared to \$43,144 in fiscal year 2008, a decrease of 84%, due to costs associated with our line of credit from Citigroup, which was paid off completely in the fourth quarter of 2008.

### *NET LOSS*

Net loss attributable to common stockholders was \$7,455,768 in 2009 as compared to a net loss of \$10,030,089 in 2008.

### **Liquidity and Capital Resources**

Cash and cash equivalents were \$3,159,468 at December 31, 2009, compared to \$6,207,074 at December 31, 2008. In addition, we held restricted cash in a standby letter of credit in favor of the landlord as security for the obligations under the facility lease. The amount of the letter of credit is \$500,000 for the first and second lease years and reduces by \$100,000 at the end of each of the second, third and fourth lease years. At December 31, 2009 and 2008, cash and cash equivalents included cash held in an operating bank account and cash invested in money market funds. The money market funds are readily convertible into known amounts of cash and therefore, are classified as cash equivalents. At December 31, 2009 and 2008, the restricted cash was held in money market funds.

The overall decrease in the Company's cash and cash equivalents is primarily attributable to cash used by operations. Our financial statements have been prepared on a "going concern basis," which assumes we will realize our assets and discharge our liabilities in the normal course of business. We have experienced recurring losses from operations of \$7,371,056 and \$10,343,886 for the years ended December 31, 2009 and 2008, respectively. In 2009, the net loss we incurred included non-cash stock-based compensation expense of \$2,026,058. The main changes in operating assets and liabilities in 2009 were a decrease in accounts receivable, net of allowance for doubtful accounts, of \$307,992, or 40%, as a result of cash collection efforts and lower sales volume, and a decrease in inventory, net of reserve, of \$302,710, or 21%, attributable to the sale of our products during 2009. Due to inventory built up in order to satisfy our contractual obligations to St. Jude Medical, we did not need to make significant inventory purchases related to our Heartwave II System. However, due to the uncertainty of realizing the value of any excess inventory, we maintain an inventory reserve, which was increased as of December 31, 2009 to \$967,148 from \$940,165 at December 31, 2008. We do not believe that the inventory is exposed to obsolescence risk. Prepaid expenses and other current assets at December 31, 2009 decreased \$4,768 compared to December 31, 2008. Fixed assets at December 31, 2009 decreased \$118,464 compared to December 31, 2008, primarily due to depreciation related to capitalized costs associated with our new facility as well as the sale of Heartwave II Systems sold through our Technology Placement Program where we retained title to the equipment originally, but upon sale, title was transferred to customers. Accounts payable and accrued expenses at December 31, 2009 decreased \$250,269 compared to December 31, 2008 as our inventory purchases subsided. As a result of the aforementioned, we have incurred negative cash flow from

operations of \$4,831,626 and \$5,684,806, for the years ended December 31, 2009 and 2008, respectively. In addition, we have an accumulated deficit at December 31, 2009 of \$95,992,519.

In order to position the Company to operate more efficiently in light of continued challenging economic conditions and to focus resources to take advantage of strategic opportunities, in March 2009, we implemented an expense reduction initiative. The initiative, in conjunction with previous measures, which included a 33% reduction in headcount, amounted to cash savings of approximately \$500,000 per quarter. The reduction in headcount, which impacted all of our operational areas, included a restructuring of the direct sales organization to improve cost effectiveness. Refer to the Employee section under Item 1. "Business" for further details regarding our headcount. During 2009, we managed to support the Company's operations with the down-sized organizational structure and may continue to do so into 2010.

In December 2009, we collected \$1,852,000 of aggregate proceeds from the Series D Financing. The Company intends to use the proceeds of the Series D Financing to fund its ongoing operations. See Note 9 of the Notes to these Financial Statements.

Going forward, we intend to further reduce our operational expenditures by eliminating and scaling back on overhead and consultative costs. In December 2009, we reduced the size of our Board of Directors from seven members to five, in order to reduce costs and streamline the Company's decision making process. In addition, we replaced 10% of senior management's salaries and 100% of senior management's 2009 earned bonuses with stock options to purchase shares of common stock of the Company; we eliminated per meeting director fees and reduced the annual retainer paid to directors. In recognition of this reduction in fees, we awarded each director stock options to purchase shares of common stock of the Company. We are also scaling back on the level of services incurred across all functions of the Company, and we have renegotiated certain consultative and advisory rates for 2010. Currently we are exploring other ways to further reduce our overhead costs and other operating expenses. As the year progresses we intend to assess the existing organizational structure relative to the level of sales and, if necessary, we may implement adjustments accordingly.

In the third quarter of 2010, we expect to commence sales of our MTWA Modules and Micro-V Alternans Sensors to Cardiac Science. Under the Cardiac Science Agreement, we may continue to sell, distribute and license our MTWA Test and Micro-V Alternans Sensors to other distributors and customers in both generic and customized versions. Given that Cardiac Science is more active in larger-sized private practices, hospitals and other institutions, in which we historically have had minimal presence, and given that our Heartwave II System is also a state-of-the art stress test system, we believe that the introduction of the MTWA Module will not cannibalize sales of our Heartwave II System in 2010. Therefore, we expect sales of our Heartwave II System to remain relatively consistent.

In summary, we have evaluated the Company's future cash flow assuming that we are able to reduce operational expenditures, sales of Heartwave II Systems remain steady, and sales of our MTWA Module and Micro-V Alternans Sensors to Cardiac Science commence in the third quarter of 2010. Further, given the build up of inventory as a result of our contractual obligations to St. Jude Medical, we do not anticipate having to make significant inventory purchases related to our Heartwave II System in 2010. Based on these expectations, we believe that our existing resources and currently projected financial results are sufficient to fund our operations through December 31, 2010. In the event the short-term warrants and/or the long-term warrants issued in connection with the private placement of Series D Preferred are exercised in 2010, which would result in \$1.2 million and \$0.9 million of proceeds, respectively, and to the extent that sales of our MTWA Module and Micro-V Alternans Sensors exceed our projected base-line levels, the Company may have sufficient resources to fund its operations beyond the end of 2010. Conversely, if we encounter material deviations from our plan including, but not limited to, a delay in gaining FDA approval for the MTWA Module, a delay in launching the MTWA Module with Cardiac Science, lower than expected level of sales to Cardiac Science, or if we experience lower than expected sales of our Heartwave II Systems, our ability to fund our operations will be negatively impacted. Therefore, we will evaluate the need to implement additional cost cutting initiatives or to raise additional capital as the year progresses. However, there can be no assurance that such capital would be available at all, or if available, that the terms of such financing would not be dilutive to other stockholders.

If we are unable to generate adequate cash flows or obtain sufficient additional funding when needed, we may have to significantly cut back our operations, sell some or all of our assets, license potentially valuable technologies to third parties, and/or cease some or all of our operations.

Our contractual obligations as of December 31, 2009 are included in the table below.

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More than 5 Years</u>
Capital Lease Obligations . . . . .	\$ 27,122	\$ 13,571	\$ 13,551	\$—	\$—
Operating Lease Obligations . . . . .	\$1,287,216	\$374,587	\$912,629	\$—	\$—
Purchase Obligations . . . . .	\$ 40,000	\$ 10,000	\$ 30,000	\$—	\$—
Total . . . . .	\$1,354,338	\$398,158	\$956,180	\$—	\$—

In November 2007, we entered into a definitive agreement with Farley White Management Company, LLC to lease 17,639 usable square feet of office space located at 100-200 Ames Pond Drive, Tewksbury, Massachusetts, which is our new executive and operating facility. The initial lease term is for 62 months with an option to extend the lease for one extension period of five years. The term of the lease commenced in February 2008 following the completion of the construction of the interior of the space that we occupy. We were not required to pay rent for the first two months of the initial lease term. Thereafter, the annual base rent for the first, second, third, fourth and fifth years of the initial lease term is \$262,500, \$367,776, \$377,992, \$388,208 and \$398,424, respectively, plus our pro-rata share of real estate taxes and property maintenance, in each case over a base year. During the term of our lease, we are required to maintain a standby letter of credit in favor of the landlord as security for the obligations under the lease. The amount of the letter of credit is \$500,000 for the first and second lease years and reduces by \$100,000 at the end of each of the second, third and fourth lease years. We occupied the space in February 2008 and therefore the reduction will begin in 2010. The landlord for the property is responsible for paying for the costs of construction for the interior of the space to be occupied by us. We are generally responsible for paying our interior furnishings, telephones, data cabling and equipment. Based on these terms, we account for this agreement as an operating lease.

In addition, under the terms of our license and consulting and technology agreements, we are required to pay royalties on sales of our Alternans products. Minimum license maintenance fees under the MIT license agreement, which is creditable against royalties otherwise payable for each year, is \$10,000 per year through 2013. We are committed to pay an aggregate of \$10,000 of such minimum license maintenance fees subsequent to December 31, 2009. In addition, monthly royalty under the Company’s consulting and technology agreement is \$10,789.

#### **Off-Balance Sheet Arrangements**

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

#### **Recent Accounting Pronouncements**

Effective January 1, 2009 the Company adopted new fair value guidance with respect to non-financial assets and liabilities measured on a non-recurring basis. The adoption of this guidance did not affect our financial position or results of operations.

In December 2007, the FASB established principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. It also established disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. This guidance became effective for the Company beginning January 1, 2009. The adoption of these requirements did not affect our financial position or results of operations, and will not unless the Company consummates an acquisition.

In December 2007, the FASB established accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The FASB also established disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. This guidance became effective for the Company beginning January 1, 2009 and did not have an impact on the Company financial position or results of operations.

In March 2008, the FASB issued a pronouncement that enhanced the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. This guidance became effective for us beginning January 1, 2009 and did not have an impact on the Company's financial position or results of operations.

In June 2008, the FASB Emerging Task Force issued guidance clarifying accounting assessing whether an equity-linked financial instrument is indexed to an entity's own stock for purposes of determining whether it should be accounted for in equity accounts or subject to derivative accounting. The guidance became effective for the Company on January 1, 2009. Management performed an analysis of the Company's existing instruments and determined that it has no impact on the Company's results of operations and financial condition.

In April 2009, the FASB issued guidance to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This became effective for our second fiscal quarter ended June 30, 2009 and had no impact on the Company's results of operations, financial condition or financial statements.

In April 2009, the FASB issued guidance to provide guidelines for making fair value measurements more consistent with the principles presented by the FASB. It is applicable to all assets and liabilities (i.e. financial and nonfinancial) and provides additional authoritative guidance to determine whether a market is active or inactive or whether a transaction is distressed. This guidance became effective for our second fiscal quarter ended June 30, 2009 and had no impact on the Company's results of operations, financial condition or financial statements.

In June 2009, the Company adopted the provisions of FASB which requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of this standard increased disclosure requirements related to the Company's interim financial statements but did not impact our financial position, results of operations or cash flows.

In June 2009, the FASB issued guidance establishing the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. The Company has updated references to GAAP in its financial statements issued for the period ended September 30, 2009. The adoption increased disclosure requirements related to the Company's interim financial statements but did not impact our financial position, results of operations or cash flows.



In June 2009, the Company adopted the FASB provisions establishing general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The guidance did not have an impact on our financial position, results of operations, or cash flows. See Subsequent Events at Note 17 to the financial statements.

In September 2009, the Emerging Issues Task Force issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules that are currently used by the company. This guidance is effective for the Company January 1, 2011 and is not expected to be material to our consolidated financial position or results of operations.

In September 2009, the Emerging Issues Task Force issued new rules which changed the accounting model for revenue arrangements that include both tangible products and software elements, such that tangible products containing both software and non-software components that function together to deliver the tangible product's essential functionality are no longer within the scope of software revenue guidance. This guidance is effective for us January 1, 2011 and is not expected to be material to our consolidated financial position or results of operations.

#### **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. None of these market-risk sensitive instruments are held for trading purposes.

In 2008, investments consisted of money market funds and marketable securities. The money market funds were readily convertible into known amounts of cash, and, therefore, were classified as cash equivalents. The marketable securities consisted of municipal bonds with long-term nominal maturities that are triple "A" credit rated debt instruments collateralized by student loans and guaranteed by the U.S. Department of Education under the Federal Family Education Loan Program ("FFELP") up to 98%. The interest rates on these municipal bonds reset through an auction process every 28 – 30 days and, therefore, are referred to as auction rate securities (ARSs). We generally had the opportunity to sell these investments during such periodic auctions subject to the availability of buyers. In November 2008, we sold all of our investments in marketable securities at par value.

During 2009, we invested our cash in money market funds. Although we have implemented policies regarding the amount and credit ratings of investments, the valuation and liquidity of these investments are exposed to some level of risk due to market conditions. Given the relative security and liquidity associated with money market funds, we do not believe that a change in market rates would have a material negative impact on the value of our investment portfolio. Declines in interests rates over time will, however, reduce our interest income from our investments. We have not had any material exposure to factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. At December 31, 2008 and 2009, our investments consisted of only money market funds.

**Item 8. Financial Statements and Supplementary Data**

**CAMBRIDGE HEART, INC.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Cambridge Heart, Inc. as of December 31, 2008 and 2009, and the related statements of operations, changes in stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cambridge Heart, Inc. as of December 31, 2008 and 2009, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses, inability to generate cash flows from operations, and liquidity uncertainties from operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Caturano and Company, P.C.

CATURANO and COMPANY, P.C.

Boston, Massachusetts

March 31, 2010

**CAMBRIDGE HEART, INC.**

**BALANCE SHEET**

	December 31,	
	2008	2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 6,207,074	\$ 3,159,468
Restricted cash, current portion .....	100,000	100,000
Accounts receivable, net of allowance for doubtful accounts of \$283,576 and \$171,515 at December 31, 2008 and 2009, respectively .....	766,879	458,887
Inventory, net .....	1,455,330	1,152,620
Prepaid expenses and other current assets .....	123,080	118,312
Total current assets .....	\$ 8,652,363	\$ 4,989,287
Fixed assets, net .....	358,434	239,970
Restricted cash, net current portion .....	400,000	400,000
Other assets .....	47,845	42,655
Total Assets .....	\$ 9,458,642	\$ 5,671,912
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable .....	\$ 475,556	\$ 383,768
Accrued expenses .....	1,275,144	1,116,663
Current portion of capital lease obligation .....	11,135	13,571
Total current liabilities .....	1,761,835	1,514,002
Capital lease obligation, net of current portion .....	27,121	13,551
Total liabilities .....	1,788,956	1,527,553
Commitments and contingencies (Note 14)		
Convertible Preferred Stock, \$.001 par value; 2,000,000 shares authorized at December 31, 2008 and 2009, respectively; 5,154 and 6,852 shares issued and outstanding at December 31, 2008 and 2009, respectively. Liquidation preference and redemption value of \$12,501,135 and \$14,352,000 as of December 31, 2008 and 2009, respectively .....		
	11,678,244	12,870,613
	11,678,244	12,870,613
Stockholders' deficit:		
Common Stock, \$.001 par value; 150,000,000 shares authorized; 65,016,521 and 64,904,955 shares issued and outstanding at December 31, 2008 and 2009, respectively .....	65,017	64,905
Additional paid-in capital .....	84,570,518	87,201,360
Accumulated deficit .....	(88,644,093)	(95,992,519)
Total stockholders' deficit .....	(4,008,558)	(8,726,254)
Total Liabilities and Stockholders' Deficit .....	\$ 9,458,642	\$ 5,671,912

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

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

	<u>2008</u>	<u>2009</u>
Revenue .....	\$ 4,238,743	\$ 3,231,909
Cost of goods sold .....	<u>3,178,849</u>	<u>1,841,926</u>
Gross profit .....	1,059,894	1,389,983
Costs and expenses:		
Research and development .....	542,102	380,840
Selling, general and administrative .....	<u>10,861,678</u>	<u>8,380,199</u>
Total costs and expenses .....	<u>11,403,780</u>	<u>8,761,039</u>
Loss from operations .....	(10,343,886)	(7,371,056)
Interest income .....	356,941	29,556
Interest expense .....	<u>(43,144)</u>	<u>(6,926)</u>
Net loss .....	(10,030,089)	(7,348,426)
Beneficial conversion feature (Note 9) .....	<u>—</u>	<u>(107,342)</u>
Net loss attributable to common stockholders .....	<u>\$(10,030,089)</u>	<u>\$(7,455,768)</u>
Net loss per common share-basic and diluted .....	<u>\$ (0.16)</u>	<u>\$ (0.12)</u>
Weighted average common shares outstanding-basic and diluted .....	<u>64,543,021</u>	<u>64,574,536</u>

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

**CAMBRIDGE HEART, INC.**

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

	Common stock, \$.001 par			Accumulated deficit	Total stockholders' equity (deficit)
	Number of Shares	Par Value	Additional paid-in Capital		
Balance at December 31, 2007	64,718,021	\$64,718	\$82,030,007	\$(78,614,004)	\$ 3,480,721
Compensation related to employee granted restricted stock			24,537		24,537
Compensation related to non-employee granted restricted stock			241,736		241,736
Issuance of restricted stock	298,500	299	(299)		—
Stock options granted			2,278,372		2,278,372
Compensation related to non-employee stock options granted			(3,835)		(3,835)
Net Loss				(10,030,089)	(10,030,089)
Balance at December 31, 2008	65,016,521	\$65,017	\$84,570,518	\$(88,644,093)	\$ (4,008,558)
Issuance of common stock warrants			604,218		604,218
Beneficial conversion feature recognized on issuance of Series D Preferred Stock			107,342		107,342
Accretion of beneficial conversion feature related to Series D Preferred Stock			(107,342)		(107,342)
Redemption of Series A Preferred Stock			454		454
Compensation related to employee granted restricted stock			20,312		20,312
Compensation related to non-employee granted restricted stock			233,181		233,181
Cancellation of restricted stock	(111,566)	(112)	112		—
Compensation related to employee stock options granted			1,769,705		1,769,705
Compensation related to non-employee stock options granted			2,860		2,860
Net Loss				(7,348,426)	(7,348,426)
Balance at December 31, 2009	64,904,955	\$64,905	\$87,201,360	\$(95,992,519)	\$ (8,726,254)

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

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

	Year ended December 31,	
	2008	2009
Cash flows from operating activities:		
Net loss .....	\$(10,030,088)	\$(7,348,426)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization .....	90,199	91,888
Inventory provision .....	924,825	26,983
Stock based compensation expense .....	2,540,810	2,026,058
Provisions for allowance for bad debts .....	33,360	33,404
Gain on sale of fixed assets .....	(14,100)	—
Changes in operating assets and liabilities:		
Accounts receivable .....	1,147,653	274,588
Inventory .....	(112,358)	309,380
Prepaid expenses and other current assets .....	(52,354)	4,768
Other assets .....	19,921	—
Accounts payable and accrued expenses .....	(232,673)	(250,269)
Net cash used for operating activities .....	(5,684,806)	(4,831,626)
Cash flows from investing activities:		
Purchases of fixed assets .....	(178,431)	(1,889)
Proceeds from the sale of fixed assets .....	14,100	—
Purchases of marketable securities .....	(2,472,000)	—
Proceeds from the maturity of marketable securities .....	13,672,000	—
Net cash provided by (used in) investing activities .....	11,035,669	(1,889)
Cash flows from financing activities:		
Proceeds from exercise of common and convertible preferred stock warrants .....	852	—
Redemption of Series A Preferred Stock .....	—	(681)
Proceeds from revolving line of credit .....	5,672,302	—
Payments on revolving line of credit .....	(5,672,302)	—
Proceeds from issuance of preferred stock and stock warrants, net issuance costs .....	—	1,797,724
Principal payments on capital lease obligations .....	(11,151)	(11,134)
Net cash provided by (used in) financing activities .....	(10,299)	1,785,909
Net increase (decrease) in cash and cash equivalents .....	5,340,564	(3,047,606)
Cash and cash equivalents, beginning of year .....	866,510	6,207,074
Cash and cash equivalents, end of year .....	\$ 6,207,074	\$ 3,159,468

***Supplemental Disclosure of Cash Flow Information***

During 2008 and 2009, the Company paid \$43,144 and \$6,926 respectively, in interest expense.

