CAMBRIDGE HEART

Annual Report

2010

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, 2010

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	13-3679946
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
100 Ames Pond Drive, Tewksbury, MA	01876
(Address of Principal Executive Offices)	(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 $17,785,539 computed by reference to the last reported sale price of the common stock on the OTC Bulletin Board on June 30, 2010.

As of March 23, 2011, 97,494,185 shares of the registrant's common stock were outstanding.

CAMBRIDGE HEART, INC.

2010 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 as performed on a treadmill similar to a standard stress test, pharmacologic agents, or pacing with electrical pulses. Our proprietary products 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 approximately 300,000 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 System and second generation HearTwave II System, CH 2000 Cardiac Stress Test System, MTWA OEM (Original Equipment Manufacturer) Module ("MTWA Module") and Micro-V Alternans Sensors have received 510(k) clearance from the FDA for sale in the U.S. Our products have also received the CE mark for sale in Europe, which certifies that a product has met European Union consumer, health and environmental requirements. Our first generation HearTwave System, CH 2000 Cardiac Stress Test System and the HearTwave II 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 patients 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.

In March 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a National Coverage Determination ("NCD") 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 (the "Company") 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. 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 non-invasive diagnostic monitoring regime used to identify and manage the risk of cardiac disease. In the past, the Company's marketing strategy was focused on providing MTWA testing to those patients at highest risk for SCA, who were already likely candidates to receive an implantable defibrillation device ("ICD"). Although MTWA testing has clearly been demonstrated to be useful in this patient population, 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 cardiac patients in the U.S. who are at risk of SCA and can benefit from annual MTWA testing. Our strategy now includes accessing this broader patient population.

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, who have established distribution networks and existing installed base of users, to integrate our MTWA technology into their systems. In addition to being sold to the manufacturers' new customers, the Company expects that the MTWA technology will be marketed as an upgrade to the manufacturers' existing installed base of 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 leveraging larger and more established distribution networks 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.

Pursuant to this strategy, in September 2010 we launched our MTWA Module in connection with our Development, Supply and Distribution Agreement (the "Cardiac Science Agreement") with Cardiac Science Corporation ("Cardiac Science"). The MTWA Module developed under the Cardiac Science Agreement allows our MTWA Test, using our proprietary Micro-V Alternans Sensors, to be performed on Cardiac Science's Q-Stress test platform.

The Company is pursuing other similar partnerships that will enable us to broaden the adoption and utilization of MTWA testing.

Principal Products and Applications

Microvolt T-Wave Alternans Module

In April 2010, we received clearance from the FDA to begin marketing the MTWA Module. The MTWA Module is designed to work with existing cardiac stress test platforms distributed by other manufacturers as an add-on Module to enable MTWA testing to be performed using our Micro-V Alternans Sensors. The electrocardiographic signals are captured by the Micro-V Alternans Sensors placed at designated locations on the patient's chest and analyzed by the MTWA Module using our proprietary Analytic Spectral Method for measuring the microvolt levels of T-Wave Alternans. The FDA 510(k) clearance allows us to market the MTWA Module integrated with the Q-Stress line of stress systems manufactured by Cardiac Science. In September 2010, Cardiac Science began marketing the MTWA Module for Q-Stress.

The HearTwave II System

Our HearTwave II System, which has replaced our original HearTwave System, is used to perform both MTWA testing and standard cardiac stress testing.

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.

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. 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 peer reviewed journals including 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 1-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 $\leq$ 40%, MTWA can identify not only a high-risk group, but also a low-risk group unlikely to benefit from ICD prophylaxis." This clinical study was republished in the January 17, 2006 issue of *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.

In July 2010, the first patients were enrolled in our MTWA-CAD study (Evaluation of Microvolt T-Wave Alternans Testing for the Detection of Active Ischemia in Patients with Known or Suspected Coronary Artery Disease). MTWA-CAD is a feasibility study, sponsored by the Company, designed to evaluate MTWA testing for the purpose of detecting active ischemia in patients with known or suspected coronary artery disease (CAD). Ischemia is defined as inadequate blood supply to the coronary arteries, which can lead to myocardial infarction or what is commonly referred to as a "heart attack." Ischemia, a common trigger for arrhythmias, is a well-documented cause of repolarization alternans. Human studies have shown that active ischemia can be associated with visible as well as microvolt-level T-wave alternans. While MTWA testing is currently used to evaluate arrhythmic risk, this known association with ischemia may allow MTWA testing to be used as a diagnostic tool to detect underlying CAD. An estimated 40 million cardiac stress tests in various modalities are performed annually in the United States. We filed a patent application related to ischemia in December of 2009. The MTWA-CAD study will assess the feasibility of this concept by measuring MTWA during routine nuclear stress testing or stress echocardiography with treadmill exercise. This is a feasibility study designed to verify preliminary observations under controlled environments and to generate hypotheses, endpoints, and sample sizes for future investigations. The MTWA-CAD trial is expected to enroll up to 200 patients. We estimate that the enrollments will be completed by mid-2011.

Reimbursement

In December 2005, CMS released a draft of its NCD, which became final on March 21, 2006. This broad coverage policy allows for payment to physicians for MTWA testing of patients at risk of SCA only when a MTWA Test is performed using the Analytic Spectral Method, which is our patented and proprietary method of analysis. 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 cardiac arrest. We estimate that at least 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 approximately 50% are covered by private insurers.

Reimbursement rates for services covered by Medicare are determined by reference to the Medicare Physician Fee Schedule ("MPFS"), and are calculated based on multiple components, including relative value units, conversion factor and geographical adjustment. The MPFS rates are updated annually and have resulted in negative updates since 2002.

During 2010, the reimbursement amount for cardiovascular services, including the MTWA Test, was set on a temporary basis throughout the year. Consequently, there was significant uncertainty regarding the economic

benefit to physicians of providing these cardiovascular services. In November 2009, CMS issued its final ruling on the MPFS effective January 1, 2010. This ruling set forth a reduction in relative value unit for nearly all cardiovascular services to be phased in over a four-year period. The final rule also included an additional 21% reduction in the conversion factor component of the reimbursement calculations. However, CMS subsequently decided to temporarily maintain the conversion factor at the 2009 level until June 1, 2010. In July 2010, CMS issued a revised MPFS reflecting, among other things, a change in the conversion factor as a result of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, which was signed into law on June 25, 2010. This legislation provided for a 2.2% increase to the 2010 MPFS, effective for dates of service June 1, 2010 through November 30, 2010, which set the national average Medicare payment amount for a MTWA Test at $205.31. In November 2010, CMS published their final reimbursement rules for 2011, effective January 1, 2011, which would have resulted in a decrease in reimbursement rates by as much as 30%. However, subsequently in December 2010, Congress enacted legislation to sustain reimbursement at the 2010 level through December 2011. Effective January 1, 2011 through December 31, 2011, the national average Medicare payment amount for a MTWA Test is $200.

In July 2010, CMS's National Correct Coding Initiative (NCCI) changed the edits associated with MTWA testing, allowing our MTWA Tests to be performed on the same day as several stress procedures. The CMS update removes a previous restriction that substantially limited the reimbursement amount when a patient underwent a MTWA Test on the same day as the patient underwent a standard cardiac stress test, echocardiography stress test, nuclear cardiac stress test, or pulmonary stress test. As a result, effective July 1, 2010, CMS allows full reimbursement for both an MTWA Test and a stress test when both tests are performed during the same patient visit.

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.

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, the MTWA Module, or Micro-V Alternans Sensors, any of which may in turn have a material adverse effect on our business.

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. Under our new strategy, 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 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 for sudden cardiac arrest and, therefore, may be treated more conservatively, typically through drug therapy.

At December 31, 2010, we had four direct sales representatives who sell our products in the United States. In addition, we had 8 clinical application specialists to install systems, train customers and enhance utilization.

In June 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 allows 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. Launched in September 2010, Cardiac Science markets 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 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 resells 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 has primary responsibility for preparing sales and marketing materials and for training its sales and service personnel regarding the Products. We provide clinical and technical training and support to Cardiac Science. In addition, we provide installation training service to each purchaser of a MTWA Module for use on Cardiac Science's Q-Stress test platform. We also 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 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 2010, approximately 20% 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. We market the HearTwave II System, the CH 2000 Cardiac Stress Test System and our Micro-V Alternans Sensors internationally through independent distributors. In April 2010, the Japanese regulatory authorities cleared our HearTwave II System to be marketed in Japan on a non-exclusive basis by Fukuda Denshi Co LTD. Previously, our distribution arrangement with Fukuda Denshi was limited to our CH2000 Cardiac Stress Test System and our first generation HearTwave System. In addition, effective August 2010, we appointed Mayerick S.A. de S.V. as the exclusive distributor of our HearTwave II System in Mexico. Sales of our HearTwave II System in Mexico will not commence unless and until the necessary regulatory approvals have been received from the Mexican regulatory authorities. The initial term of our distribution arrangement with Mayerick expires on July 31, 2012. We may terminate the distribution arrangement with Mayerick early if Mayerick fails to introduce the HearTwave II System in Mexico for purchase generally by end-users by July 1, 2011 due to reasons within Mayerick's control or by January 1, 2012 due to any other reason.