**CAMBRIDGE HEART, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. Organization and Basis of Presentation**

*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.

*Basis of Presentation and Liquidity*

The accompanying financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board, the ("FASB"). The FASB sets generally accepted accounting principles ("GAAP") that we follow to ensure our financial condition, results of operations, and cash flows are consistently reported.

The preparation of financial statements requires the Company's management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Company evaluates its estimates on an on-going basis, including those related to incentive compensation, revenue recognition, allowance for doubtful accounts, inventory valuation, income taxes, warranty obligations, the fair value of preferred stock and warrants, stock-based compensation and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to the financial statements.

The accompanying financial statements have been prepared on a "going concern basis," which assumes we will realize our assets and discharge our liabilities in the normal course of business. We have experienced recurring losses from operations of \$7,371,056 and \$10,343,886 for the years ended December 31, 2009 and 2008, respectively. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

In March 2009, the Company underwent a significant cost reduction initiative that affected all functions of the Company and included a headcount reduction and the restructuring of the sales organization. In June 2009, we partnered with Cardiac Science to develop and market the MTWA Module, which we expect to begin selling to Cardiac Science in the third quarter of 2010. In December 2009, we received \$1.8 million in aggregate proceeds from the Series D Financing. In December 2009, the Company reduced the size of its Board of Directors from seven members to five, in order to reduce costs and streamline the Company's decision making process. In March 2010, the Company replaced 10% of senior management's salaries and 100% of senior management's 2009 earned bonuses with stock options to purchase shares of common stock of the Company; the Company eliminated per meeting director fees and reduced the annual retainer paid to directors. The Company is also scaling back on the level of consulting services incurred across all functions of the Company and have renegotiated certain consultative and advisory rates for 2010. Additionally, the Company is currently exploring other ways to further reduce its overhead costs and other operating expenses. As the year progresses, the Company intends to assess the existing organizational structure relative to the level of sales and, if necessary, may implement adjustments accordingly.



The Company has evaluated its future cash flow assuming that the existing business remains steady, operational costs are reduced and sales of the MTWA Module to Cardiac Science commence in the third quarter of 2010. Further, given the build up of inventory as a result of the contractual obligations to St. Jude Medical, the Company does not anticipate having to make significant inventory purchases in 2010 related to the Heartwave II System. Based on this assessment, the Company believes that the existing resources and currently projected financial results, which include sales of the MTWA Module and Micro-V Alternans Sensors to Cardiac Science, are sufficient to fund its operations through December 31, 2010. In the event the short-term warrants and/or the long-term warrants issued in connection with the Series D Preferred private placement are exercised in 2010, which would result in \$1.2 million and \$0.9 million, respectively, of proceeds, and to the extent that sales of the MTWA Module and Micro-V Alternans Sensors exceed the Company's projected base-line levels, the Company may have sufficient resources to fund its operations beyond the end of 2010.

Conversely, if the Company encounters material deviations from the projections including, but not limited to, a delay in gaining FDA clearance for the MTWA Module, a delay in launching the MTWA Module, lower than expected level of sales to Cardiac Science, or if the Company experiences an adverse effect on the expected sales of the existing Heartwave II post the launch of the MTWA Module, the time-line may be negatively impacted. Therefore, the Company will evaluate the need to implement additional cost cutting initiatives or to raise additional capital as the year progresses.

If we are unable to generate adequate cash flows or obtain sufficient additional funding when needed, we may have to significantly cut back our operations, sell some or all of our assets, license potentially valuable technologies to third parties, and/or cease some or all of our operations.

## **2. Summary of Significant Accounting Policies**

Significant accounting policies followed by the Company are as follows:

### ***Cash and Cash Equivalents***

The Company maintains its cash and cash equivalents in bank deposit accounts, which may, at times, exceed federally insured limits. The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. The carrying amount of the Company's cash equivalents approximates fair value due to the short maturities of these investments. This may include short-term commercial paper, short-term securities of state government agencies with maturities less than three months from date of purchase, money market funds and demand deposits with financial institutions.

At December 31, 2009, \$3,152,042 of the Company's cash and cash equivalent was in a transaction account which is fully covered by Federal Deposit Insurance Coverage ("FDIC") through June 30, 2010 under the Temporary Liquidity Guarantee Program. At December 31, 2008 and 2009, the Company classified investments in money market funds totaling \$3,196,586 and \$7,426, respectively, as cash equivalents since these investments are readily convertible into known amounts of cash and do not have significant valuation risk. These investments are currently in a fund that invests exclusively in short-term U.S. Government obligations, including securities issued or guaranteed by the U.S. Government, its agencies and U.S. Treasury securities. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

In June 2008, the Company entered into a revolving credit facility with Citigroup Global Markets, Inc. for borrowings of up to, and secured by, 50% of the Company's auction rate securities ("ARS") owned at the time. The revolving credit facility contained no financial covenants. Any borrowings under the revolving credit facility accrued interest at a variable rate based on short-term market interest rates. During 2008, the Company borrowed \$5,672,302 under the revolving credit facility bearing an annual interest rate of 3.175%. The Company used the funds to support working capital needs. In November 2008, the total amount outstanding under the credit facility was repaid with proceeds from the liquidation of the Company's investments in ARS at par value.

In November 2007, the Company entered into a definitive agreement with Farley White Management Company, LLC to lease 17,639 usable square feet of office space. The initial lease term was for 62 months with an option to extend the lease for one extension period of five years. During the term of the lease, the Company is required to maintain a standby letter of credit in favor of the landlord as security for the Company's obligations under the lease. The amount of the letter of credit is \$500,000 for the first and second lease years and is reduced by \$100,000 at the end of the second, third and fourth lease years. The Company occupied the space in February 2008 and therefore the reduction will begin in 2010. The Company has recorded this letter of credit as restricted cash on its balance sheets.

### ***Investments***

In 2008, investments consisted of money market funds and marketable securities. The money market funds were readily convertible into known amounts of cash, and, therefore, classified as cash equivalents. See "Cash and Cash Equivalents" in Note 2 for further details regarding cash equivalents. The marketable securities consisted of municipal bonds with long-term nominal maturities that were triple "A" credit rated debt instruments collateralized by student loans and guaranteed by the U.S. Department of Education under the Federal Family Education Loan Program ("FFELP") up to 98%. The interest rates on these municipal bonds reset through an auction process every 28 – 30 days and, therefore, are referred to as auction rate securities (ARSs). Investments which are considered held-to-maturity are stated at amortized cost plus accrued interest, which approximates market value. Investments which are considered available-for-sale are carried at fair market value plus accrued interest. Unrealized gains and losses are included in accumulated other comprehensive income (loss) as a separate component of stockholders' deficit. Realized gains and losses, dividends and interest income, including amortization of the premium and discount arising at purchase, are included in interest and investment income. In November 2008, we sold all of our investments in marketable securities at par value. During 2009, we invested our cash in money market funds. At December 31, 2008 and 2009 the Company's investments consisted solely of money market funds classified in cash and cash equivalents.

### ***Revenue Recognition and Accounts Receivable***

Revenue from the sale of product to all of the Company's customers is recognized upon shipment of goods provided that risk of loss has passed to the customer, all of the Company's obligations have been fulfilled, persuasive evidence of an arrangement exists, the fee is fixed or determinable, and collectability is probable. Revenue from the sale of product to all of our third-party distributors is subject to the same recognition criteria. These distributors provide all direct repair and support services to their customers. The Heartwave II System and the CH 2000 Cardiac Stress Test System can be sold with a treadmill or as standalone systems. As necessary, the Company allocates the purchase price to the separate items proportionately based on fair value or amounts charged when sold on a stand-alone basis and, accordingly, defers revenue recognition on unshipped elements until shipment. The Company also sells maintenance agreements with the HearTwave System. Revenue from maintenance contracts is recognized separately based on amounts charged when sold on a stand-alone basis and is recorded over the term of the underlying agreement. Payments of \$302,573 at December 31, 2009 (\$362,938 at December 31, 2008) received in advance of services being performed are recorded as deferred revenue and included in current liabilities in the accompanying balance sheet. The Company offers usage agreements under its Technology Placement Program ("TPP") whereby customers have use of the HearTwave System and a pre-set level of Micro-V Alternans Sensors for a 90-day period. Under the TPP, the Company retains title to the HearTwave System. The revenue from the TPP is recognized over the term of the usage agreement, which is generally three months.

Accounts receivable are stated at the amount management expects to collect from outstanding balances. An allowance for doubtful accounts is provided for those accounts receivable considered to be uncollectible based upon historical experience and management's evaluation of outstanding accounts receivable at the end of the year. Bad debts are written off when identified. The Company's actual experience of customer receivables written off directly during 2008 and 2009 was \$3,764 and \$145,465, respectively. At December 31, 2008 and 2009 the allowance for doubtful accounts was \$283,576 and \$171,515, respectively.

### ***Shipping and Handling Costs***

The Company classifies freight and handling billed to customers as sales revenue and related costs as cost of sales.

### ***Stock-Based Compensation***

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the statement of operations over the requisite service period.

The Company uses the Black-Scholes option pricing model which requires extensive use of financial estimates and accounting judgment, including the expected volatility of the Company's common stock over the estimated term of the options granted, estimates of the expected time period that employees will retain their vested stock options prior to exercising them, and the number of shares that are expected to be forfeited before the options are vested. The use of alternative assumptions could produce significantly different estimates of the fair value of the stock-based compensation and, as a result, provide significantly different amounts recognized in the Company's statement of operations.

The following weighted average assumptions were used to estimate the fair market value of options granted using the Black-Scholes valuation method:

	<u>2008</u>	<u>2009</u>
Dividend Yield .....	0.0%	0.0%
Expected Volatility .....	124%	134%
Risk Free Interest Rate .....	1.49%	1.39%
Expected Option Terms (in years) .....	5	5

The expected volatility is based on the price of the Company's common stock over a historical period which approximates the expected term of the options granted. The risk-free interest rate is based on the U.S. Treasury constant maturity interest rate with a term consistent with the expected life of the options granted. The expected term is estimated based on historical experience and comparable peer group data.

### ***Net Loss Per Share***

Basic loss per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Due to experiencing a net loss in 2008 and 2009, the impact of options to purchase 6,909,868 and 5,928,367 shares of common stock, short term warrants to purchase 0 and 11,292,686 shares of common stock, long term warrants to purchase 0 and 6,775,611 shares of common stock, warrants for the purchase of 115,231 and 0 shares of Series A Convertible Preferred Stock, 154 and 0 shares of Series A Convertible Preferred Stock, 5,000 and 0 shares of Series C Convertible Preferred Stock, 0 and 5,000 shares of Series C-1 Convertible Preferred Stock, 0 and 1,852 shares of Series D Convertible Preferred Stock and 473,500 and 293,800 restricted shares have been excluded from the calculation of diluted weighted average share amounts as their inclusion would have been anti-dilutive as of December 31, 2008 and 2009, respectively.

### ***Comprehensive Loss***

Comprehensive loss is comprised of two components, net loss and other comprehensive income (loss). In June 2008, the Company recorded other comprehensive loss consisting of unrealized gains and losses on investments classified as available-for-sale totaling \$412,079. In September 2008, the Company reversed the unrealized loss in connection with the Company's sale of investments in ARSs at par value. See Note 3 of the notes to these financial statements. For the years ended December 31, 2008 and 2009, the Company had no elements of other comprehensive loss.

### ***Financial Instruments***

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and capital lease obligations, approximate their fair values at December 31, 2008 and 2009 because of their short term nature. The fair value of capital lease obligations is estimated at its carrying value based on current rates.

### ***Inventory Valuation***

Inventories are stated at the lower of cost or market. Cost is computed using standard cost, which includes allocations of labor and overhead. Standard cost approximates actual cost on a first-in, first-out method. Management assesses the value of inventory for estimated obsolescence or unmarketable inventory. If necessary, inventory value may be written down to the estimated fair market value based upon assumptions about future demand and market conditions. In the fourth quarter of 2008, the Company recorded a provision of \$920,787 for excess inventory built up in connection with our contractual obligation as part of the Co-Marketing Agreement with St. Jude Medical. The provision is based on the uncertainty about realizing the value of the excess inventory. In 2009, we increased the reserve by \$26,983. The Company does not believe that the inventory is exposed to obsolescence risk. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required from time to time that could adversely affect operating results for the fiscal period in which such write-downs are affected.

### ***Product Warranty***

The Company warrants all non-disposable products as compliant with their specifications and that the products are free from defects in material and workmanship for a period of 13 months from the date of delivery. A reserve is maintained for the estimated cost of potential future repairs of products during this warranty period. The amount of the reserve is based on actual return and repair cost experience. If the rate and cost of future warranty activities materially differs from the Company's historical experience, additional costs would have to be reserved that could materially affect operating results.

### ***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 loss. At year end 2008 and 2009, the Company had \$14,100 and \$0 gain from the sale of fixed assets.

### ***Licensing Fees and Patent Costs***

The Company has entered into a licensing agreement giving the Company the exclusive rights to certain patents and technologies and the right to market and distribute any products developed, subject to certain covenants. Payments made under this licensing agreement and costs associated with patent applications have generally been expensed as incurred, because recovery of these costs is uncertain. However, certain costs associated with patent applications for products and processes which have received regulatory approval and are available for commercial sale have been capitalized and are being amortized over their estimated economic life of 5 years. The amount of unamortized cost capitalized and included in other assets in the accompanying balance sheets at December 31, 2008 and 2009 was \$47,767 and \$42,577, respectively.

### ***Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax reporting bases of assets and liabilities and are measured by applying the enacted tax rates and laws to taxable years in which the differences are expected to reverse. The Company recognizes a deferred tax asset for the tax benefit of net operating loss carry forwards when it is more likely than not that the tax benefits will be realized

and reduce the deferred tax asset with a valuation reserve when it is more likely than not that some portion of the tax benefits will not be realized.

We use a comprehensive model for the recognition, measurement, and financial statement disclosure of uncertain tax positions. Unrecognized tax benefits are the differences between tax positions taken, or expected to be taken, in tax returns, and the benefits recognized for accounting purposes.

### ***Recent Accounting Pronouncements***

Effective January 1, 2009 the Company adopted new fair value guidance with respect to non-financial assets and liabilities measured on a non-recurring basis. The adoption of this guidance did not affect our financial position or results of operations.

In December 2007, the FASB established principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. It also established disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. This guidance became effective for the Company beginning January 1, 2009. The adoption of these requirements did not affect our financial position or results of operations, and will not unless the Company consummates an acquisition.

In December 2007, the FASB established accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The FASB also established disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. This guidance became effective for the Company beginning January 1, 2009 and did not have an impact on the Company financial position or results of operations.

In March 2008, the FASB issued a pronouncement that enhanced the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. This guidance became effective for us beginning January 1, 2009 and did not have an impact on the Company's financial position or results of operations.

In June 2008, the FASB Emerging Issues Task Force issued guidance clarifying whether an equity-linked financial instrument is indexed to an entity's own stock for purposes of determining whether it should be accounted for in equity accounts or subject to derivative accounting. The guidance became effective for the Company on January 1, 2009. Management performed an analysis of the Company's existing instruments and determined that it has no impact on the Company's results of operations and financial condition.

In April 2009, the FASB issued guidance to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This became effective for our second fiscal quarter ended June 30, 2009 and had no impact on the Company's results of operations, financial condition or financial statements.

In April 2009, the FASB issued guidance to provide guidelines for making fair value measurements more consistent with the principles presented by the FASB. It is applicable to all assets and liabilities (i.e. financial and nonfinancial) and provides additional authoritative guidance to determine whether a market is active or inactive or whether a transaction is distressed. This guidance became effective for our second fiscal quarter ended June 30, 2009 and had no impact on the Company's results of operations, financial condition or financial statements.

In June 2009, the Company adopted the provisions of FASB which requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of this standard increased disclosure requirements related to the Company's interim financial statements but did not impact the Company's financial position, results of operations or cash flows.

In June 2009, the FASB issued guidance establishing the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. The Company has updated references to GAAP in its financial statements issued for the period ended September 30, 2009. The adoption increased disclosure requirements related to the Company's interim financial statements but did not impact the Company's financial position, results of operations or cash flows.

In June 2009, the Company adopted the FASB provisions establishing general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The guidance did not have an impact on the Company's financial position, results of operations, or cash flows. See Subsequent Events at Note 17.

In September 2009, the Emerging Issues Task Force issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules that are currently used by the Company. This guidance is effective for the Company on January 1, 2011 and is not expected to be material to the Company's consolidated financial position or results of operations.

In September 2009, the Emerging Issues Task Force issued new rules which changed the accounting model for revenue arrangements that include both tangible products and software elements, such that tangible products containing both software and non-software components that function together to deliver the tangible product's essential functionality are no longer within the scope of software revenue guidance. This guidance is effective for the Company on January 1, 2011 and is not expected to be material to the Company's consolidated financial position or results of operations.