Manufacturing

The in-house manufacturing process for our HearTwave II System, MTWA Module 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 of our products takes place in our facility in Tewksbury, Massachusetts. We believe that our 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 2010, 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 developing and gaining regulatory approval for our MTWA Module. In addition, we allocated research and development resources to our MTWA-CAD feasibility study, which is designed to evaluate MTWA testing for the purpose of detecting active ischemia in patients with known or suspected coronary artery disease.

As of December 31, 2010, we had two full-time employees and one temporary resource engaged in research and development activities along with several independent research and engineering consultants whose services are utilized as necessary.

Patents, Trade Secrets and Proprietary Rights

Some of the initial methods that we used in the measurement of 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 17 additional 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 pharmalogical 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, and from GE Medical Systems, although GE Medical Systems' methodology for determining MTWA is not covered by CMS.

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 NCD for Microvolt T-Wave Alternans to include GE's Modified Moving Average (MMA) methodology.

In February 2008, CMS released a Proposed Decision Memo stating that there was 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 Analytic Spectral Method, which is our patented and proprietary method of analysis, and found insufficient evidence for coverage of MTWA using any other method.

Government Regulation

Our HearTwave Systems, MTWA Module, 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, MTWA Module 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. The 510(k) clearance for the MTWA Module allows us to market the MTWA Module integrated with the Q-Stress line of stress systems manufactured by Cardiac Science.

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, MTWA Module, 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 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 products, and in 2006, we received ISO-13485-2003 for our HearTwave products. The Japanese Ministry of Health, Labor and Welfare has also approved our original HearTwave System and most recently the HearTwave II system for sale. Furthermore, in connection with our distribution agreement with Mayerick S.A. de S.V., we are pursuing regulatory approval from the Mexican authorities for the sale of HearTwave II Systems in Mexico. 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, 2010, we had 23 full-time and 7 part-time employees. None of our employees are represented by a collective bargaining agreement, and we have not experienced work stoppages. We believe that our relations with our employees are good.

Item 1A. Risk Factors

Statements in this Annual Report on Form 10-K that are not strictly historical are 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 likely will need additional financing to fund our operations and may not be able to raise additional funds on terms acceptable to us, if at all.

We have incurred substantial operating losses through December 31, 2010 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. We do not expect to generate sufficient cash from our business to fund our operations without having to raise additional capital through the sale of debt or equity securities and/or the exercise of outstanding common stock warrants. We believe that our existing resources and currently projected financial results are only sufficient to fund our operations through approximately December 31, 2011. If we encounter material deviations from our plans including, but not limited to, any lower than expected level of sales to Cardiac Science, or if we continue to experience lower than expected sales of our HearTwave II Systems, our ability to fund our operations will be negatively impacted. While the proceeds from our December 2010 private placement of common stock and the exercise of common stock warrants provides the Company with financing to fund the Company's operations for a period of time, the Company anticipates that it will need to raise additional capital to fund operations beyond 2011.

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 the Company by our stockholders would be diluted. In addition, we may have to issue equity or debt securities that have rights, preferences and privileges senior to our existing securities, including our common stock.

If we cannot increase revenue significantly, or obtain sufficient capital through the sale of equity or debt securities and/or the exercise of outstanding common stock warrants, we may not be able to continue as a going concern.

For the year ended December 31, 2010, 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 uncertainties. If we are unable to generate adequate cash flow or obtain sufficient additional funding when needed, we may have to sell some or all of our assets, license potentially valuable technologies to third parties and/or cease some or all of our operations. This would have a material adverse effect on our operations and the market price of our common stock.

In order to raise additional capital through the sale of equity or convertible debt securities, we will be required to obtain stockholder approval to increase the number of shares authorized for issuance under our Certificate of Incorporation.

On an as-converted basis, the Company has 124,260,153 shares of common stock issued and outstanding, including 97,494,185 shares of common stock issued, 4,180,602 shares issuable upon conversion of the Series C-1 Convertible Preferred Stock and 22,585,366 shares issuable upon conversion of the Series D Convertible Preferred Stock. Additionally, the Company has reserved 15,660,000 shares of common stock for issuance upon exercise of outstanding warrants issued to investors and the selling agent in connection with the sale of our common stock in December 2010 and has stock options outstanding to purchase up to an aggregate of 9,816,545 shares of common stock. Under the Company's Certificate of Incorporation there are only 150,000,000 shares of common stock authorized. Consequently, the Company will be limited in its ability to issue additional common stock or debt or equity convertible into common stock without amending the Certificate of Incorporation, which would require the approval of the holders of 75% of the voting power of all shares of the Company's capital stock, voting together as a class. If the stockholders do not approve such an amendment, we would not be able to raise capital through the sale of equity securities, which could have a material adverse effect on the Company's ability to continue as a going concern and could cause the Company to cease operations.

Our outstanding preferred stock has rights, preference and privileges senior to our common stock.

At December 31, 2010, there are 5,000 shares of our Series C-1 Convertible Preferred Stock and 1,852 shares of our Series D Convertible Preferred Stock outstanding. The Series C-1 Preferred Stock and the Series D Preferred Stock have rights, preferences and privileges senior to our common stock. See note 8 of the notes to the financial statements contained in this Annual Report on Form 10-K for a discussion of these rights, preferences and privileges.

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 any current or future 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 had, and may continue to have, an adverse impact on our business.

The weak economic conditions have had an adverse impact on our existing and target customers. These conditions, also have had 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 practices with limited financial resources, 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 allows our MTWA Test, using our proprietary Micro-V Alternans Sensors, to be performed on Cardiac Science's Q-Stress test platform. Cardiac Science markets 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 the relationship with Cardiac Science will succeed in increasing sales or market acceptance of our MTWA Module. Furthermore, we cannot predict whether additional relationships are attainable at all, and if so, whether they would be on terms favorable or acceptable 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.

Under our agreement with Cardiac Science, we sell and deliver to Cardiac Science the MTWA Module and our Micro-V Alternans Sensors. Cardiac Science is reselling 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, and GE Medical Systems. GE Medical Systems has introduced an analysis system to measure t-wave alternans and has received concurrence from the FDA of its 510(k) allowing it to distribute the product in the United States. However, GE Medical Systems' methodology for determining MTWA is not covered by CMS. CMS continues coverage of MTWA testing using the Analytic Spectral Method, which is our patented and proprietary method of analysis, and found insufficient evidence for coverage of MTWA testing using any other method. 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 *Competition* in Item 1. "Business" for a discussion of the competitive factors affecting our 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;
- 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 that will render our current or planned products obsolete or inferior will not be developed. 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.

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 ability to successfully commercialize our 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, investigative unnecessary or inappropriate.

Reimbursement rates for services covered by Medicare are determined by reference to the Medicare Physician Fee Schedule, and are calculated based on multiple components, including relative value units, conversion factor and geographical adjustment. The Medicare Physician Fee Schedule rates are updated annually and have resulted in negative updates since 2002. In November 2009, the Centers for Medicare and Medicaid Services, which we refer to as CMS, issued its final ruling on the Medicare Physician Fee Schedule effective January 1, 2010. This ruling set forth a reduction in relative value unit for nearly all cardiovascular services to be phased in over a four-year period. The final rule also included an additional 21% reduction in the conversion factor component of the reimbursement calculations. However, CMS temporarily maintained the conversion factor at the 2009 level until June 1, 2010. In July 2010, CMS issued a revised Medicare Physician Fee Schedule reflecting, among other things, a change in the conversion factor as a result of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, which was signed into law on June 25, 2010. This legislation provided for a 2.2% increase to the 2010 Medicare Physician Fee Schedule, effective for dates of service June 1, 2010 through November 30, 2010, which sets the national average Medicare payment amount for a MTWA Test at $205.31. In November 2010, CMS published their final reimbursement rules for 2011, effective January 1, 2011, which would have resulted in a decrease in reimbursement rates by as much as 30%. However, in December 2010, Congress enacted legislation to sustain reimbursement at the 2010 level through December 2011. Effective January 1, 2011 through December 31, 2011, the national average Medicare payment amount for a MTWA Test is $200.