In January 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-06 Fair Value Measurements and Disclosures (Topic 820) which improves disclosures about fair value measurements. More specifically, ASU 2010-06 updates Topic 820-10 to require disclosure of transfers in and out of levels 1 and 2 and the reason for the transfers. Additionally, it requires separate reporting of purchases, sales, issuances and settlements for level 3. This update is effective for periods beginning after December 15, 2009. The adoption of this standard will not have an impact on the Company's financial position or results of operations.

### **3. Investments**

The Company's investments at December 31, 2008 and 2009 consisted of money market funds. As discussed in Note 2 of the notes to these financial statements, the Company classifies investments in money market funds as cash equivalents since these investments are readily convertible into known amounts of cash and have insignificant valuation risk.

The Company had no investments in marketable debt and equity securities at December 31, 2008 and 2009.

#### 4. Inventory

Inventories consisted of the following at December 31, 2008 and 2009, respectively:

	<u>2008</u>	<u>2009</u>
Raw materials .....	\$ 383,152	\$ 379,423
Work in process .....	10,927	3,818
Finished goods .....	<u>1,061,251</u>	<u>769,379</u>
	<u>\$1,455,330</u>	<u>\$1,152,620</u>

#### 5. Fixed Assets

Fixed assets consist of the following:

	<u>Estimated useful lives (years)</u>	<u>December 31,</u>	
		<u>2008</u>	<u>2009</u>
Computer equipment .....	3-5	\$ 914,565	\$ 916,451
Manufacturing equipment .....	5	424,668	424,670
Office furniture .....	7	130,396	130,395
Sales demonstration and clinical equipment .....	3-5	1,210,609	1,174,163
Leasehold Improvements .....	Life of Lease	<u>47,204</u>	<u>47,204</u>
		2,727,442	2,692,883
Less-accumulated depreciation .....		<u>2,369,008</u>	<u>2,452,913</u>
		<u>\$ 358,434</u>	<u>\$ 239,970</u>

The Company recorded depreciation expense of \$78,757 and \$86,698 for the years ended December 31, 2008 and 2009, respectively.

#### 6. Other Assets

Other assets consist of the following:

	<u>Estimated useful lives (years)</u>	<u>December 31,</u>	
		<u>2008</u>	<u>2009</u>
Capitalized software development costs .....	3	\$1,482,728	\$1,482,728
Patents .....	5	228,548	228,548
Other assets .....		<u>78</u>	<u>78</u>
		1,711,354	1,711,354
Less-accumulated amortization .....		<u>1,663,509</u>	<u>1,668,699</u>
		<u>\$ 47,845</u>	<u>\$ 42,655</u>

The Company recorded amortization expense of \$11,442 and \$5,190 for the years ended December 31, 2008 and 2009, respectively.

## 7. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2008	2009
Accrued employee compensation .....	268,803	321,227
Deferred revenue .....	362,938	302,573
Deferred rent .....	114,500	129,216
Accrued consulting costs .....	26,000	—
Accrued product warranty costs .....	39,076	29,384
Accrued professional fees .....	235,073	171,236
Accrued co-marketing agent fees .....	91,361	—
Accrued other .....	137,393	163,027
	<u>\$1,275,144</u>	<u>\$1,116,663</u>

## 8. Capital Lease

The Company is the lessee of office equipment under a capital lease expiring in 2011. The assets and liabilities under capital leases are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The assets are amortized over their estimated productive lives. Amortization of assets under capital leases is included in depreciation expense for fiscal year 2009.

Following is a summary of property held under capital leases:

Office equipment .....	\$ 56,000
Accumulated amortization .....	<u>(28,878)</u>
	<u>\$ 27,122</u>

Minimum future lease payments under capital leases as of December 31, 2009, were as follows:

	Amount
2010 .....	\$17,784
2011 .....	<u>14,821</u>
Net minimum lease payments .....	32,605
Amount representing interest .....	<u>(5,483)</u>
Present value of net minimum lease payments .....	<u>\$27,122</u>

Interest rate on capital leases is 20% and is imputed based on the lower of the Company's incremental borrowing rate at the inception of each lease or the lessor's implicit rate of return. Certain capital leases provide renewal or purchase options.

## 9. Convertible Preferred Stock

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



Total shares of Convertible Preferred Stock issued and outstanding at December 31, 2008 and 2009, respectively, are as follows:

	December 31,	
	2008	2009
<i>Series A Convertible Preferred</i>		
Shares issued and outstanding . . . . .	154	—
Liquidation preference and redemption value . . . . .	\$ 1,135	—
<i>Series C Convertible Preferred</i>		
Shares issued and outstanding . . . . .	5,000	—
Liquidation preference and redemption value . . . . .	\$12,500,000	—
<i>Series C-1 Convertible Preferred</i>		
Shares issued and outstanding . . . . .	—	5,000
Liquidation preference and redemption value . . . . .	—	\$12,500,000
<i>Series D Convertible Preferred</i>		
Shares issued and outstanding . . . . .	—	1,852
Liquidation preference and redemption value . . . . .	—	\$ 1,852,000
<i>Total Convertible Preferred</i>		
Shares issued and outstanding . . . . .	5,154	6,852
Liquidation preference and redemption value . . . . .	\$12,501,135	\$14,352,000

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

*Series A Convertible Preferred Stock*

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

The holders of Series A Preferred Stock are entitled to receive dividends in an amount at least equal to the product of (i) the per share dividend to be declared, paid or set aside for the common stock, multiplied by (ii) the number of shares of common stock into which such share of Series A Preferred Stock is then convertible. The Series A dividend is payable prior and in preference to any declaration or payment of any dividend on common stock.

In the event of any voluntary or involuntary liquidation (including change-in-control events), dissolution or winding up of the Company, the holder of Series A Preferred Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to holders of common stock or any other class or series of stock ranking on liquidation junior to the Series A Preferred Stock, an amount equal to the greater of (i) par value per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares), plus any

dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had each such share been converted into common stock, as per the conversion price feature, immediately prior to such liquidation, dissolution or winding up.

The conversion price feature of the Series A Preferred Stock was subject to adjustment in certain circumstances if the Company issued shares of common stock under those circumstances on or before November 12, 2004 at a purchase price below the conversion price of the Series A Preferred Stock. No additional shares were issued as a result of this provision.

The holders of Series A Preferred Stock are entitled to vote, on an as-if converted basis, along with the holders of the Company's common stock on all matters on which holders of common stock are entitled to vote.

On December 21, 2009, the Company purchased and redeemed 154 shares of Series A Preferred Stock, representing 100% of the issued and outstanding shares of Series A Preferred Stock, from the holder thereof for an aggregate purchase price of \$681.

Under EITF issued guidance, preferred securities that are redeemable for cash or other assets are to be classified outside of permanent equity if they are redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the control of the issuer. Accordingly, the Company classified the Series A Preferred Stock outside of permanent equity based on the rights of the Series A Preferred Stock in a deemed liquidation.

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

As part of the financing described above, the Company also issued to both Medtronic and the private investors warrants exercisable for 471,703 shares of Series A Preferred Stock. The exercise price of Medtronic's warrant is \$4.42 and the exercise price per share of the warrants issued to the other investors is \$5.525. During the twelve month periods ended December 31, 2008 and 2009, 154 and 0 warrants to purchase Series A stock were exercised. The Company had warrants for the purchase of 115,231 and 0 shares of Series A Preferred Stock, which are convertible into an additional 1,498,003 and 0 shares of common stock, outstanding at December 31, 2008 and December 31, 2009, respectively. The expiration date of these warrants was extended from January 1, 2009 to June 30, 2009 in accordance with the terms of the registration rights agreement between the Company and the investors. Warrants for the purchase of 115,231 shares of Series A Preferred Stock expired unexercised during 2009.

#### *Series C and Series C-1 Convertible Preferred Stock*

On March 21, 2007, the Company and St. Jude Medical entered into an agreement for the sale of \$12.5 million of the Company's Series C Convertible Preferred Stock (the "Series C Preferred Stock") to St. Jude Medical resulting in \$11.7 million net of issuance costs. Under the terms of the financing, the Company issued and sold 5,000 shares of its Series C Preferred Stock at a purchase price of \$2,500 per share (the "Series C Original Issue Price"). Each share of Series C Preferred Stock was convertible into a number of shares of common stock equal to \$2,500 divided by the conversion price of the Series C Preferred Stock, which was initially \$2.99. Each share of Series C Preferred Stock was convertible into approximately 836.12 shares of common stock. The total number of shares of common stock initially issuable upon conversion of the 5,000 shares of Series C Preferred Stock issued and sold in the financing was approximately 4,180,602.

The holders of the Series C Preferred Stock were entitled to receive cumulative cash dividends at the rate of eight percent (8%) of the Series C Original Issue Price per year (the "Series C Dividend") on each outstanding share of Series C Preferred Stock, provided, however, that the Series C Dividend is only payable when, and if declared by the Board of Directors. The Series C Dividend was payable prior and in preference to any declaration or payment of any dividend on Common Stock, other series of Preferred Stock or any other capital stock of the Company.

The conversion price feature of the Series C Preferred Stock was subject to adjustment in certain circumstances if the Company issued shares of common stock under those circumstances on or before March 21, 2008 at a purchase price below the conversion price of the Series C Preferred Stock. No additional shares were issued as a result of this provision.

The holders of Series C Preferred Stock were entitled to receive, prior and in preference to any distribution of the proceeds from any liquidation (including change-in-control events), dissolution or winding up of the Company, whether voluntary or involuntary, to holders of common stock, other series of preferred stock or any other capital stock of the Company, an amount per share equal to the Series C Preferred Stock par value, plus declared but unpaid dividends on such shares.

The holders of Series C Preferred Stock were entitled to vote, on an as-if converted basis, along with holders of the Company's common stock on all matters on which holder of common stock are entitled to vote.

In order to be able to issue securities in the Series D Financing, described below, that are senior to the Series C Preferred Stock previously issued by the Company, the Company entered into a Share Exchange Agreement with St. Jude Medical, dated as of December 23, 2009, pursuant to which St. Jude Medical exchanged 5,000 shares of the Company's Series C Preferred Stock, representing 100% of the issued and outstanding Series C Preferred Stock, for 5,000 newly issued shares of the Company's Series C-1 Convertible Preferred Stock (the "Series C-1 Preferred Stock"). The terms of the Series C-1 Preferred Stock are substantially the same as the terms of the Series C Preferred Stock except that the Series C-1 Preferred Stock is junior to the Series D Preferred Stock in the event of a liquidation or deemed liquidation of the Company.

In the event of a liquidation of the Company (including an Acquisition Transaction or Asset Transfer, each as defined in the Series C-1 Certificate of Designation), the holders of Series C-1 are entitled to receive an amount equal to the Deemed Series C-1 Original Issue Price plus declared but unpaid dividends after the payment to the holders of Series D Preferred Stock, but before any amount to the holders of common stock, and all other equity or equity equivalent securities of the Company other than those securities that are explicitly senior to or on parity with the Series C Preferred Stock with respect to liquidation preference.

Under EITF issued guidance, preferred securities that are redeemable for cash or other assets are to be classified outside of permanent equity if they are redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the control of the issuer. Accordingly, the Company classified the Series C-1 Preferred Stock outside of permanent equity based on the rights of the Series C-1 Preferred Stock in a deemed liquidation.

#### *Series D Convertible Preferred Stock*

On December 23, 2009, the Company issued and sold 1,852 shares of the Company's Series D Convertible Preferred Stock (the "Series D Preferred Stock") and common stock warrants described below to new and current institutional and private investors pursuant to the terms of a Securities Purchase Agreement dated December 23, 2009 between the Company and the purchasers of Series D Preferred Stock (the "Series D Financing"). The aggregate proceeds from the Series D Financing were \$1.8 million, net of issuance costs.

Under the terms of the Series D Financing, the Company issued 1,852 shares of its Series D Preferred Stock at a purchase price of \$1,000 per share (the “Series D Original Issue Price”). Each share of Series D Preferred Stock is convertible into a number of shares of common stock of the Company equal to \$1,000 divided by the conversion price of the Series D Preferred Stock, which is initially \$0.082, representing a 15% premium to the 20-day trailing average of the Company’s closing common stock price as of December 21, 2009 (the “Closing Price”). Each share of Series D Preferred Stock is currently convertible into approximately 12,195 shares of common stock. The total number of shares of common stock initially issuable upon conversion of the 1,852 shares of Series D Preferred Stock issued and sold in the financing is 22,585,366, or approximately 32.69% of the Company’s issued and outstanding common stock assuming that all outstanding shares of preferred stock are converted to common stock.

The Company also issued to the investors two types of warrants. The first warrant, which expires on December 23, 2010, entitles the investor to purchase a number of shares of common stock equal to 50% of the number of shares of common stock into which the Series D Preferred Stock purchased by the investor is convertible (the “Short-Term Warrant”). A total of 11,292,686 shares of common stock are issuable under the Short-Term Warrants. The exercise price of the Short-Term Warrants is \$0.107 per share, which is 150% of the Closing Price. The second warrant, which expires on December 23, 2014, entitles the investor to purchase a number of shares of common stock equal to 30% of the number of shares of common stock into which the Series D Preferred Stock purchased by the investor is convertible (the “Long-Term Warrant”). A total of 6,775,611 shares of common stock are issuable under the Long-Term Warrants. The exercise price of the Long-Term Warrants is \$0.142 per share, or 200% of the Closing Price. The Company may call the Long-Term Warrants if the closing price of the Company’s common stock is at least \$0.284 for a period of 20 consecutive trading days. An analysis was performed on the exercise and settlement provisions of the Long-Term and Short-Term Warrants. As a result, it was determined that they are not considered derivative instruments under ASC 815—*Derivatives and Hedging* as they meet the scope exception since they are both indexed to the Company’s own stock and are classified in stockholders’ equity (deficit) in the Company’s balance sheet.

The conversion price of the Series D Preferred Stock is subject to adjustment in certain circumstances. If the Company issues shares of common stock at a purchase price below the conversion price of the Series D Preferred Stock at any time on or before August 23, 2011, the conversion price of the Series D Preferred Stock will be adjusted as set forth in the Series D Certificate of Designation (as defined below). In determining the appropriate accounting for the conversion feature for the Series D Preferred Stock, the Company determined that the conversion feature does not require bifurcation, and as a result is not considered a derivative under the provisions of ASC 815—*Derivatives and Hedging*.

The holders of the Series D Preferred Stock are entitled to share in any dividends declared and paid, or set aside for payment, on the common stock, pro rata, in accordance with the number of shares of common stock into which such shares of Series D Preferred Stock are then convertible.

The holders of the Series D Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which such shares of Series D Preferred Stock could be converted immediately after the close of business on the record date fixed for such meeting or the effective date of such written consent and shall have voting rights and powers equal to the voting rights and powers of the common stock and shall be entitled to notice of any stockholders’ meeting in accordance with the Bylaws of the Company. The Series D Preferred Stock shall vote together with the common stock at any annual or special meeting of the stockholders and not as a separate class, and act by written consent in the same manner as the common stock.

In the event of a liquidation of the Company (including an Acquisition Transaction or Asset Transfer, each as defined in the Series D Certificate of Designation), the holders of Series D Preferred Stock are entitled to receive an amount equal to the Series D Original Issue Price plus declared but unpaid dividends before the payment of any amount to the holders of common stock, Series C-1 Convertible Preferred Stock and all other equity or equity equivalent securities of the Company other than those securities that are explicitly senior to or on parity with the Series D Preferred Stock with respect to liquidation preference.

Under EITF issued guidance, preferred securities that are redeemable for cash or other assets are to be classified outside of permanent equity if they are redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the control of the issuer. Accordingly, the Company classified the Series D Preferred Stock outside of permanent equity based on the rights of the Series D Preferred Stock in a deemed liquidation.

Under GAAP, proceeds from the sale of securities are to be allocated to each financial instrument based on their relative fair market value. Further, if the convertible preferred stock has an effective price that is less than the fair value of the common stock into which it is convertible on the date of issuance, the difference between the effective price and the fair value represents a beneficial conversion feature. In this regard, we allocated the net proceeds from the Series D Financing based on the relative fair market value of the Series D Preferred Stock using the Company's closing common stock price as of December 23, 2009 and to the related warrants using the Black-Scholes option pricing model. The following assumptions were used to estimate the fair market value of the warrants using the Black-Scholes option pricing model:

	<u>Short-Term</u>	<u>Long-Term</u>
Dividend Yield .....	0.0%	0.0%
Expected Volatility .....	170%	132%
Risk Free Interest Rate .....	0.41%	2.51%
Expected Option Terms (in years) .....	1	5

Based on this allocation, the relative fair value of the Series D Preferred Stock was \$1,247,780. The aggregate fair value of the common stock into which the Series D Preferred Stock are convertible was \$1,355,122. Therefore, the difference between the relative fair value of the Series D Preferred Stock and the fair value of the common stock into which the Series D Preferred Stock are convertible represents a beneficial conversion feature of \$107,342. The amount of the beneficial conversion feature was immediately accreted and the accretion resulted in a deemed dividend as the Series D Preferred Stock was immediately convertible. The deemed dividend was reflected as an adjustment to the net loss applicable to common shareholders on the Company's Statement of Operations for the year ended December 31, 2009.

## **10. Stockholders' Equity**

### ***Common Stock***

The Company's Board of Directors has authorized 150,000,000 shares of the Company's \$0.001 par value common stock. At December 31, 2009, the Company had 64,904,955 common shares outstanding. At March 31, 2010, the Company had 64,904,955 common shares outstanding.

### ***Warrants***

At December 31, 2008, there were 0 warrants for the purchase of common stock outstanding. At December 31, 2009, there were short term warrants to purchase 11,292,686 shares of common stock outstanding and long term warrants to purchase 6,775,611 shares of common stock outstanding.

## **11. Stock Plans**

### ***1993 and 1996 Stock Option Plans***

During 1993, the Company adopted the 1993 Incentive and Non-Qualified Stock Option Plan (the "1993 Plan") and in 1996 the Board of Directors authorized the 1996 Equity Incentive Plan (the "1996 Plan"). The Plans provide for the grant of incentive and non-qualified stock options to management, other key employees, consultants and directors of the Company. No new awards may be made under the 1993 Plan. In 1999, the Board of Directors authorized and the stockholders approved an amendment to the 1996 Plan to increase the total number of shares authorized for issuance under the plan from 1,000,000 to 1,300,000 shares of the Company's common stock. The total shares of common stock that may be issued pursuant to the exercise of options granted under the 1993 and 1996 Plans are 155,000. All of these options were exercisable at December 31, 2007. No new

awards may be made under the 1993 Plan or the 1996 Plan. Under the terms of both plans, incentive stock options may not be granted at less than fair market value of the Company's common stock at the date of the grant and for a term not to exceed ten years.