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, MTWA Module or 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 licenses of patents and patent applications impose various commercialization, sublicensing, insurance, royalty and other obligations on our part. If we fail to comply with these requirements, licenses could convert from being exclusive to 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

Not applicable.

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 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.

	2009		2010	
Period	High	Low	High	Low
First Quarter	$0.18	$0.07	$0.45	$0.07
Second Quarter	$0.17	$0.09	$0.75	$0.21
Third Quarter	$0.12	$0.06	$0.33	$0.16
Fourth Quarter	$0.12	$0.06	$0.26	$0.15

The depositary for our common stock is American Stock Transfer & Trust Company, 40 Wall Street, New York, New York 10005. On March 4, 2011, we had approximately 199 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

Statements in this Annual Report on Form 10-K that are not strictly historical are 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, and 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.

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 who have established distribution networks and existing installed base of users, 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 already 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 cardiac 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 partner's 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 stress test 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 the MTWA Module, which was launched in September 2010. Under the Cardiac Science Agreement, we 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 is reselling 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 has primary responsibility for preparing sales and marketing materials and for training its sales and service personnel

regarding the Products. We provide clinical and technical training and support to Cardiac Science. In addition, we provide installation training service to each purchaser of a MTWA Module for use on Cardiac Science's Q-Stress test platform. We also have customary warranty obligations with respect to the Products sold under the Cardiac Science Agreement.

During 2010, we achieved a number of objectives relating to the Cardiac Science partnership including completing the development of the MTWA Module, obtaining FDA clearance, providing training to Cardiac Science personnel, establishing intra-company operational processes and collaborating with Cardiac Science on sales and marketing activities in support of the product launch. On September 21, 2010, the MTWA Module was launched within the timeframe originally projected. The companies collaborated on extensive marketing and sales initiatives in support of the product launch. While the initial market preparation, product launch and lead generation activities were in line with our expectations, the number of units placed in 2010 was below our projections. We believe that this shortfall is partly attributable to organizational changes that occurred within Cardiac Science subsequent to the product launch. In October 2010, Cardiac Science announced it was being acquired by Opto Circuits (India), which was completed in December 2010. We believe that while Opto Circuits' purchase of Cardiac Science is strategically positive for the partnership in the long run by providing Cardiac Science with more financial resources and a broader global reach, the organizational restructuring of Cardiac Science, including certain key personnel changes within sales and marketing, coupled with shifts in priorities and focus, negatively impacted sales of our MTWA Module. In addition, given the breadth and depth of the Cardiac Science direct sales force and distributor networks, fully preparing and engaging all layers of their sales organization in presenting the MTWA Module to their customers is taking more time than the Company originally expected. We believe that these issues are temporary and that working with Cardiac Science's new sales and marketing team over the coming quarters will refocus selling efforts on our MTWA Module.

In July 2010, the first patients were enrolled in our MTWA-CAD study (Evaluation of Microvolt T-Wave Alternans Testing for the Detection of Active Ischemia in Patients with Known or Suspected Coronary Artery Disease). MTWA-CAD is a feasibility study, sponsored by the Company, designed to evaluate MTWA testing for the purpose of detecting active ischemia in patients with known or suspected coronary artery disease (CAD). Ischemia is defined as inadequate blood supply to the coronary arteries, which can lead to myocardial infarction or what is commonly referred to as a "heart attack." Ischemia, a common trigger for arrhythmias, is a well-documented cause of repolarization alternans. Human studies have shown that active ischemia can be associated with visible as well as microvolt-level T-wave alternans. While MTWA testing is currently used to evaluate arrhythmic risk, this known association with ischemia may allow MTWA testing to be used as a diagnostic tool to detect underlying CAD. An estimated 40 million cardiac stress tests in various modalities are performed annually in the United States. We filed a patent application related to ischemia in December of 2009. The MTWA-CAD study will assess the feasibility of this concept by measuring MTWA during routine nuclear stress testing or stress echocardiography with treadmill exercise. This is a feasibility study designed to verify preliminary observations under controlled environments and to generate hypotheses, endpoints, and sample sizes for future investigations. The MTWA-CAD trial is expected to enroll up to 200 patients. We estimate that the enrollments will be completed by mid-2011.

In July 2010, the NCCI changed the edits associated with MTWA testing, allowing our MTWA Test to be performed on the same day as several stress procedures. As a result, effective July 1, 2010, CMS allows full reimbursement for both an MTWA Test and a stress test when both tests are performed during the same patient visit. The CMS update removes a previous restriction that substantially limited reimbursement when a patient underwent a MTWA Test on the same day as the patient underwent a standard cardiac stress test, echocardiography stress test, nuclear cardiac stress test, or pulmonary stress test.

During 2010, the Medicare reimbursement amount for cardiovascular services, including the MTWA Test, was set on a temporary basis throughout the year. Consequently, there was significant uncertainty regarding the economic benefit to physicians of providing these cardiovascular services. In November 2009, CMS issued its final ruling on the MPFS effective January 1, 2010. This ruling set forth a reduction in relative value unit for

nearly all cardiovascular services to be phased in over a four-year period. The final rule also included an additional 21% reduction in the conversion factor component of the reimbursement calculations. However, CMS subsequently decided to temporarily maintained the conversion factor at the 2009 level until June 1, 2010. In July 2010, CMS issued a revised MPFS reflecting, among other things, a change in the conversion factor as a result of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, which was signed into law on June 25, 2010. This legislation provided for a 2.2% increase to the 2010 MPFS, effective for dates of service June 1, 2010 through November 30, 2010, which sets the national average Medicare payment amount for a MTWA Test at $205.31. In November 2010, CMS published their final reimbursement rules for 2011, effective January 1, 2011, which would have resulted in a decrease in reimbursement rates by as much as 30%. However, in December 2010, Congress enacted legislation to sustain reimbursement at the 2010 level through December 2011. Effective January 1, 2011 through December 31, 2011, the national average Medicare payment amount for a MTWA Test is $200.

In December 2010, the Company completed a private placement to accredited investors (the "December 2010 Private Placement"). The transaction raised gross proceeds of $2.9 million and consisted of units ("Units") that were comprised of one share of common stock and a warrant to purchase one share of common stock. The Company sold 14,500,000 Units at a price of $0.20 per Unit. Each warrant included in the Unit entitles the holder to purchase one share of common stock for $0.25 for a period of five years from the date of issuance. Exercise of the warrants would provide an additional $3.6 million in capital. In addition, the Company issued 1,160,000 warrants to purchase common stock to the selling agent in connection with the private placement. The Company filed a Registration Statement covering the resale of the common stock and the shares of common stock issuable upon the exercise of the warrants in connection with the private placement in January 2011.

In connection with the Company's December 2009 sale of Series D Convertible Preferred Stock, the Company issued to the investors two types of warrants. The first warrant, which had a term of one year following the date of issuance, entitled investors to purchase an aggregate of 11,292,686 shares of common stock at an exercise price of $0.107 per share (the "Short-Term Warrants"), and the second warrant, which had a term of five years following the date of issuance, entitled investors to purchase an aggregate of 6,775,611 shares of common stock at an exercise price of $0.142 per share (the "Long-Term Warrants"). In May 2010, certain of the investors exercised their Short-Term Warrants, resulting in the issuance of 4,268,294 shares of common stock of the Company and generating aggregate proceeds of $456,708. In December 2010, the remaining outstanding Short-Term Warrants were exercised resulting in the issuance of 7,024,392 shares of common stock of the Company and generating aggregate proceeds of $751,610. Pursuant to the terms of the Long-Term Warrants, the Company called the Long-Term Warrants in May 2010 resulting in the issuance of 6,775,611 shares of common stock of the Company and generating aggregate proceeds of $962,138. The shares of common stock issued by the Company as a result of the exercise of the warrants are subject to customary restrictions on the transfer of securities issued in a private placement under the federal securities laws.

In 2011, we intend to continue to broaden our distribution channels through strategic alliances with medical device companies that offer synergistic opportunities and offer 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 and other pertinent groups through marketing initiatives and education programs. We also intend to continue to seek additional third party payer reimbursement from third party insurers that currently do not cover MTWA testing.

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 $260,564 at December 31, 2010 ($302,573 at December 31, 2009) 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, 2010, our allowance for doubtful accounts was $174,650. 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 2010, we had a reserve of $1,091,624, mostly related to the inventory that was built up in order to satisfy our contractual obligations to St. Jude Medical. 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. The agreement with St. Jude Medical ended on November 5, 2008. Pursuant to the terms of the co-marketing agreement, we were contractually obligated to build up our inventory for HearTwave II Systems. Consequently, the level of our inventory exceeds our current sales projections for the HearTwave II Systems for the next 12 months. Therefore we maintain a reserve 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.