**2001 Stock Incentive Plan**

The 2001 Stock Incentive Plan (the "2001 Plan") provides for the grant of stock options and restricted stock awards to eligible employees, officers, directors, consultants and advisors of the Company. During 2008, the Board of Directors authorized and the stockholders approved an amendment of the 2001 Plan to increase the total number of shares authorized for issuance under the 2001 Plan from 8,250,000 to 9,750,000 shares of the Company's common stock and to increase the number of shares of restricted common stock authorized for issuance under the 2001 Plan from 1,500,000 to 2,100,000 shares of the Company's common stock. A total of 175,000 shares of restricted stock were granted under the 2001 Plan in 2007 and 322,400 shares of restricted stock were granted under the 2001 Plan in 2008. Under the terms of the plan, 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.

Options granted under all of the Company's equity incentive plans generally vest annually over a three to four year vesting period. Certain stock option awards are subject to accelerated vesting.

**Non-Plan Options**

At December 31, 2009, the Company had 650,000 non-plan stock options outstanding which were granted in 2006 and 2007 to senior executives. Although granted outside of the Company's 2001 Incentive Plan, the options nevertheless are subject to the terms and conditions of the 2001 Plan as if granted thereunder.

There were 322,400 new restricted stock grants issued for the year ended December 31, 2008 and 1,011,350 shares of restricted stock were available for future grant on December 31, 2008. Included in the Company's statement of operations was \$266,273 of compensation expense related to restricted stock for the year ended December 31, 2008. There were 473,500 shares of restricted stock unvested at December 31, 2008. There were 0 new restricted stock grants issued for the year ended December 31, 2009 and 1,120,217 shares of restricted stock were available for future grant on December 31, 2009. Included in the Company's statement of operations was \$262,455 of compensation expense related to restricted stock for the year ended December 31, 2009. Unvested restricted stock activity for the years ended December 31, 2008 and 2009 was as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Nonvested balance as of December 31, 2007 .....	175,000	\$3.58
Granted .....	322,400	0.47
Vested .....	—	—
Forfeited .....	<u>(23,900)</u>	<u>0.48</u>
Nonvested balance as of December 31, 2008 .....	<u>473,500</u>	<u>\$1.62</u>
Granted .....	—	—
Vested .....	(68,133)	0.46
Forfeited .....	<u>(111,567)</u>	<u>0.48</u>
Nonvested balance as of December 31, 2009 .....	<u>293,800</u>	<u>\$2.32</u>

There were 1,398,000 new stock options granted during 2008, including 550,000 stock options granted to the Company's Chairman. At December 31, 2008, 6,889,868 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there were 1,289,650 options available for future grant.

There were 75,000 new stock options granted during 2009. At December 31, 2009, 5,928,367 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there are 2,186,110 options available for future grant.

Stock option transactions under all of the Company's equity incentive plans during the years ended December 31, 2008 and 2009 summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2008	7,173,784	\$ 1.99		
Granted	1,398,000	0.57		
Exercised	—	—		
Canceled/Forfeited	(1,661,916)	2.87		
Outstanding at December 31, 2008	<u>6,909,868</u>	<u>\$ 1.50</u>	8.00	<u>\$ —</u>
Exerciseable at December 31, 2008	<u>3,509,466</u>	<u>\$ 1.55</u>	7.06	<u>\$ —</u>
Outstanding at January 1, 2009	6,909,868	\$ 0.57		
Granted	75,000	0.09		
Exercised	—	—		
Canceled/Forfeited	(1,056,501)	1.63		
Outstanding and expected to vest at December 31, 2009	<u>5,928,367</u>	<u>\$ 1.47</u>	7.21	<u>\$ —</u>
Exerciseable at December 31, 2009	<u>4,562,199</u>	<u>\$ 1.59</u>	6.85	<u>\$ —</u>

The fair value of the options granted in 2009 was \$5,880 with a per share weighted average fair value of \$0.078. The fair value of options granted in 2008 was \$615,052, with a per share weighted average fair value of \$0.44. The amount was estimated using the Black-Scholes option pricing model with the assumptions listed in Note 2. All stock options granted have exercise prices equal to the fair market value of the common stock on the date of grant.

As of December 31, 2009, there was \$1,202,506 of total unrecognized compensation cost related to approximately 1,366,167 unvested outstanding stock options. The expense is anticipated to be recognized over a weighted average period of 3 years. There were no stock option exercises during 2008 and 2009.

The following table summarizes information about stock options outstanding under all of the Company's stock option plans at December 31, 2009:

Range of exercise prices	Number Outstanding	Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number of Options Exerciseable	Average Remaining Contractual Life in Years	Weighted Average Exercise Price of Options Exerciseable
\$0.08 – \$0.19	625,000	9.01	0.14	225,000	8.90	0.15
\$0.20 – \$0.50	1,506,667	6.23	0.31	1,469,999	6.17	0.31
\$0.51 – \$1.00	175,000	7.82	0.67	76,333	7.09	0.68
\$1.01 – \$2.50	2,192,500	7.66	1.41	1,487,500	7.43	1.50
\$2.51 – \$4.00	1,320,200	6.96	3.22	1,206,033	6.91	3.21
\$4.01 – \$9.38	109,000	3.16	6.19	97,333	2.64	6.42
	<u>5,928,367</u>	7.21	<u>\$1.47</u>	<u>4,562,199</u>	6.85	<u>\$1.59</u>

The Company recognized the full impact of its share-based payment plans in the statement of operations for 2008 and 2009 and did not capitalize any such costs on the balance sheets. The following table presents share-based compensation expense included in the Company's statements of operations:

	2008	2009
Cost of goods sold	\$ 12,281	\$ 2,417
Research and development	110,407	32,807
Selling, general and administrative	2,418,122	1,990,834
Stock-based compensation expense	<u>\$2,540,810</u>	<u>\$2,026,058</u>

The Company has recorded compensation expense (benefit) related to options granted to non-employee consultants for services rendered, totaling \$(3,835) in 2008 and \$2,860 in 2009 based on the fair value of our common stock.

## 12. Income Taxes

The income tax benefit consists of the following:

	<u>2008</u>	<u>2009</u>
Income tax benefit:		
Federal .....	2,679,401	1,763,340
State .....	233,147	123,273
	<u>2,912,548</u>	<u>1,886,613</u>
Deferred tax asset valuation allowance .....	<u>(2,912,548)</u>	<u>(1,886,613)</u>
	<u>—</u>	<u>—</u>

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

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

Net operating loss carryforwards .....	13,423,325	15,592,026
Research and development tax credit carryforwards .....	251,342	310,311
Capitalized research and development .....	1,300,464	859,141
Stock-based compensation .....	1,126,416	1,116,136
Other .....	<u>1,475,265</u>	<u>1,539,001</u>
Gross deferred tax assets .....	17,576,812	19,416,615
Capitalized software .....	(102,782)	(99,843)
Fixed assets .....	(4,706)	14,154
Patent costs .....	<u>(39,759)</u>	<u>(14,748)</u>
Net deferred tax assets .....	17,429,565	19,316,178
Deferred tax asset valuation allowance .....	<u>(17,429,565)</u>	<u>(19,316,178)</u>
	<u>—</u>	<u>—</u>

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

During 2009, the valuation allowance increased by \$1,886,613, net of expired federal and state net operating loss carryforwards.



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

*Summary*

Statutory US federal tax rate .....	(34%)
State taxes, net of federal benefit .....	(3.7%)
Non-deductible expenses .....	8.0%
Other .....	3.9%
Valuation allowance .....	25.8%
Net .....	0%

As of December 31, 2009, the Company has approximately \$41,415,000 federal and \$28,577,000 state net operating loss carryforwards and \$21,000 and \$446,000 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 2010 to 2025.

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. Cambridge Heart has performed a preliminary analysis of its change in ownership and believes that ownership changes have occurred that will limit the future utilization of the Company's loss carryforwards. The Company has estimated that as of December 31, 2009 approximately \$31,802,000 of Federal and \$0 state NOLs may be limited and unavailable to offset future taxable income, resulting in a reduction of the related deferred tax asset and valuation allowance of approximately \$10,813,000. The Company has also estimated that as of December 31, 2009 approximately \$1,061,000 of Federal and \$0 state R&D credits may be limited and unavailable to offset future taxable income, resulting in a reduction of the related deferred tax asset and valuation allowance of approximately \$1,061,000. It is possible that additional changes in ownership can further limit the amounts of net operating losses which may be utilized. As the Company finalizes this analysis, these amounts may change.

As of December 31, 2009 and 2008, the total amount of unrecognized tax benefits was \$166,000, all of which, if recognized, would affect the effective tax rate prior to the adjustment for the Company's valuation allowance. The Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that would offset this liability.

The change in unrecognized tax benefits for the 12 months ended December 31, 2009 is as follows:

Balance beginning January 1, 2009 .....	\$166,000
Inc/Dec for tax positions related to prior years .....	—
Inc/Dec for tax positions related to the current year .....	—
Settlements .....	—
Reductions for Expiration of Statue of Limitations .....	—
Balance ending December 31, 2009 .....	<u>\$166,000</u>

The Company recognizes interest and penalties related to unrecognized tax benefits in operating expenses. Since a full valuation allowance was recorded against the Company's net deferred tax assets and the unrecognized tax benefits determined under ASC 740 – Income Taxes would not result in a tax liability, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits.

Tax years ended December 31, 2006, 2007, 2008 and 2009 remain subject to examination by major taxing jurisdictions, which are Internal Revenue Service and the Commonwealth of Massachusetts. However, since the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, all years that include carryforwards are subject to review by relevant taxing authorities to the extent of the carryforward utilized.

### 13. Savings Plan

In January 1995, the Company adopted a retirement savings plan for all employees pursuant to Section 401(k) of the Internal Revenue Code. Employees become eligible to participate on the first day of the calendar quarter following their hire date. Employees may contribute any whole percentage of their salary, up to a maximum annual statutory limit. The Company is not required to contribute to this plan. The Company made no contributions to this plan in 2008 or 2009.

### 14. Commitments and Contingencies

#### *Guarantor Arrangements*

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company maintains a products liability insurance policy that limits its exposure. Based on the Company's historical activity in combination with its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2008 and 2009.

The Company warrants all of its non-disposable products as to compliance with their specifications and that the products are free from defects in material and workmanship for a period of 13 months from the date of delivery. The Company maintains a reserve for the estimated costs of potential future repair of our products during this warranty period. The amount of reserve is based on the Company's actual return and repair cost experience. The Company has \$39,076 and \$29,384 of accrued warranties at December 31, 2008 and 2009, respectively.

	<b>December 31,</b>	
	<b>2008</b>	<b>2009</b>
Balance at beginning of period . . . . .	\$ 99,800	\$ 39,076
Provision for warranty for units sold . . . . .	57,125	55,575
Cost of warranty incurred . . . . .	(117,849)	(65,267)
Balance at end of period . . . . .	<u>\$ 39,076</u>	<u>\$ 29,384</u>

For the years ended December 31, 2008 and 2009, the Company incurred product warranty expenses of \$57,125 and \$55,575, respectively.

#### *Operating Leases*

The Company has a five-year operating lease for office space, expiring in 2013, with a renewal option for an additional five years. Total rent expense under all operating leases was approximately \$342,189 and \$347,400 for the years ended December 31, 2008 and 2009, respectively. At December 31, 2009, future minimum rental payments under the non-cancelable leases are \$374,587, \$384,803, \$395,019, and \$132,808 for fiscal years 2010, 2011, 2012 and 2013, respectively.

### ***Contingencies***

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

### ***License Maintenance Fees***

Under the terms of certain license, consulting and technology agreements, the Company is required to pay royalties on sales of its products. Minimum license maintenance fees under the license agreement, which can be credited against royalties otherwise payable for each year, are \$10,000 per year through 2013. The Company is committed to pay an aggregate of \$40,000 of such minimum license maintenance fees subsequent to December 31, 2009 as the technology is used. License maintenance fees paid during 2008 and 2009 amounted to \$10,000 each year. The future minimum license maintenance fee commitments at December 31, 2009 are approximately as follows:

2010 .....	\$10,000
2011 .....	10,000
2012 .....	10,000
2013 .....	10,000
Total .....	<u>\$40,000</u>

During the term of these license agreements, the Company is obligated to pay a 1.5% royalty 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.

## **15. Related Party Transactions, Including Royalty Obligations**

### ***License Agreement/Consulting and Technology Agreement***

On May 14, 2007, the Company entered into an Amended and Restated Consulting and Technology Agreement with Dr. Richard J. Cohen, M.D. Ph.D. (the "Consulting Agreement") who serves as the Chairman of the Company's Scientific Advisory Board, and until December 30, 2009, served as a member of the Company's Board of Directors and continues to serve as Chairman of the Company's Scientific Advisory Board. The Consulting Agreement amended and restated the terms of a Consulting and Technology Agreement dated as of February 8, 1993, as amended, between Dr. Cohen and the Company.

Under the terms of the Consulting Agreement, Dr. Cohen agrees to be available to the Company for consultation for a minimum of 18 days per year (the "Base Consulting Services") until the expiration of the consulting period on December 31, 2015 (the "Consulting Period"). During the period beginning January 1, 2007 and ending on December 31, 2009 (the "Interim Consulting Period"), Dr. Cohen agreed to be available for consultation for up to 42 days per year. On March 11, 2010, the Company and Dr. Cohen entered into Amendment No. 1 to the Consulting Agreement ("Amendment No. 1") which extended the Interim Consulting Period to December 31, 2010.

Under the Consulting Agreement, the Company will pay Dr. Cohen royalties on net sales related to certain technologies (including the sale of the Company's Heartwave II System and other Microvolt T-Wave Alternans products) equal to 1.5% of such net sales until December 31, 2015. Additionally, if the Company sublicenses, or grants rights to any sublicense with respect to, such technologies to an unrelated company, Dr. Cohen will receive royalties equal to 7% of gross revenue to the Company from the sublicense. Pursuant to the terms of the Consulting Agreement, the Company will pay Dr. Cohen monthly royalties of \$10,000 per month during the

Interim Consulting Period, subject to an annual percentage increase equal to the annual percentage increase in the National Consumer Price Index for the prior year (the “Monthly Royalty”). Pursuant to Amendment No. 1, Dr. Cohen will receive a reduced Monthly Royalty payment of \$5,811.17 per month for the period beginning on January 1, 2010 and ending on December 31, 2010. Dr. Cohen will not receive any additional compensation for the Base Consulting Services.

Under the Consulting Agreement, the Company will have the right, but not the obligation, to terminate the Consulting Agreement within the 30-day period immediately following a Change in Control (as defined in the Consulting Agreement) of the Company, in which case the Company shall pay Dr. Cohen a termination royalty equal to a percentage of the consideration paid or deemed paid to the Company or its security holders in the Change in Control transaction (the “Termination Percentage”). The Termination Percentage decreases over the term of the Consulting Agreement from 2.67%, in case of a January 2007 transaction, to zero, in the case of a December 2015 transaction. Either party may terminate the Consulting Agreement for material breach or default by the other party of the other party’s obligations under the Amended Agreement upon 90 days notice.

Under the Consulting Agreement, Dr. Cohen also received an aggregate of 175,000 shares of restricted common stock of the Company (the “Restricted Shares”) subject to the terms and conditions of the Company’s 2001 Stock Incentive Plan. The Restricted Shares vested on January 1, 2010. Pursuant to Amendment No. 1, in consideration for the reduction in Monthly Royalty payments noted above, Dr. Cohen received a stock option to purchase 561,982 shares of common stock of the Company, which becomes exercisable in nine equal monthly installments beginning on April 11, 2010 and which was granted outside of the Company’s 2001 Stock Incentive Plan, but nevertheless subject to the terms and conditions of the 2001 Stock Incentive Plan. Pursuant to Amendment No. 1, in recognition of his service as Chairman of the Scientific Advisory Committee, Dr. Cohen received a stock option, under the Company’s 2001 Stock Incentive Plan, to purchase 100,000 shares of the common stock of the Company, which becomes exercisable in full on March 11, 2010. Additionally, in consideration for his services as Chairman of the Company’s Scientific Advisory Board during 2010, Dr. Cohen received a stock option to purchase 43,407 shares of common stock of the Company, which becomes exercisable in nine equal monthly installments beginning on April 11, 2010 and which was granted outside of the Company’s 2001 Stock Incentive Plan, but nevertheless subject to the terms and conditions of the 2001 Stock Incentive Plan, and will be paid a total cash fee of \$5,000, payable monthly for the fiscal year 2010.

The Company recognized royalty expense in connection with the Consulting Agreement of \$171,951 and \$178,202 during fiscal 2008 and 2009, respectively.

### ***Voting Agreement***

On October 29, 2007, the Company entered into a Voting Agreement with Robert P. Khederian, who at the time served as the Chairman of the Board of Directors. The Voting Agreement was executed by the parties in connection with the election of two independent directors to the Board of Directors. On December 14, 2007, the parties entered into an Amended and Restated Voting Agreement (the “Amended Voting Agreement”) in connection with the appointment of Ali Haghighi-Mood as the Company’s new President and Chief Executive Officer and the election of Mr. Haghighi-Mood to the Board of Directors.

The Certificate of Designations of the Preferred Stock of Cambridge Heart, Inc. to be Designated Series A Convertible Preferred Stock (the “Series A Certificate of Designations”) provides that the holders of Series A Convertible Preferred Stock (the “Series A Preferred Stock”), voting as a separate class, are entitled to elect up to four members of the Board and that at such time the total number of directors may not exceed nine. At the time, there were 154 shares of Series A Preferred Stock outstanding, all of which were held by Mr. Khederian. There also were an aggregate of 115,229 Series A warrants outstanding. Mr. Khederian was the holder of record of 77,900 Series A warrants, which together with his Series A Preferred Stock, represented approximately 67.6% of the outstanding Series A Preferred Stock and Series A warrants.

Under the Amended Voting Agreement, Mr. Khederian agreed to hold and not transfer or otherwise dispose of any of the Series A warrants registered in his name or any shares of Series A Preferred Stock that he may acquire upon exercise of his Series A warrants if, as a result of such transfer or disposition, he will not hold a majority of the Series A Preferred Stock (assuming the exercise of all outstanding Series A warrants). Mr. Khederian also agreed that upon the request of the Board he would exercise that number of Series A warrants so that he holds at least a majority of the shares of Series A Preferred Stock then outstanding and entitled to vote. Mr. Khederian further agreed to vote all of his shares of Series A Preferred Stock so as to elect up to three individuals that are nominated or recommended for election as Series A stock directors by a majority of the Board, provided that, in the case of each such director, the Board has determined that such individual qualifies as an independent director under the Nasdaq Marketplace Rules then in effect or such director is serving at the time of the election as the Chief Executive Officer of the Company.

The Amended Voting Agreement terminates on the earliest of the following dates: (i) the date as of which there are no shares of Series A Stock or Series A Warrants outstanding; (ii) the date as of which the Certificate of Incorporation (including the Series A Certificate of Designations) has been amended so that holders of Series A Stock are no longer entitled, voting as a separate class, to elect any members of the Board; and (iii) the date as of which the Company and Mr. Khederian agree to terminate the Amended Voting Agreement with the approval of a majority of the Board.

On May 14, 2008, the Company and Mr. Khederian entered into Amendment No. 1 to the Amended Voting Agreement (“Amendment No. 1”). Under Amendment No. 1, Mr. Khederian agreed that, upon the request of the Board of Directors, Mr. Khederian would vote all of his shares of Common Stock and all of his shares of Series A Preferred Stock in favor of any amendment to the Company’s certificate of incorporation in order to eliminate the staggered Board of Directors and any amendment to the certificate of incorporation to eliminate the rights of the holders of Series A Preferred Stock, as a separate class, to elect any members of the Board of Directors.

Effective May 31, 2008, the Company and Mr. Khederian entered into Amendment No. 2 to the Amended Voting Agreement (“Amendment No. 2”). Under Amendment No. 2, Mr. Khederian agrees to vote all of his shares of Series A Preferred Stock so as to elect up to four individuals (increased from three under the Amended Voting Agreement) who are nominated or recommended for election as Series A Preferred directors by a majority of the Board, provided that, in the case of each such director, the Board has determined that such individual qualifies as an independent director under the Nasdaq Marketplace Rules then in effect or such director is serving at the time of the election as the Chief Executive Officer of the Company.

On June 29, 2009, the Company’s stockholders approved amendments to the Company’s Certificate of Incorporation to eliminate the provisions allowing for the election of directors by the holders of the Series A Convertible Preferred Stock, voting separately as a class. The amendment was made effective for elections taking place after the 2009 Annual Meeting.

#### ***Series A Convertible Preferred Stock Redemption***

On December 21, 2009, the Company purchased and redeemed 154 shares of Series A Preferred Stock, representing 100% of the issued and outstanding shares of Series A Preferred Stock, from Mr. Khederian for an aggregate purchase price of \$681.

### ***Series D Financing***

On December 23, 2009, the Company issued and sold 1,852 shares of the Company's Series D Convertible Preferred Stock (the "Series D Preferred Stock") and common stock warrants to new and current institutional and private investors pursuant to the terms of a Securities Purchase Agreement dated December 23, 2009 between the Company and the purchasers of Series D Preferred Stock (the "Series D Financing"). The aggregate proceeds from the Series D Financing were \$1.8 million, net of issuance costs. The Company intends to use the proceeds of the Series D Financing to fund its ongoing operations. See Note 9 of the notes to these financial statements.

The terms and conditions of the Series D Financing were approved by a special committee comprised of three independent directors that was formed by the Company's Board of Directors in connection with the transaction. The members of the special committee of the Board did not participate in the Series D Financing. Three directors of the Company purchased an aggregate of 385 shares of Series D Preferred Stock for a total purchase price of \$385,000. Specifically, Roderick de Greef, who serves as Chairman of the Board, Richard J. Cohen and Jeffery Wiggins purchased 50, 35 and 300 shares of Series D Preferred Stock, respectively, and were issued Short-Term Warrants to purchase 304,878, 213,415 and 1,829,269 shares of common stock, respectively, and Long-Term Warrants to purchase 182,927, 128,049 and 1,097,561 shares of common stock, respectively.

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

No customer accounted for 10% or higher of total revenue and accounts receivable as of December 31, 2008 and 2009. During the years ended December 31, 2008 and 2009, international sales accounted for 15.8% and 14.3% of the total revenue, respectively. Company policy does not require collateral on accounts receivable balances.

### **17. Subsequent Event**

In February 2010, Bailard Emerging Life Sciences Fund I, L.P., an institutional investor who participated in the Series D Financing, exercised their short-term and long-term warrants to purchase 609,756 and 365,854, respectively, of the Company's common stock resulting in aggregate proceeds of \$117,195.

On March 11, 2010, the Compensation Committee of the Board of Directors of the Company approved the grant of stock option awards to certain employees, directors and consultants of the Company to purchase an aggregate of 7,028,512 shares of common stock of the Company. Of the option awards granted, 4,988,858 shares were granted outside of the Company's stock option plans. The remaining 2,039,654 options were granted under the Company's 2001 Stock Incentive Plan. Each of the option awards has a term of ten years and an exercise price of \$0.16, which was the closing price of the Company's common stock on the date of grant. In connection with the approval of certain option awards granted outside of the Company's stock option plans, stock options to purchase an aggregate of 2,983,333 shares of common stock of the Company previously granted to members of senior management were cancelled.

We have assessed and reported on subsequent events through the date of issuance of these financial statements.

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

Not applicable.

**Item 9A. Controls and Procedures*****(a) Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2009. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2009, to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

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

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934) during the fiscal quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***(c) Report of Management on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of our financial reporting for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the company's internal control over financial reporting was effective as of December 31, 2009.

This annual report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our company's registered public accounting firm pursuant to temporary rules of the SEC that permit the company to provide only management's report in this annual report on Form 10-K.

**Item 9B. Other Information**

Not applicable.

## **PART III**

### **Item 10. Directors, Executive Officers and Corporate Governance**

Information required by this Item 10 and not already provided in Item 3A will be contained in our proxy statement for our 2010 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2009, and such information is incorporated herein by reference.

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

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

Information required by this Item 11 will be contained in our proxy statement for our 2010 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2009, and such information is incorporated herein by reference.

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

Information required by this Item 12 will be contained in our proxy statement for our 2010 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2009, and such information is incorporated herein by reference.

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

Information required by this Item 13 will be contained in our proxy statement for our 2010 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2009, and such information is incorporated herein by reference.

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

Information required by this Item 14 will be contained in our proxy statement for our 2010 Annual Meeting of Stockholders, which we intend to file within 120 days following our fiscal year ended December 31, 2009, and such information is incorporated herein by reference.



## **PART IV**

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

(a) Financial Statements.

For a list of the financial information included herein, see Index to the Financial Statements on page 31 of this Annual Report on Form 10-K.

(b) List of Exhibits.

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

(c) Financial Statement Schedules.

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

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2010.

CAMBRIDGE HEART, INC.

By:           /s/ ALI HAGHIGHI-MOOD            
**Ali Haghghi-Mood**  
**President and Chief Executive Officer**

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ ALI HAGHIGHI-MOOD          </u> <b>Ali Haghghi-Mood</b>	President and Chief Executive Officer (Principal Executive Officer)	March 31, 2010
<u>          /s/ VINCENZO LICAUSI          </u> <b>Vincenzo LiCausi</b>	Vice President, Chief Financial Officer, Treasurer, Corporate Secretary	March 31, 2010
<u>          /s/ RODERICK DE GREEF          </u> <b>Roderick de Greef</b>	Chairman	March 31, 2010
<u>          /s/ PAUL MCCORMICK          </u> <b>Paul McCormick</b>	Director	March 31, 2010
<u>          /s/ JOHN MCGUIRE          </u> <b>John McGuire</b>	Director	March 31, 2010
<u>          /s/ JEFFREY WIGGINS          </u> <b>Jeffrey Wiggins</b>	Director	March 31, 2010

## EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Registrant is incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant is incorporated herein by reference to Exhibit 3.2 to the Registrant's Form 10-K for the fiscal year ended December 31, 2001 (File No. 0-20991).
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant is incorporated by reference to Exhibit 3.3 to the Registrant's Form 10-K for the fiscal year ended December 31, 2003 (File No. 0-20991).
3.4	Certificate of Designations of the Preferred Stock of the Registrant to be Designated Series A Convertible Preferred Stock, dated as of May 12, 2003 is incorporated herein by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, dated as of December 6, 2004 is incorporated herein by reference to Exhibit 3.5 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant is incorporated by reference to Exhibit 3.6 to the Registrant's Form 10-K for the fiscal year ended December 31, 2005 (File No. 0-20991).
3.7	Certificate of Designation Preferences and Rights of Series C Convertible Preferred Stock of the Registrant, dated as of March 21, 2007 is incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated March 27, 2007 (File No. 0-20991).
3.8	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant is incorporated by reference to Exhibit 3.8 to the Registrant's Current Report on Form 8-K dated June 30, 2009 (File No. 0-20991).
3.9	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant is incorporated by reference to Exhibit 3.9 to the Registrant's Current Report on Form 8-K dated June 30, 2009 (File No. 0-20991).
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series C-1 Convertible Preferred Stock, dated as of December 23, 2009 is incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated December 30, 2009 (File No. 0-20991).
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock, dated as of December 23, 2009 is incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K dated December 30, 2009 (File No. 0-20991).
3.12	By-Laws of the Registrant, as amended are incorporated herein by reference to Exhibit 3.10 to the Registrant's Current Report on Form 8-K dated June 30, 2009 (File No. 0-20991).
4.1	Specimen Certificate for shares of Common Stock, \$.001 par value, of the Registrant is incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
4.2	See Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11 and 3.12 for provisions of the Registrant's certificate of incorporation, certificate of designations and by-laws defining the rights of holders of common stock.
10.1#	1993 Incentive and Non-Qualified Stock Option Plan, as amended is incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).

<b>Exhibit No.</b>	<b>Description</b>
10.2#	1996 Equity Incentive Plan, as amended is incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.3#	1996 Director Stock Option Plan is incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.4#	2001 Stock Incentive Plan is incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement as filed on May 21, 2008 (File No. 0-20991).
10.5#	Summary of Amendments to Certain of the Registrant's Equity Plans is incorporated herein by reference to Exhibit 10.7 to the Registrant's Form 10-K for the fiscal year ended December 31, 2004 (File No. 0-20991).
10.6#	Form of Exchange Agreement between the Registrant and Certain Executive Officers dated August 15, 2005 is incorporated by reference to Exhibit 10.8 to the Registrant's Form 10-K for the fiscal year ended December 31, 2005 (File No. 0-20991).
10.7#	Form of Exchange Agreement between the Registrant and Certain Non-Employee Directors dated September 19, 2005 is incorporated by reference to Exhibit 10.9 to the Registrant's Form 10-K for the fiscal year ended December 31, 2005 (File No. 0-20991).
10.8#+	Amended and Restated Consulting and Technology Agreement between the Registrant and Dr. Richard J. Cohen, dated May 14, 2007 is incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-3 (File No. 333-143091).
10.9#	License Agreement By and Between the Registrant and Dr. Richard J. Cohen, dated February 8, 1993 is incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-04879).
10.10	License Agreement by and between the Registrant and the Massachusetts Institute of Technology, dated September 28, 1993, relating to the technology of "Assessing Myocardial Electrical Stability" is incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 0-20991).
10.11	First Amendment to the License Agreement by and between the Registrant and the Massachusetts Institute of Technology dated May 21, 1998, relating to the technology of "Assessing Myocardial Electrical Stability" is incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-20991).
10.12	Summary of terms of Revolving Credit Line with Citigroup Global Markets, Inc. is incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 0-20991).
10.13#	Severance Agreement dated September 17, 2003 between the Registrant and Ali Haghghi-Mood is incorporated herein by reference to Exhibit 10.20 to the Registrant's Form 10-K for the fiscal year ended December 31, 2004 (File No. 0-20991).
10.14#	Summary of Amendment dated December 14, 2006 to Severance Agreement dated September 17, 2003 between the Registrant and Ali Haghghi-Mood incorporated herein by reference to Exhibit 10.16 of the Registrant's Form 10-K for the fiscal year ended December 31, 2006 (File No. 0-20991).
10.15#	Employment Agreement dated December 14, 2007 between the Registrant and Ali Haghghi-Mood incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008
10.16#	Severance Agreement dated May 18, 2007 between the Registrant and Vincenzo LiCausi is incorporated by reference to Exhibit 10.16 of the Registrant's Form 10-K for the fiscal year ended December 31, 2007 (File No. 0-20991).

<u>Exhibit No.</u>	<u>Description</u>
10.17#	Non-Statutory Stock Option Agreement Granted Under 2001 Stock Incentive Plan dated December 11, 2007 between the Registrant and Ali Haghighi-Mood is incorporated by reference to Exhibit 10.29 of the Registrant's Form 10-K for the fiscal year ended December 31, 2007 (File No. 0-20991).
10.18#	Employment Agreement dated November 28, 2008 between the Registrant and Roderick de Greef.
10.19	Securities Purchase Agreement among the Registrant and The Tail Wind Fund, Ltd. and Robert P. Khederian dated December 21, 2001 is incorporated herein by reference to Exhibit 10.31 to the Registrant's Form 10-K for the fiscal year ended December 31, 2001 (File No. 0-20991).
10.20	Amendment to Registration Rights Agreement and Waiver, dated May 12, 2003, by and among the Registrant, The Tail Wind Fund, Ltd. and Robert P. Khederian is incorporated herein by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended March 31, 2003 (File No. 0-20991).
10.21	Amendment No. 1, dated May 12, 2003, to the Warrant issued as of September 14, 2000 to the Tail Wind Fund Ltd. by and between the Registrant and the Tail Wind Fund Ltd. is incorporated herein by reference to Exhibit 10.3 to the Registrant's Form 10-Q for the quarter ended March 31, 2003 (File No. 0-20991).
10.22	Securities Purchase Agreement among the Registrant and the Purchasers dated May 12, 2003 is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.23	Registration Rights Agreement, dated as of May 12, 2003, by and among the Registrant and the signatories thereto is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.24	Form of Long-Term Warrant to purchase shares of Series A Preferred Convertible Stock of the Registrant issued on May 12, 2003 in connection with the sale of the Series A Convertible Preferred Stock is incorporated herein by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K dated May 13, 2003 (File No. 0-20991).
10.25	Securities Purchase Agreement, dated as of December 6, 2004 by and among the Registrant and the signatories thereto is incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
10.26	Registration Rights Agreement, dated as of December 6, 2004 by and among the Registrant and the signatories thereto is incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated December 7, 2004 (File No. 0-20991).
10.27	Form of Warrant to purchase shares of common stock, dated as of December 6, 2004 issued to placement agent in connection with the sale of shares of Series B Convertible Preferred Stock is incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-2, as amended (File No. 333-121915).
10.28	Securities Purchase Agreement, dated as of March 21, 2007 between the Registrant and St. Jude Medical, Inc. is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated March 27, 2007 (File No. 0-20991).
10.29	Registration Rights Agreement, dated as of March 21, 2007 between the Registrant and St. Jude Medical, Inc. is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated March 27, 2007 (File No. 0-20991).

<b>Exhibit No.</b>	<b>Description</b>
10.30	Restated Co-Marketing Agreement dated July 8, 2008 between the Registrant and St. Jude Medical, Inc. is incorporated by reference to Exhibit 10.4 to the Registrant's 10-Q for the quarter ended June 30, 2008 (File No. 0-20991).
10.31#	Form of Memorandum to Board of Directors dated October 1, 2007 Confirming Amendment of Non-Employee Director Stock Options is incorporated by reference to Exhibit 10.43 of the Registrant's Form 10-K for the fiscal year ended December 31, 2007 (File No. 0-20991).
10.32	Amended and Restated Voting Agreement dated December 14, 2007 between the Registrant and Robert Khederian is incorporated by reference to Exhibit 10.44 of the Registrant's Form 10-K for the fiscal year ended December 31, 2007 (File No. 0-20991).
10.33	Amendment No 1 to Amended and Restated Voting Agreement dated May 19, 2008 between the Registrant and Robert Khederian is incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed dated May 23, 2008 (File No. 0-20991).
10.34	Amendment No. 2 to Amended and Restated Voting Agreement dated May 31, 2008 between the Registrant and Robert Khederian is incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed dated June 5, 2008 (File No. 0-20991).
10.35	Settlement Agreement dated May 19, 2008 between the Registrant, AFB Fund, LLC, Louis Blumberg and Laurence Blumberg is incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed dated May 23, 2008 (File No. 0-20991).
10.36+	Lease Agreement dated November 21, 2007 by and between the Registrant and Farley White Management Company, LLC. is incorporated by reference to Exhibit 10.45 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 0-20991).
10.37#	Summary of Non-Employee Director Fees is incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 0-20991).
10.38#	Form of Management Incentive Stock Option Award under 2001 Stock Incentive Plan is incorporated herein by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
10.39	Form of Director Non-Qualified Stock Option Award under 2001 Stock Incentive Plan is incorporated herein by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008.
10.40+	Development, Supply and Distribution Agreement, dated June 22, 2009 between the Registrant and Cardiac Science Corporation is incorporate by reference to Exhibit 10.1 of Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as filed on February 22, 2010 (File No. 0-20991)
10.41	Securities Purchase Agreement, dated as of December 23, 2009 by and among the Registrant and the signatories thereto is incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 30, 2009 (File No. 0-20991).
10.42	Form of Short-Term Warrant to purchase Common Stock of the Registrant issued on December 23, 2009 in connection with the sale of the Series D Convertible Preferred Stock is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated December 30, 2009 (File No. 0-20991).