Common Stock and Warrants

The Company initially accounted for common stock and associated warrants issued in 2010 by allocating the proceeds received net of transaction costs based on the relative fair value of the common stock and the warrants issued to the investors. The Company determined the initial value of the common stock and warrants using valuation models the Company considered to be appropriate.

Preferred Stock and Warrants

The Company initially accounted for convertible preferred stock and associated warrants issued in 2009 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 Company operates as one reportable segment. 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.

	2009	% of Total	2010	% of Total	% Inc/(Dec) 2010 vs 2009
Alternans Products:					
U.S.	$1,988,416	62%	$1,477,532	52%	(26)%
Rest of World	293,041	9%	322,608	11%	10%
Total	2,281,457	71%	1,800,140	64%	(21)%
Non-Alternans Products:					
U.S.	781,737	24%	770,978	27%	(1)%
Rest of World	168,715	5%	248,125	9%	47%
Total	950,452	29%	1,019,103	36%	7%
Total Revenues	$3,231,909	100%	$2,819,243	100%	(13)%

2010 Compared to 2009

REVENUE

Total revenue for 2010 and 2009 was $2,819,243 and $3,231,909, respectively, a decrease of 13%. Revenue from the sale of our MTWA product line, which we call our Alternans Products, was $1,800,140 in 2010 compared to $2,281,457 in 2009, a decrease of 21%. Alternans Products accounted for 64% and 71% of total revenue for 2010 and 2009, respectively. In 2010, we sold fewer Alternans Products overall compared to 2009 due to a number of factors including continued weak economic conditions, which have had a significant adverse impact on medical capital equipment sales as a whole in the past couple of years, uncertainty about Medicare reimbursement and the general healthcare reform in the U.S. Specifically, during 2010, the Medicare reimbursement amount for all cardiovascular services, including the MTWA Test, was set on a temporary basis throughout the year by CMS, temporarily delaying a planned reduction by as much as 30%. This uncertainty about the reimbursement amounts persisted throughout the year until December 2010 when Congress enacted legislation that negated the planned reduction in reimbursement, effective for January 1, 2011 through December 31, 2011.

We faced a number of other challenges in 2010 including overcoming our historical marketing strategy, practice integration issues and a lack of a distribution network. We believe that these challenges can be addressed via our new strategy, announced in June 2009, predicated on making our technology available in multiple product embodiments and by partnering with manufacturers of cardiac testing equipment, enabling us to 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. We believe this new strategy will make 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.

GROSS PROFIT

Gross profit was 30% of total revenue in 2010 compared to 43% of total revenue in 2009. This decrease in gross margin is primarily due to lower overall volume relative to fixed overhead costs compared to the prior year. We anticipate that overall gross profit will improve in 2011 to the extent that sales of our MTWA Module, which carry a higher profit margin, increase and as we begin to sell HearTwave II Systems that contain inventory parts that were previously reserved for as excess inventory.

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.

	2009	% of Total Revenue	2010	% of Total Revenue	% Inc/(Dec) 2010 vs 2009
Operating Expenses:					
Research and development	$ 380,840	13%	$ 575,960	20%	51%
Selling, general and administrative	8,380,199	256%	5,432,703	193%	(35)%
Total	$8,761,039	269%	$6,008,663	213%	(31)%

RESEARCH AND DEVELOPMENT

Research and development (R&D) expenses were $575,960 in 2010 compared to $380,840 in 2009, an increase of 51%. The increase is primarily attributable to costs related to the development of the MTWA Module, the launch of our ischemia pilot study, as well as various new product enhancements to the HearTwave II and Micro-V Alternans Sensors. We expect R&D costs to remain consistent as we continue to make product improvements and fund our ischemia pilot study, but may increase in the event of the development of new products or product applications.

SELLING, GENERAL AND ADMINISTRATIVE

Selling, general and administrative (SG&A) expenses were $5,432,703 in 2010 compared to $8,380,199 in 2009, a decrease of 35%. Selling and marketing costs, which accounted for 41% of total SG&A in 2010, decreased 36% from 2009. The decrease in selling and marketing expense from 2009 was driven partly by lower headcount, lower variable selling expenses as a result of lower commissionable sales and certain non-recurring marketing costs incurred in 2009. General and administrative costs, which accounted for 59% of total SG&A, decreased 34% from 2009 due to lower consultative and advisory costs, director fees and non-cash compensation due to the full vesting of certain previously issued stock option awards and restricted stock awards. SG&A costs for 2010 included $920,328 in non-cash stock-based compensation expense, compared to $1,990,834 in 2009. We anticipate that SG&A expenses will increase in 2011 primarily as we execute on plans to expand selling and marketing and heighten activities in public and investor relations.