<b>Exhibit No.</b>	<b>Description</b>
10.43	Form of Long-Term Warrant to purchase Common Stock of the Registrant issued on December 23, 2009 in connection with the sale of the Series D Convertible Preferred Stock is incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated December 23, 2009 (File No. 0-20991).
10.44	Share Exchange Agreement between the Registrant and St. Jude Medical, Inc. is incorporated herein by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K dated December 23, 2009 (File No. 0-20991).
23.1	Consent of Caturano and Company P.C.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K/A  
AMENDMENT NO. 1**

(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, 2009

or

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

**100 Ames Pond Road, Tewksbury, MA**  
(Address of Principal Executive Offices)

**13-3679946**  
(I.R.S. Employer  
Identification No.)

**01876**  
(Zip Code)

**(978) 654-7600**

(Registrant's telephone number, including area code)

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

**Securities registered pursuant to Section 12(g) of the Act:**  
**Common Stock, \$0.001 par value**  
Title of class

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the common stock held by non-affiliates of the registrant was \$5,705,827 computed by reference to the last reported sale price of the common stock on the OTC Bulletin Board on June 30, 2009.

As of March 31, 2010, 64,904,955 shares of the registrant's common stock were outstanding.



**CAMBRIDGE HEART, INC.**  
**INDEX TO ANNUAL REPORT ON FORM 10-K/A**  
**AMENDMENT NO. 1**

**Securities and Exchange Commission**

**Item Number and Description**

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**PART III**

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**PART IV**

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**EXPLANATORY NOTE**

Cambridge Heart, Inc. (“Cambridge Heart” or the “Company”) is filing this Amendment No. 1 to its Annual Report on Form 10-K, originally filed with the Securities and Exchange Commission on March 31, 2010 (the “Initial Filing”), solely for the purpose of amending and supplementing Part III of the Annual Report on Form 10-K. This amendment changes our Annual Report by including information required by Part III (Items 10, 11, 12, 13 and 14).

Pursuant to Rule 12b-15 promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Company has filed the certificates required by Rule 13a-14(a) or 15d-14(a) of the Exchange Act as Exhibits 31.1 and 31.2.

Except as contained herein, this Amendment No. 1 does not modify or update disclosures contained in the Initial Filing. This Amendment No. 1 should be read in conjunction with the Company’s other filings made with the Securities and Exchange Commission subsequent to the date of the Initial Filing.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

#### Background of Directors and Executive Officers

Set forth below are the name and age of each of our current directors and the positions held by him with us, his principal occupation and business experience during the last five years, the names of other publicly held companies of which he serves or has served as a director in the previous five years, the year of the commencement of his term as a director and the specific experience, qualifications, attributes and skills that contributed to the decision of the Board of Directors to nominate him for election as a director. Information concerning the background of our executive officers is included in Part I, Item 3A of this Annual Report on Form 10-K. No director or executive officer is related by blood, marriage or adoption to any other director or executive officer.

RODERICK DE GREEF

Director since 2008

Age: 49

Mr. de Greef has been Chairman of the Board of the Company since November 2008. During the same period, Mr. de Greef has been employed by the Company to work with the Company's Chief Executive Officer and the Board of Directors to formulate the strategic plan of the Company and to oversee the execution of corporate strategy. In addition to serving as the Company's Chairman of the Board, Mr. de Greef provides corporate advisory services to several other companies. Mr. de Greef served as the Company's Chief Financial Officer from October 2005 to July 2007 and as the Company's Vice President of Finance and Administration from June 2006 to July 2007. From February 2001 to September 2005, Mr. de Greef was Executive Vice President and Chief Financial Officer of Cardiac Science, Inc., which merged with Quinton Cardiology, Inc. From 1995 to 2001, Mr. de Greef provided independent corporate advisory services to a number of early-stage companies. From 1986 to 1995, Mr. de Greef served as Chief Financial Officer of several publicly held, development stage medical technology companies. Mr. de Greef is a member of the board of directors of Endologix, Inc. and Bio Life Solutions Inc., both of which are in the life sciences field, and Elephant Talk Communications, Inc. Mr. de Greef has a B.A. in Economics and International Relations from California State University at San Francisco and earned his M.B.A. from the University of Oregon. Mr. de Greef's extensive business, managerial, executive and leadership experience in the medical device industry, including service on the boards of directors and as an executive officer of other public companies, as well as his position as Chairman of the Board and right to be nominated to the Board under the terms of his employment agreement, were among the factors considered by the Board of Directors in determining that Mr. de Greef should be nominated for election as a director.

ALI HAGHIGHI-MOOD, Ph.D.

Director since 2007

Age: 50

Dr. Haghighi-Mood has been the President and Chief Executive Officer of the Company since December 2007. From December 2006 to December 2007, Dr. Haghighi-Mood served as the Company's Executive Vice President, Chief Operating Officer and Chief Technology Officer. From July 2003 to December 2006, Dr. Haghighi-Mood served as the Company's Vice President, Operations, Research and Development. From January 2002 to July 2003, he served as the Company's Director of Research and has worked in the Company's research and development department since January 1997. Dr. Haghighi-Mood holds B.S. and M.S. degrees in Electrical Engineering from the University of Tehran and a Ph.D. degree in Biomedical Engineering from the University of Sussex. Dr. Haghighi-Mood's long history with and extensive knowledge of the technology and operations of the Company, as well as his position as President and Chief Executive Officer and right to be nominated to the Board under the terms of his employment agreement, were among the factors considered by the Board of Directors in determining that Dr. Haghighi-Mood should be nominated for election as a director.

PAUL MCCORMICK

Director since 2009  
Age: 57

Mr. McCormick currently serves as the Executive Chairman of Cardiogenesis, Inc. From April 2007 until July 2009, Mr. McCormick served as Chairman of the Board of Cardiogenesis, Inc. Mr. McCormick was a member of the executive management team of Endologix, Inc. from 1998 until 2008, most recently serving as President and Chief Executive Officer from January 2003 until May 2008. He served as a director of Endologix from February 2002 until May 2010. Mr. McCormick also serves as a director of Cianna Medical, Inc. Mr. McCormick holds a B.A. in Economics from Northwestern University and an Executive Sales and Marketing certification from Columbia University. Mr. McCormick's extensive executive, sales and marketing experience in the medical device industry were among the factors considered by the Board of Directors in determining that Mr. McCormick should be nominated for election as a director.

JOHN F. MCGUIRE

Director since 2007  
Age: 63

Mr. McGuire is retired. From 2004 to 2007, he was President and Chief Executive Officer of the American Red Cross. Between 2003 and 2004, Mr. McGuire served as an Executive Vice President at the American Red Cross. Prior to joining the American Red Cross, Mr. McGuire was President of Whatman North America, an international leader in separations technology and provider of materials and devices to laboratory and healthcare markets. Previously, he served as President, Chief Executive Officer and a director of HemaSure, Inc., a publicly-traded blood filtration company. In addition, Mr. McGuire has held prominent positions for over 22 years in the field of biomedical technology. Mr. McGuire holds an MBA from Harvard University. Mr. McGuire's substantial experience as an executive officer at numerous public companies, his prior leadership of the American Red Cross Blood Program, and his qualification as an audit committee financial expert were among the factors considered by the Board of Directors in determining that Mr. McGuire should be nominated for election as a director.

JEFFREY WIGGINS

Director since 2008  
Age: 54

Mr. Wiggins is a former Principal of Dresdner RCM Capital Management, where he was responsible for in excess of \$4 billion dollars in health care related investments. Mr. Wiggins joined Dresdner RCM in 1993 and became a Principal in 1997. While there, he started and managed several portfolios, advised other managers in their health care holdings, and initiated two public mutual funds. Prior to that time, Mr. Wiggins managed a derivative-based hedge fund portfolio investing in biotechnology, medical technology, pharmaceuticals, and health care services at O'Connor & Associates. Mr. Wiggins holds a B.A. from Hope College, with majors in Biology and Chemistry, Masters degrees from Northwestern University in Music and Management, and an M.F.A. from Vermont College. Mr. Wiggins' business and investment experience in biotechnology, life sciences and other industries, as well as his qualification as an audit committee financial expert, were among the factors considered by the Board of Directors in determining that Mr. Wiggins should be nominated for election as a director.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our directors, executive officers and holders of more than 10% of our Common Stock ("Reporting Persons") to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our Common Stock and other equity securities. Based solely on its review of copies of reports filed by the Reporting Persons furnished to us, or written representations from Reporting Persons, we believe that, during the fiscal year ended December 31, 2008, the Reporting Persons complied with all Section 16(a) filing requirements.

## Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on our website, which is located at [www.cambridgeheart.com](http://www.cambridgeheart.com). In addition, we intend to post on our website all disclosures that are required by law concerning any amendments to, or waivers from, any provision of the code.

## Audit Committee

The Board of Directors has established a standing Audit Committee of the Board of Directors, which operates under a charter that has been approved by the Board. A current copy of the charter of the Audit Committee is posted on the Corporate Governance section of our website, [www.cambridgeheart.com](http://www.cambridgeheart.com). The members of the Audit Committee are Mr. McGuire (Chairman), Mr. McCormick and Mr. Wiggins. The Board of Directors has determined that Mr. McGuire and Mr. Wiggins are “audit committee financial experts” as defined in Item 407(d) of Regulation S-K. The Board of Directors has determined that all members of the Audit Committee are independent as determined under Rule 10A-3 promulgated under the Exchange Act and as defined by the rules of The Nasdaq Stock Market.

## Item 11. Executive Compensation

The following table sets forth information for the fiscal years ended December 31, 2008 and 2009 concerning the compensation paid to each person serving as the Company’s Chief Executive Officer or acting in a similar capacity during the last completed fiscal year and the Company’s Chief Financial Officer (the “Named Executive Officers”). No other executive officer of the Company received total compensation in excess of \$100,000 during the fiscal year ended December 31, 2009.

**Summary Compensation Table For 2008 and 2009**

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option Award \$(1)</u>	<u>Non-Equity Incentive Compensation \$(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Ali Haghighi-Mood . . . . .	2009	275,000	1,032,545	77,000	—	1,384,545
President and Chief Executive Officer	2008	275,000	1,091,939	—	—	1,366,939
Vincenzo LiCausi . . . . .	2009	155,000	245,958	26,040	—	426,998
Vice President Finance and Administration, Chief Financial Officer	2008	155,000	244,595	23,000	—	422,595
Roderick de Greef(3) . . . . .	2009	120,000	55,176	—	—	175,176
Chairman of the Board	2008	12,308	6,930	—	32,916(4)	52,154

- (1) Reflects the compensation cost related to all outstanding awards recognized in 2008 and 2009 for financial statement reporting purposes in accordance with FASB ASC Topic 718, excluding the impact of estimated forfeitures related to service-based vesting conditions. Assumptions made in the calculation of these amounts are included in Note 2 to the Company’s audited financial statements for the fiscal year ended December 31, 2009, included in the Company’s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission.
- (2) For 2008, consists of cash bonus earned pursuant to non-equity incentive plan awards. For 2009, represents the cash bonuses earned pursuant to non-equity incentive plan awards but foregone by the Named Executive Officers. In March 2010, Dr. Haghighi-Mood and Mr. LiCausi agreed to accept options to purchase 668,468 and 226,064 shares of common stock, respectively, in lieu of earned cash bonuses for 2009 of \$77,000 in the case Dr. Haghighi-Mood, and \$26,040 in the case of Mr. LiCausi. See “Senior Management Bonus Plan for 2009” for a description of the terms of these option awards.
- (3) Mr. de Greef became our Chairman of the Board in November 2008.
- (4) Consists of fees paid to Mr. de Greef for consulting services provided from July 2008 until November 2008.

## **Severance Arrangements with Chief Executive Officer and Chief Financial Officer**

The Company has entered into agreements with Dr. Haghghi-Mood and Mr. LiCausi providing for the payment of severance benefits in the event of a qualifying termination of employment. Under these agreements, if the executive officer's employment is terminated by the Company without cause (as defined in the respective agreement), the executive officer will be entitled to receive severance compensation equal to the executive officer's base salary as in effect at the time of such termination and continued healthcare benefits for a period of six months in the case of Mr. LiCausi and 12 months in the case of Dr. Haghghi-Mood.

In the event that Dr. Haghghi-Mood terminates his employment within 30 days following the occurrence of changed circumstances, he is entitled to receive the severance benefits as though his employment had been terminated by the Company without cause. For purposes of his employment agreement, changed circumstances includes (i) a material reduction in the nature or scope of Dr. Haghghi-Mood's responsibilities, authority or powers as President and Chief Executive Officer of the Company, including, without limitation, due to the Board having hired or appointed another senior executive officer to whom Dr. Haghghi-Mood is requested by the Board to report or who reports directly to the Board or who is given responsibilities or authority normally exercised by an executive in the positions of President and Chief Executive Officer of a company generally comparable to the Company, in each case without Dr. Haghghi-Mood's consent; and (ii) any failure by the Company to nominate and recommend to stockholders that they reelect Dr. Haghghi-Mood to serve as a director of the Company upon the expiration of his term.

In the event of a change in control (as defined in the severance agreements) that does not result in termination of the executive officer's employment, 50% of Mr. LiCausi's unvested options and 100% of Dr. Haghghi-Mood's unvested options that are then outstanding will become immediately exercisable. In the event of a change in control that results in the termination of the executive officer's employment without cause or by the executive officer for good reason (each as defined in the severance agreements), the executive officer will be entitled to receive severance compensation in an amount equal to the executive officer's base salary as in effect at the time of such termination for a period of 12 months, continued healthcare benefits for a period of 12 months, and all of the executive officer's unvested options which are then outstanding will become immediately exercisable.

The Company included enhanced severance benefits in the event of a change in control of the Company in order to remove any financial concerns an executive may have when evaluating a potential transaction and to allow the executive to focus on maximizing value for the Company's stockholders. The Board of Directors determined that these change in control benefits are necessary given the volatility and uncertainty inherent in the Company's line of business.

## **Employment Agreement with Chief Executive Officer**

On December 14, 2007, the Company appointed Dr. Haghghi-Mood as the Company's President and Chief Executive Officer and elected him as a director of the Company. Dr. Haghghi-Mood and the Company entered into an employment agreement dated December 14, 2007, the terms of which were approved by the Board of Directors of the Company after negotiations with Dr. Haghghi-Mood.

Under the terms of the employment agreement, Dr. Haghghi-Mood will be paid an annual base salary of \$275,000 per year and will be entitled to receive the severance benefits described above under the title "Severance Arrangements with Named Executive Officers." Dr. Haghghi-Mood also will have the opportunity to earn an annual performance bonus based upon the achievement by the Company of performance goals to be agreed upon by Dr. Haghghi-Mood and the Board of Directors or the Compensation Committee.

Under the terms of the employment agreement, Dr. Haghghi-Mood will have the opportunity to earn an annual performance bonus in the amount, and contingent upon the achievement by the Company or Dr. Haghghi-Mood, as the case may be, of performance goals to be agreed upon by Dr. Haghghi-Mood and the Board of Directors of the Company. See "Senior Management Bonus Plan for 2009" for a description of the 2009 performance bonus criteria for Dr. Haghghi-Mood.

Effective March 1, 2010, Dr. Haghghi-Mood agreed to a 10% reduction in his base salary for 2010. See “Management Stock Option Awards” for a description of the terms of a stock option awarded to Dr. Haghghi-Mood in recognition of the reduced base salary.

### **Senior Management Bonus Plan for 2009**

Dr. Haghghi-Mood and Mr. LiCausi, as well as other senior management of the Company (excluding Mr. de Greef), were eligible to participate in the Senior Management Bonus Plan for 2009 (the “200 Bonus Plan”). The objective of the 2009 Bonus Plan is to provide an effective tool to help motivate the senior management team’s performance in achieving the Company’s defined strategy and goals by aligning measurement and accountability with cash incentive rewards. The total bonus potential under the 2009 Bonus Plan for Dr. Haghghi-Mood and Mr. LiCausi was 50% and 30% of annual base pay, respectively.

Rewards under the 2009 Bonus Plan were based on the achievement of performance goals for the Company established by the Compensation Committee and approved by the Board of Directors in consultation with Mr. Haghghi-Mood. The performance goals under the 2009 Bonus Plan consisted of four separate goals each weighted between 8% and 60% relating to:

- the execution of one or more strategic distribution agreements approved by the Board of Directors;
- the completion of the development of a MTWA OEM Module and any other requirements of any strategic distribution agreements to which the Company is a party;
- the achievement of a cash balance at December 31, 2009 in an amount determined by the Board of Directors; and
- the completion of a capital raising transaction upon terms agreed to by the Board of Directors that results in the Company achieving a total cash balance at December 31, 2009 in an amount determined by the Board of Directors.

The Compensation Committee determined that a portion of the performance goal related to the execution of one or more strategic distribution agreements, the entire performance goal related to the development of a MTWA OEM Module, and a portion of the performance goal related to the completion of a capital raising transaction had been achieved, and that the performance goal related to the achievement of an amount of cash at December 31, 2009 had not been achieved. Based on the foregoing, the Compensation Committee determined that the bonus amounts earned by Dr. Haghghi-Mood and Mr. LiCausi under the 2009 Bonus Plan were \$77,000 and \$26,040, respectively.

On March 11, 2010, the Compensation Committee awarded, and Dr. Haghghi-Mood and Mr. LiCausi agreed to accept, stock options in lieu of any cash bonus for 2009. Specifically, Dr. Haghghi-Mood and Mr. LiCausi were awarded options to purchase 668,468 and 226,064 shares of common stock, respectively, at an exercise price of \$0.16 per share, which was the closing price of the Company’s common stock on the date of grant. The number of shares covered by each option award was determined based on the amount of the 2009 bonus earned by each recipient and the fair value of the option awards using the Black-Scholes option pricing model, which requires the Company to make certain assumptions regarding the expected term of the options, forfeiture rate and volatility of the underlying stock. The option awards are immediately exercisable and will continue to be exercisable following the termination of the employment of the recipient until the expiration of the ten-year term.

### **Employment Agreement with Chairman of the Board**

On November 24, 2008, the Board of Directors elected Mr. de Greef as a member of the Board of Directors and appointed him to serve as the Chairman of the Board. Mr. de Greef and the Company entered into an employment agreement dated November 24, 2008 the terms of which were approved by the Board of Directors of the Company after negotiations with Mr. de Greef.

The employment agreement provides that Mr. de Greef will devote approximately 50% of a regular work week to the business and interests of the Company. Specifically, the employment agreement provides that Mr. de Greef will work with the Company's Chief Executive Officer and the Board of Directors to formulate the strategic plan of the Company and to oversee the execution of corporate strategy. Mr. de Greef will serve on the Company's Board as the Chairman of the Board. During the term of Mr. de Greef's employment by the Company, at each annual meeting of the Company's stockholders at which Mr. de Greef's membership on the Board has expired, the Company will nominate Mr. de Greef to serve as a member of the Board.

The Employment Agreement has a term of three years commencing on November 24, 2008 and ending on November 24, 2011 (the "Employment Period"). The Employment Period will automatically be extended for successive one year periods unless either party gives the other 30 days written notice that it does not wish to extend the term of the employment agreement.

The employment agreement provides that Mr. de Greef will be paid an annual base salary of \$120,000 per year. He will be entitled to participate in any and all of the Company's employee benefit plans in effect for part-time employees, except to the extent that such benefits are in a category otherwise specifically provided to Mr. de Greef. In the event that Mr. de Greef is not eligible to participate in the Company's health insurance benefit plan, the Company will reimburse Mr. de Greef up to \$2,000 per month for the cost of maintaining his current family medical insurance coverage.

On November 24, 2008, the Board awarded to Mr. de Greef a stock option to purchase 550,000 shares of common stock of the Company. The option was granted under and subject to the terms of the Company's 2001 Stock Incentive Plan (the "2001 Plan"). The exercise price of the option was the closing price per share of the Company's common stock on November 24, 2008 (the "Grant Date"). The option becomes exercisable in three equal annual installments, beginning on the first anniversary of the Effective Date. The option will expire on the tenth anniversary of the Grant Date. The dates on which the option will become exercisable will accelerate with regard to a specified number of shares upon the occurrence of certain performance goals (the "Performance Goals"). The Performance Goals include: (i) the achievement by the Company of a specified 12-month trailing revenue target of \$7.0 million (the "Revenue Target"); (ii) the consummation by the Company of one or more equity financing transactions in a twelve-month period that result in the receipt by the Company of sufficient proceeds to fund the Company's operations for a 12-month period as determined in good faith by the Board (the "Financing Target"); and (iii) the consummation by the Company of a strategic distribution agreement (the "Strategic Transaction Target"). Upon the occurrence of a Performance Goal, the stock option will become exercisable with respect to a number of shares equal to the lesser of (A) the number of shares specified in the employment agreement for each Performance Goal (162,500 shares for each of the Revenue Target and the Financing Target and 62,500 shares for the Strategic Transaction Target) and (B) the positive difference between total number of shares under the stock option that are not yet exercisable and the number of shares specified in the employment agreement for the Performance Goal. The shares that become exercisable upon the achievement of a Performance Goal will reduce the number of shares that otherwise would next become exercisable on a regular annual vesting date following the date of achievement of the Performance Goal. As of December 31, 2009, both the Financing Target and the Strategic Transaction Target had been achieved.

In addition, prior to his appointment as Chairman of the Board, from July 2008 to November 2008, Roderick de Greef served as a consultant pursuant to the terms of a consulting agreement between the Company and Mr. de Greef dated July 29, 2008 (the "Consulting Agreement"). The Consulting Agreement provided that Mr. de Greef would provide consulting services to the Company to promote and execute the Company's business development activities as an independent contractor. Mr. de Greef was paid a total of \$32,916 in fees under the Consulting Agreement. On July 29, 2008, Mr. de Greef received an option to purchase 100,000 shares of the Common Stock of the Company at an exercise price of \$0.33 per share (the "July 2008 Option"). The option becomes exercisable if, during the term of the Consulting Agreement or within 12 months thereafter, the Company executes a strategic transaction in which Mr. de Greef was involved. The July 2008 Option became exercisable in 2009.

In the event the Company terminates Mr. de Greef's employment without cause, he would be entitled to severance benefits as set forth in the employment agreement, including payment of Mr. de Greef's salary for three months following termination. Mr. de Greef would also receive continuation of his health care benefits or reimbursement, as the case may be, for three months following termination. In addition, the stock option granted under the employment agreement would become exercisable for the number of shares that would have become exercisable had Mr. de Greef remained employed with the Company for an additional six months following termination and had the stock option become exercisable in 12 equal quarterly installments. If termination occurs prior to November 24, 2011, Mr. de Greef will have the right to exercise the stock option received under the Employment Agreement as well as the July 2008 Option for a period of two years following termination (but in no event after the expiration of the stock option) to the extent that he was entitled to exercise the stock option on that date.

In the event that a change in control of the Company occurs and Mr. de Greef's employment is terminated without cause within 12 months following the change in control, Mr. de Greef is entitled to receive the severance benefits described above for a period of six months following the date of termination. In the event of a change in control of the Company, Mr. de Greef's stock options received under the Employment Agreement and the July 2008 Option will become exercisable in full as of the date of the change in control, provided that all stock options must be exercised within the applicable dates provided in the applicable stock option agreement and the 2001 Plan.

In 2009, the stock options awarded to Mr. de Greef on November 24, 2008 associated with the execution of a Strategic Transaction and the Financing Target Performance Goals, and the July 2008 Option became exercisable.

Effective March 1, 2010, Mr. de Greef agreed to a 10% reduction in his base salary for 2010. See "Management Stock Option Awards" for a description of the terms of a stock option awarded to Mr. de Greef in recognition of the reduced in base salary.

### **2010 Management Stock Option Awards**

Effective March 1, 2010, the senior management team of the Company agreed to a 10% reduction in their base salaries for 2010. After giving effect to this reduction, the annual salary rates for the Named Executive Officers will be as follows: \$247,500 for Dr. Haghighi-Mood, \$108,000 for Mr. de Greef, and \$83,700 for Mr. LiCausi. In recognition of the reduction of the salaries of the senior management team, the Compensation Committee granted to each senior management member a stock option award (the "Salary Reduction Option Award") on March 11, 2010 that becomes exercisable in nine equal monthly installments beginning on April 11, 2010, and will continue to be exercisable following the termination of the employment of the recipient to the same extent that the option was exercisable on the date of termination until expiration of the ten-year term. The Salary Reduction Option Awards were granted outside of the Company's 2001 Stock Incentive Plan, but are nevertheless subject to the terms and conditions of the plan as if granted thereunder. Dr. Haghighi-Mood, Mr. de Greef and Mr. LiCausi received Salary Reduction Option Awards to purchase 198,949, 86,814 and 67,281 shares of common stock, respectively, at an exercise price of \$0.16 per share, which was the closing price of the Company's common stock on the date of grant. The number of shares covered by each Salary Reduction Option Award was determined based on the amount of the reduction of the 2010 salary for each recipient and the fair value of the Salary Reduction Option Awards using the Black-Scholes option pricing model, which requires the Company to make certain assumptions regarding the expected term of the options, forfeiture rate and volatility of the underlying stock.

Additionally, on March 11, 2010, each of the members of the senior management team of the Company (other than Mr. de Greef) entered into individual option exchange agreements with the Company whereby previously granted stock options to purchase an aggregate of 2,983,333 shares of common stock issued at varying times and at varying prices (ranging from \$0.29 per share to \$4.00 per share) were cancelled and replaced with



new stock options (the “Management Stock Option Awards”) to purchase an aggregate of 3,583,333 shares of common stock of the Company at an exercise price of \$0.16 per share, which was the closing price of the Company’s common stock on the date of grant. The Management Stock Option Awards become exercisable in three equal annual installments beginning on first anniversary of the date of grant. Dr. Haghighi-Mood and Mr. LiCausi received awards to purchase 2,383,333 and 450,000 shares of common stock of the Company, respectively, in exchange for the cancellation of previously granted stock options to purchase 2,383,333 and 350,000 shares of common stock. The Management Stock Option Awards were granted outside of the Company’s 2001 Stock Incentive Plan, but are nevertheless subject to the terms and conditions of the plan as if granted thereunder.

The following table sets forth certain information concerning stock options held by the Named Executive Officers as of December 31, 2009.

### Outstanding Equity Awards At Fiscal Year-end For 2009

Name	Option Awards(1)			
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date
Ali Haghighi-Mood, Ph.D. ....	333,333		\$0.29	8/15/2015
Ali Haghighi-Mood, Ph.D. ....	700,000		\$3.30	12/14/2016
Ali Haghighi-Mood, Ph.D. ....	600,000	300,000	\$1.15	12/11/2017
Ali Haghighi-Mood, Ph.D. ....	300,000	150,000	\$1.15	12/11/2017
Vincenzo LiCausi ....	50,000	100,000	\$2.53	10/16/2016
Vincenzo LiCausi ....	20,000		\$3.26	4/30/2017
Vincenzo LiCausi ....	20,000	10,000	\$4.00	5/18/2017
Vincenzo LiCausi ....	100,000	50,000	\$1.07	2/12/2018
Roderick de Greef ....	345,833	204,167(2)	\$0.15	11/24/2018
Roderick de Greef ....	100,000		\$0.33	7/29/2018

- (1) Except as otherwise noted, each option becomes exercisable in three equal annual installments, beginning on the first anniversary of the date of grant.
- (2) Option becomes exercisable in three equal annual installments, beginning on the first anniversary of the date of grant. The dates on which the option will become exercisable will accelerate with regard to a specified number of shares upon the occurrence of certain performance goals (the “Performance Goals”). The Performance Goals include: (i) the achievement by the Company of a 12-month trailing revenue target of \$7.0 million (the “Revenue Target”); (ii) the consummation by the Company of one or more equity financing transactions in a 12-month period that result in the receipt by the Company of sufficient proceeds to fund the Company’s operations for a 12-month period as determined in good faith by the Board (the “Financing Target”); and (iii) the consummation by the Company of a strategic distribution agreement (the “Strategic Transaction Target”). Upon the occurrence of a Performance Goal, the stock option will become exercisable with respect to a number of shares equal to the lesser of (A) the number of shares specified for each Performance Goal (162,500 shares for each of the Revenue Target and the Financing Target and 62,500 shares for the Strategic Transaction Target) and (B) the positive difference between total number of shares under the stock option that are not yet exercisable and the number of shares specified for the Performance Goal. The shares that become exercisable upon the achievement of a Performance Goal will reduce the number of shares that otherwise would next become exercisable on a regular annual vesting date following the date of achievement of the Performance Goal.

## Director Compensation

In 2009, non-employee directors received a fee of \$2,500 per in-person meeting of the Board of Directors and \$500 per telephonic meeting of the Board of Directors or committee meeting, and non-employee directors who served as Chairman of the Board or as chairman of one or more committees of the Board of Directors (currently Messrs. McGuire, Wiggins and McCormick) received a fee of \$3,125 per in-person meeting of the Board of Directors and \$625 per telephonic meeting of the Board of Directors or committee meeting. In 2009, each of the Company's non-employee directors received an annual retainer of \$15,000, payable in equal quarterly installments.

Effective March 31, 2010, the Board of Directors has reduced the amount of cash compensation paid to the non-employee directors of the Company. Specifically, all per meeting fees have been eliminated and the cash annual retainer paid to non-employee directors has been reduced to \$12,000 per year, payable in equal quarterly installments.

In recognition of this reduction in fees, each of the non-employee directors was awarded a stock option to purchase 112,858 shares of common stock of the Company (the "Director Fee Reduction Option Award"), having a fair value of \$13,000 using the Black Scholes option pricing model. The Director Fee Reduction Option Awards become exercisable in nine equal monthly installments beginning on April 11, 2010 and will continue to be exercisable following the termination of the director's service with the Company to the same extent that the stock option was exercisable on the date of resignation or termination until expiration of the ten-year term. The Director Fee Reduction Option Awards were granted outside of the Company's 2001 Stock Incentive Plan, but are nevertheless subject to the terms and conditions of the plan as if granted thereunder.

Additionally, on March 11, 2010, the Compensation Committee granted each of the non-employee directors a stock option to purchase 100,000 shares of the common stock of the Company under and pursuant to the Company's 2001 Stock Incentive Plan. The stock options become exercisable in full on the one-year anniversary of the date of grant and will continue to be exercisable following the termination of services of the recipient to the same extent that it was exercisable on the date of termination until the expiration of the ten-year term.

The following table sets forth compensation actually paid, earned or accrued during 2009 by the Company's directors.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Stock Awards \$(1)</u>	<u>Option Awards \$(1)</u>	<u>Total (\$)</u>
Richard J. Cohen(2) . . . . .	27,500	233,180(3)	20,147(4)	280,828
Kenneth V. Hachikian(5) . . . . .	36,250	—	22,398(6)	58,648
Reed Malleck(7) . . . . .	33,500	—	20,147(8)	53,647
John F. McGuire . . . . .	40,625	—	64,331(9)	104,956
Keith M. Serzen(10) . . . . .	6,250	—	—	6,250
Jeffrey Wiggins . . . . .	36,875	—	17,059(11)	53,934
Paul McCormick . . . . .	—	—	—	—

- (1) Reflects the dollar amounts recognized for financial statement reporting purposes for the fiscal year ended December 31, 2009, in accordance with FASB ASC Topic 718 (excluding the impact of estimated forfeitures related to service-based vesting conditions), and thus may include amounts attributable to awards granted during and before 2009. Assumptions made in the calculation of these amounts are included in Note 2 to the Company's audited financial statements for the fiscal year ended December 31, 2009, included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission.
- (2) Dr. Cohen resigned as director on December 30, 2009. See "Consulting and Technology Agreement with Richard J. Cohen, M.D., Ph.D." contained in Item 13 for a description of royalty fees paid to Dr. Cohen under an Amended and Restated Consulting and Technology Agreement between Dr. Cohen and the Company.
- (3) As of December 31, 2009, Dr. Cohen held 175,000 shares of restricted stock.

- (4) As of December 31, 2009, Dr. Cohen held options to purchase (a) 287,500 shares of Common Stock at exercise price of \$0.30 per share, (b) 30,000 shares of Common Stock at an exercise price of \$2.90 per share and (c) 300,000 shares of Common Stock at an exercise price of \$0.34 per share.
- (5) Mr. Hachikian resigned as director on December 30, 2009.
- (6) As of December 31, 2009, Mr. Hachikian held options to purchase (a) 80,000 shares of Common Stock at an exercise price of \$0.30 per share and (b) 30,000 shares of Common Stock at an exercise price of \$2.90 per share.
- (7) Mr. Malleck resigned as director on December 30, 2009.
- (8) As of December 31, 2009, Mr. Malleck held options to purchase (a) 80,000 shares of Common Stock at an exercise price of \$0.30 per share and (b) 30,000 shares of Common Stock at an exercise price of \$2.90 per share.
- (9) As of December 31, 2009, Mr. McGuire held options to purchase 100,000 shares of Common Stock at an exercise price of \$2.40 per share.
- (10) Mr. Serzen resigned as a director on April 22, 2009.
- (11) As of December 31, 2009, Mr. Wiggins held options to purchase 100,000 shares of common stock at an exercise price of \$0.63 per share.

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

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of December 31, 2009.

**Securities Authorized for Issuance Under Equity Compensation Plans**

<u>Plan Category</u>	<u>(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>(b) Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(3))</u>
Equity compensation plans approved by security holders . . . . .	5,278,366	\$1.60	2,186,110
Equity compensation plans not approved by security holders . . . . .	650,000	\$1.56	—
Total . . . . .	5,928,366	\$1.59	2,186,110

- (1) Consists of the Amended and Restated 1993 Incentive and Non-Qualified Stock Option Plan, the 1996 Equity Incentive Plan, and the 2001 Stock Incentive Plan.
- (2) Consists of a stock option to purchase 200,000 shares of Common Stock awarded to Jeffrey J. Langan, and a stock option to purchase 450,000 shares of Common Stock awarded to Ali Haghighi-Mood.
- (3) Consists of shares of Common Stock issuable under the 2001 Stock Incentive Plan. In addition to being available for future issuance upon exercise of options that may be granted after December 31, 2009, 1,120,217 shares of Common Stock under the 2001 Stock Incentive Plan may instead be issued in the form of restricted stock.

In October 2006, as an inducement to Jeffrey J. Langan to accept the position of President and Chief Executive Officer, Mr. Langan was awarded stock options to purchase 2,000,000 shares of Common Stock at an exercise price of \$2.49 per share, which is equal to the closing price per share of the Company's Common Stock on the date of grant. Mr. Langan's Employment Agreement with the Company provided that the stock options would vest in quarterly installments over a three-year period with 100,000 shares vesting on each of January 13, 2007 and April 13, 2007 and 180,000 shares vesting each quarter thereafter. In connection with Mr. Langan's resignation as President and Chief Executive Officer in December 2006, the Company entered into a separation

agreement with Mr. Langan. Under the terms of the separation agreement, all of the shares covered by the inducement stock options were cancelled and forfeited except for 200,000 shares, 100,000 of which became exercisable on January 12, 2007 and 100,000 of which became exercisable on April 13, 2007. A portion of the inducement stock options, including the 200,000 shares that remain exercisable following Mr. Langan's separation from the Company, were granted outside of the Company's equity incentive plans but are nevertheless subject to the terms and conditions of the Company's 2001 Plan.

On December 11, 2007, as an inducement to Ali Haghighi-Mood to accept the position as President and Chief Executive Officer, Dr. Haghighi-Mood was awarded: (a) a stock option to purchase 900,000 shares of common stock of the Company, which was granted under and subject to the terms and conditions of the Company's 2001 Plan, and (b) a stock option to purchase 450,000 shares of common stock of the Company, which was granted as a stand-alone award outside of the Company's equity incentive plans but is nevertheless governed by the terms and conditions of the 2001 Plan as though it was granted under the 2001 Stock Incentive Plan. The exercise price of the options is \$1.15 per share, which is equal to the closing price per share of the Company's common stock on the date of grant. The options become exercisable in three equal annual installments beginning on the first anniversary of the grant date. The options become exercisable in full in the event of a Change in Control (as defined in the Severance Agreement dated September 17, 2003 between the Company and Dr. Haghighi-Mood, as amended by letter agreement dated December 14, 2006). The options will expire on the tenth anniversary of the grant date.

## Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of Common Stock, Series C-1 Convertible Preferred Stock (the "Series C-1 Preferred") and Series D Convertible Preferred Stock (the "Series D Preferred") by: (i) each director and nominee, (ii) each of the executive officers named in the Summary Compensation Table above, (iii) all current directors and executive officers as a group, and (iv) each stockholder known to the Company to be the beneficial owner of more than 5% of the outstanding shares of Common Stock, Series C-1 Preferred or Series D Preferred.

Unless otherwise indicated in the footnotes to the table, all information set forth in the table is as of April 30, 2010, and the address for each director and executive officer of the Company is: c/o Cambridge Heart, Inc., 100 Ames Pond Drive, Tewksbury, MA 01876. The addresses for the greater than 5% stockholders are set forth in the footnotes to this table.

	Common Stock		Series C-1 Preferred		Series D Preferred	
	Number of Shares Beneficially Owned(1)	Percentage of Class Outstanding(2)	Number of Shares Beneficially Owned(1)	Percentage of Class Outstanding	Number of Shares Beneficially Owned(1)	Percentage of Class Outstanding
<b>Directors</b>						
Ali Haghighi-Mood, Ph.D. . . . .	734,784(3)	1.1%	—	—	—	—
Roderick de Greef . . . . .	1,572,332(4)	2.3%	—	—	50	2.7%
Paul McCormick . . . . .	37,619(5)	*	—	—	—	—
John McGuire . . . . .	104,286(6)	*	—	—	—	—
Jeffrey Wiggins . . . . .	6,689,653(7)	9.2%	—	—	300	16.2%
<b>Named Executive Officers</b>						
Ali Haghighi-Mood, Ph.D. . . . .	734,784(3)	1.1%	—	—	—	—
Vincenzo LiCausi . . . . .	248,491(8)	*	—	—	—	—
All directors and executive officers as a group (6 persons) . . . . .	9,387,165(9)	12.5%	—	—	350	18.9%
<b>5% Stockholders</b>						
Vincente Madrigal . . . . .	6,585,367(10)	9.1%	—	—	300	16.2%
Saba Malak . . . . .	8,608,924(11)	11.9%	—	—	300	16.2%
Luis Martins . . . . .	9,814,634(12)	13.5%	—	—	315	17.0%
St. Jude Medical, Inc. . . . .	4,180,602(13)	6.0%	5,000	100%	—	—
Samana Capital, L.P. . . . .	3,754,736(14)	5.70%	—	—	—	—

\* Represents less than 1% of the outstanding Common Stock.

- (1) The Company believes that each stockholder has sole voting and investment power with respect to the shares of Common Stock, Series C-1 Preferred and Series D Preferred listed, except as otherwise noted. The number of shares beneficially owned by each stockholder is determined under rules of the Securities and Exchange Commission, and the information is not necessarily indicative of ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the person has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days after April 30, 2010 through the exercise of any stock option, warrant, conversion of preferred stock or other right. The inclusion herein of any shares of Common Stock, Series C-1 Preferred or Series D Preferred deemed beneficially owned does not constitute an admission by such stockholder of beneficial ownership of those shares of Common Stock, Series C-1 Preferred or Series D Preferred. Shares of Common Stock, Series C-1 Preferred or Series D Preferred which an individual or entity has a right to acquire within the 60-day period following April 30, 2010 pursuant to the exercise of options, warrants or conversion rights are deemed to be outstanding for the purposes of computing the percentage ownership of such individual or entity, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person or entity shown in the table.

- (2) Based on 65,872,365 shares of Common Stock outstanding as of April 30, 2010.
- (3) Consists of 734,784 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010.
- (4) Consists of (i) 609,756 shares of Common Stock issuable upon the conversion of 50 shares of Series D Preferred, (ii) 474,771 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010, and (iii) 487,805 shares of Common Stock issuable upon the exercise of warrants to purchase Common Stock.
- (5) Consists of 37,619 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010.
- (6) Consists of 104,286 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010.
- (7) Consists of (i) 3,658,537 shares of Common Stock issuable upon the conversion of 300 shares of Series D Preferred beneficially owned by Mr. Wiggins through his relationship with the Jeffrey Wiggins Trust, (ii) 104,286 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010, and (iii) 2,926,830 shares of Common Stock issuable upon the exercise of warrants to purchase Common Stock beneficially owned by Mr. Wiggins through his relationship with the Jeffrey Wiggins Trust.
- (8) Consists of 248,491 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on June 29, 2010.
- (9) See notes 2 through 8 above.
- (10) As described in a Schedule 13G filed with the Securities and Exchange Commission on January 4, 2010, Vicente Madrigal beneficially owns 6,585,367 shares of Common Stock, including (i) 3,658,537 shares of Common Stock issuable upon conversion of 300 shares of Series D Preferred and (ii) 2,926,830 shares of Common Stock issuable upon exercise of warrants to purchase Common Stock. Mr. Madrigal's address is 79 East 79th Street, Apartment 12, New York, New York 10075.
- (11) As described in a Schedule 13G filed with the Securities and Exchange Commission on January 4, 2010, Saba Malak beneficially owns 8,608,924 shares of Common Stock, including (i) 2,023,557 shares of Common Stock, (ii) 3,658,537 shares of Common Stock issuable upon conversion of 300 Shares of Series D Preferred, and (iii) 2,926,830 shares of Common Stock issuable upon exercise of warrants to purchase Common Stock. Mr. Malak's address is 225 Commonwealth Avenue, Apartment 4, Boston,.
- (12) As described in a Schedule 13G filed with the Securities and Exchange Commission on January 4, 2010, Luis Martins beneficially owns 9,814,634 share of Common Stock, including (i) 2,900,000 shares of Common Stock, (ii) 3,841,463 shares of Common Stock issuable upon conversion of 315 shares of Series D Preferred, and (iii) 3,073,171 shares of Common Stock issuable upon exercise of warrants to purchase Common Stock. Mr. Martins' address is 1886 Beacon Street, Waban/Newton, Massachusetts 02468.
- (13) Includes 4,180,602 shares of Common Stock issuable upon the conversion of shares of Series C-1 Preferred. The business address of St. Jude Medical, Inc. is One Lillehei Plaza, St. Paul, MN 55117.
- (14) As described in a Schedule 13G/A (Amendment No. 3) filed with the Securities and Exchange Commission on February 16, 2010 by Samana Capital, L.P., Morton Holdings, Inc., and Philip B. Korsant, which share the power to vote and dispose of the shares of Common Stock. The principal business address of Samana Capital, L.P., Morton Holdings, Inc., and Philip B. Korsant is 283 Greenwich Avenue Greenwich, CT 06830.

## **Item 13. Certain Relationships and Related Transactions, and Director Independence**

### **Transactions with Related Persons**

The Board of Directors of the Company reviews the material facts of transactions with a related person that are required to be disclosed under Item 404(a) of Regulation S-K under the Securities Exchange Act of 1934, as amended. In general, that rule requires disclosure of any transaction in which the Company is a participant, the aggregate amount involved exceeds \$120,000, and any related person has or will have a direct or indirect material interest. A “related person” means any director or executive officer, any nominee for director, or any immediate family member of a director or executive officer of the registrant, or of any nominee for director. In reviewing related party transactions, the Board will take into account, among other factors it deems appropriate, whether the related party transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person’s interest in the transaction. Related party transactions are referred to the Board by management for review, approval, ratification or other action. This policy is not in writing but is followed consistently by the Board.

### **Consulting and Technology Agreement with Richard J. Cohen, M.D., Ph.D.**

The Company and Richard J. Cohen, M.D., Ph.D., who serves as the Chairman of the Company’s Scientific Advisory Board and, until December 30, 2009, served as a member of the Company’s Board of Directors, are parties to a Consulting and Technology Agreement pursuant to which Dr. Cohen agreed to provide consulting services and license certain technologies to the Company in exchange for compensation and the payment of certain royalties by the Company. In May 2007, the Company and Dr. Cohen entered into an Amended and Restated Consulting and Technology Agreement (the “Consulting Agreement”), the material terms of which are described below.

Under the terms of the Consulting Agreement, during the period beginning January 1, 2007 and ending on December 31, 2009 (the “Interim Consulting Period”), Dr. Cohen agrees to be available to the Company for consultation for up to 42 days per year. Thereafter, Dr. Cohen agrees to be available to the Company for consultation for a minimum of 18 days per year until the expiration of the consulting period on December 31, 2015 (the “Additional Consulting Period”).

Under the Consulting Agreement, the Company will pay Dr. Cohen royalties on net sales related to certain technologies (including the sale of the Company’s HearTwave II System and other Microvolt T-Wave Alternans products) equal to 1.5% of such net sales. If the Company sublicenses, or grants rights to any sublicense with respect to, such technologies to an unrelated company, Dr. Cohen shall receive royalties equal to 7% of gross revenue to the Company from the sublicense. Pursuant to the terms of the Consulting Agreement, the Company will pay Dr. Cohen additional royalties of \$10,000 per month during the Interim Consulting Period, subject to an annual percentage increase equal to the annual percentage increase in the National Consumer Price Index for the prior year (the “Monthly Royalty”).

Under the Consulting Agreement, Dr. Cohen received in May 2007, as compensation for his consulting effort, an aggregate of 175,000 shares of restricted common stock of the Company subject to the terms and conditions of the Company’s 2001 Stock Incentive Plan. The restricted shares vested on January 1, 2010. Dr. Cohen will not receive any additional compensation for the Additional Consulting Period.

In March 2010, the Company entered into Amendment No. 1 to the Amended and Restated Consulting and Technology Agreement with Dr. Cohen (“Amendment No. 1”). Pursuant to Amendment No. 1, the Interim Consulting Period is extended to December 31, 2010. Additionally, Dr. Cohen agreed to accept a reduced Monthly Royalty payment of \$5,811.17 per month for the period beginning on January 1, 2010 and ending on December 31, 2010. In consideration for the reduction in Monthly Royalty payments, Dr. Cohen received a stock option to purchase 561,982 shares of common stock of the Company, which becomes exercisable in nine equal monthly installments beginning on April 11, 2010 and which was granted outside of the Company’s 2001 Stock

Incentive Plan, but nevertheless subject to the terms and conditions of the 2001 Stock Incentive Plan. Pursuant to Amendment No. 1, in recognition of his service as Chairman of the Scientific Advisory Committee, Dr. Cohen received a stock option, under the Company's 2001 Stock Incentive Plan, to purchase 100,000 shares of the common stock of the Company, which becomes exercisable in full on March 11, 2010. Additionally, in consideration for his services as Chairman of the Company's Scientific Advisory Board during 2010, Dr. Cohen received a stock option to purchase 43,407 shares of common stock of the Company, which becomes exercisable in nine equal monthly installments beginning on April 11, 2010 and which was granted outside of the Company's 2001 Stock Incentive Plan, but nevertheless subject to the terms and conditions of the 2001 Stock Incentive Plan, and will be paid a total cash fee of \$5,000, payable monthly for the fiscal year 2010. All of the options granted to Dr. Cohen in connection with Amendment No. 1 have an exercise price of \$0.16 per shares, which is the closing price of the common stock on the date of grant.

In 2009, the Company paid Dr. Cohen approximately \$178,202 in royalties under the Consulting Agreement.

Under the Consulting Agreement, the Company will have the right to terminate the Consulting Agreement within the 30-day period immediately following a Change in Control (as defined in the Consulting Agreement) of the Company, in which case the Company shall pay Dr. Cohen a termination royalty as determined in the Consulting Agreement. Either party may terminate the Consulting Agreement for material breach or default by the other party of the other party's obligations under the Consulting Agreement upon 90 days' notice.

#### **Securities Purchase Agreement for Series D Convertible Preferred Stock**

On December 23, 2009, the Company issued and sold 1,852 shares of the Company's Series D Convertible Preferred Stock (the "Series D Preferred") at a purchase price of \$1,000 per share (the "Series D Original Issue Price") and common stock warrants described below to new and current institutional and private investors, including three directors of the Company, pursuant to the terms of a Securities Purchase Agreement dated December 23, 2009 between the Company and the purchasers of Series D Preferred (the "Series D Financing"). Three directors of the Company purchased an aggregate of 385 shares of Series D Preferred for a total purchase price of \$385,000. Specifically, Roderick de Greef, who serves as Chairman of the Board, Richard J. Cohen, who was then serving as a member of the Board, and Jeffery Wiggins purchased 50, 35 and 300 shares of Series D Preferred, respectively, and were issued Short-Term Warrants (as defined below) to purchase 304,878, 213,415 and 1,829,269 shares of common stock, respectively, and Long-Term Warrants (as defined below) to purchase 182,927, 128,049 and 1,097,561 shares of common stock, respectively.

Each share of Series D Preferred is convertible into a number of shares of common stock of the Company equal to \$1,000 divided by the conversion price of the Series D Preferred, which is initially \$0.082. Each share of Series D Preferred is currently convertible into approximately 12,195 shares of common stock. The total number of shares of common stock initially issuable upon conversion of the 1,852 shares of Series D Preferred issued and sold in the financing is 22,585,366, or approximately 32.69% of the Company's issued and outstanding common stock on an as converted basis.

The Company also issued to the investors two types of warrants. The first warrant, which expires on December 23, 2010, entitles the investor to purchase a number of shares of common stock equal to 50% of the number of shares of common stock into which the Series D Preferred purchased by the investor is convertible (the "Short-Term Warrant"). A total of 11,292,686 shares of common stock are issuable under the Short-Term Warrants. The exercise price of the Short-Term Warrants is \$0.107 per share. The second warrant, which expires on December 23, 2014, entitles the investor to purchase a number of shares of common stock equal to 30% of the number of shares of common stock into which the Series D Preferred purchased by the investor is convertible (the "Long-Term Warrant"). A total of 6,775,611 shares of common stock are issuable under the Long-Term Warrants. The exercise price of the Long-Term Warrants is \$0.142 per share. The Company may call the Long-Term Warrants if the closing price of the Company's common stock is at least \$0.284 for a period of 20 consecutive trading days.



The conversion price of the Series D Preferred is subject to adjustment if the Company issues shares of common stock at a purchase price below the conversion price of the Series D Preferred at any time within 18 months after the issue date. In the event of a liquidation of the Company, the holders of Series D Preferred are entitled to receive an amount equal to the Series D Original Issue Price plus declared but unpaid dividends before the payment of any amount to the holders of common stock, Series C-1 Convertible Preferred Stock and all other equity or equity equivalent securities of the Company other than those securities that are explicitly senior to or on parity with the Series D Preferred with respect to liquidation preference.

### Director Independence

The Board has determined that Messrs. Wiggins, McGuire and McCormick are independent directors, and that Messrs. Hachikian and Malleck, who served on the Board of Directors during 2009, were independent directors, as defined by the rules of The Nasdaq Stock Market. The Board of Directors has established three standing committees—Audit, Compensation, and Nominating and Governance. The Audit and Nominating and Governance Committees each operate under a charter that has been approved by the Board. Current copies of the charters of the Audit and Nominating and Governance Committees are posted in the Corporate Governance section of the Company’s website at [www.cambridgeheart.com](http://www.cambridgeheart.com).

The members of the Audit Committee are Mr. McGuire (Chairman), Mr. Wiggins and Mr. McCormick. The Board of Directors has determined that all members of the Audit Committee are independent as determined under Rule 10A-3 promulgated under the Securities Exchange Act of 1934 and as defined by the rules of The Nasdaq Stock Market.

The members of the Compensation Committee are Mr. McCormick (Chairman), Mr. Wiggins and Mr. McGuire. All members of the Compensation Committee are independent as defined under the rules of The Nasdaq Stock Market.

The members of the Nominating and Governance Committee are Mr. Wiggins (Chairman), Mr. McGuire and Mr. McCormick. All members of the Nominating Committee are independent as defined under the rules of The Nasdaq Stock Market.

### Item 14. Principal Accountant Fees and Services

#### Independent Auditor’s Fees

The following table summarizes the fees of Caturano and Company, PC billed to the Company for each of the last two fiscal years for audit services and billed to the Company in each of the last two fiscal years for other services:

<u>Fee Category</u>	<u>2009</u>	<u>2008</u>
Audit Fees . . . . .	\$137,250	\$125,000
Audit-Related Fees . . . . .	\$ —	\$ 6,050(1)
Total Fees . . . . .	\$137,250	\$131,050

(1) Consists of fees related to SEC filings and accounting consultation.

#### Pre-Approval Policies and Procedures

The Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by the Company’s independent auditor. This policy generally provides that the Company will not engage its independent auditor to render audit or non-audit services unless the service is specifically approved in advance by the Audit Committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, the Audit Committee may pre-approve specified types of services that are expected to be provided to the Company by its independent auditor during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

The Audit Committee has also delegated to the chairman of the Audit Committee the authority to approve any audit or non-audit services to be provided to the Company by its independent auditor. Any approval of services by a member of the Audit Committee pursuant to this delegated authority is reported on at the next meeting of the Audit Committee.

There were no audit or non-audit services provided to the Company for the fiscal year ended December 31, 2009 that were not approved by the Audit Committee or its chairman.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

(b) The following exhibits are filed as part of this Report on Form 10-K/A:

<u>Exhibit</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

## 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 April 30, 2010.

CAMBRIDGE HEART, INC.

By:           /s/ ALI HAGHIGHI-MOOD            
**Ali Haghghi-Mood**  
**President and Chief Executive Officer**

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ ALI HAGHIGHI-MOOD          </u> <b>Ali Haghghi-Mood</b>	President and Chief Executive Officer (Principal Executive Officer)	April 30, 2010
<u>          /s/ VINCENZO LICAUSI          </u> <b>Vincenzo LiCausi</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	April 30, 2010

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

## **BOARD OF DIRECTORS**

Roderick DeGreef  
Chairman of the Board, Cambridge Heart, Inc.

Ali Haghighi–Mood  
President and Chief Executive Officer,  
Cambridge Heart, Inc.

John McGuire  
Former President and CEO, American Red Cross

Jeffrey Wiggins  
Former Principal of Dresdner RCM Capital  
Management

Paul J. McCormick  
Executive Chairman, Cardiogenesis, Inc.

## **EXECUTIVE OFFICERS**

Ali Haghighi–Mood  
President and Chief Executive Officer

Vincenzo LiCausi  
Vice President, Chief Financial Officer, Treasurer  
and Corporate Secretary

Roderick DeGreef  
Chairman of the Board

## **ANNUAL MEETING**

The annual meeting of stockholders will be held at on  
June 28, 2010 at 8:30 a.m., local time, at the  
Corporate Office at 100 Ames Pond Drive,  
Tewksbury, Massachusetts 01876

## **INDEPENDENT ACCOUNTANTS**

Caturano and Company PC  
80 City Square  
Boston, Massachusetts 02129

## **LEGAL COUNSEL**

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

## **CORPORATE INFORMATION**

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

Investor Relations  
Cambridge Heart, Inc.  
100 Ames Pond Drive  
Tewksbury, Massachusetts 01876  
(888) 226-9283  
[www.cambridgeheart.com](http://www.cambridgeheart.com)

## **TRANSFER AGENT & REGISTRAR**

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

American Stock Transfer & Trust Company  
Shareholder Services Department  
59 Maiden Lane  
Plaza Level  
New York, New York 10038  
(800) 937-5449

## **SHAREHOLDER INFORMATION**

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