INTEREST INCOME/INTEREST EXPENSE

Interest income was $6,070 in 2010 compared to $29,556 in 2009. The decrease is primarily the result of lower amounts of invested cash and low short-term interest rates. Interest expense was $10,616 in 2010 compared to $6,926 in 2009.

NET LOSS

Net loss attributable to common stockholders was $5,168,009 in 2010 as compared to a net loss of $7,455,768 in 2009.

Liquidity and Capital Resources

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 $5,163,463 and $7,371,056 for the years ended December 31, 2010 and 2009, respectively. In 2010, the net loss we incurred included non-cash stock-based compensation expense of $936,154.

Cash and cash equivalents were $4,188,215 at December 31, 2010, compared to $3,159,468 at December 31, 2009. 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 was $500,000 for the first and second lease years and is reduced by $100,000 at the end of each of the second, third and fourth lease years. As of December 31, 2010 we held restricted cash of $400,000. At December 31, 2010 and 2009, 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, 2010 and 2009, the restricted cash was held in money market funds.

The overall increase in the Company's cash and cash equivalents is attributable to proceeds from financing and exercise of warrants to purchase common stock in 2010, offset by cash used by operations. In connection with the Company's December 2009 sale of Series D Convertible Preferred Stock, the Company issued Short-Term Warrants and Long-Term Warrants to purchase an aggregate of 11,292,686 and 6,775,611 shares of common stock, respectively. In May 2010, certain investors exercised their Short-Term Warrants, resulting in the issuance of 4,268,294 shares of common stock of the Company and generating aggregate proceeds of $456,708. Pursuant to the terms of the Long-Term Warrants, the Company called the Long-Term Warrants in May 2010 resulting in the issuance of 6,775,611 shares of common stock of the Company and generating aggregate proceeds of $962,138. In December 2010, the remaining outstanding Short-Term Warrants were exercised resulting in the issuance of 7,024,392 shares of common stock of the Company and generating aggregate proceeds of $751,610. In December 2010, the Company also completed the December 2010 Private Placement. The transaction raised net proceeds of $2.6 million and consisted of units ("Units") that were comprised of one share of common stock and a warrant to purchase one share of common stock. The Company sold 14,500,000 Units at a price of $0.20 per Unit. Each warrant included in the Unit entitles the holder to purchase one share of common stock for $0.25 for a period of five years from the date of issuance. Exercise of the warrants would provide an additional $3.6 million in capital.

The main changes in operating assets and liabilities in 2010 were an increase in accounts receivable, net of allowance for doubtful accounts, of $21,771, or 5%, as a result of the timing of sales at the end of 2010, and a decrease in inventory, net of reserve, of $466,356, or 40%, attributable to the sale of our products during 2010 and an increase to the inventory reserve. Due to the uncertainty of realizing the value of any excess inventory related to our HearTwave II System built up in order to satisfy our contractual obligations to St. Jude Medical, we maintain an inventory reserve, which was increased as of December 31, 2010 to $1,091,624 from $967,148 at December 31, 2009. However, we do not believe that the inventory is exposed to obsolescence risk. Prepaid expenses and other current assets at December 31, 2010 decreased $23,075 compared to December 31, 2009. Fixed assets at December 31, 2010 decreased $49,676 compared to December 31, 2009, primarily due to depreciation related to capitalized costs associated with our current 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, 2010 decreased $52,786 compared to December 31, 2009 as a result of lower inventory purchases and operating expenses. As a result of the aforementioned, we have incurred negative cash flow from operations of $3,658,826 and $4,831,626, for the years ended December 31, 2010 and 2009, respectively. In addition, we have an accumulated deficit at December 31, 2010 of $101,160,528.

We have evaluated the Company's future cash flow assuming that revenue from our base business remains relatively consistent with 2010 results, that sales of our MTWA Module and Micro-V Alternans Sensors to Cardiac Science improve in 2011 and that operating expenses are in accordance with our plans. 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 2011. Based on these expectations, we believe that our existing resources and currently projected financial results are sufficient to fund our operations only through approximately December 31, 2011. To the extent that sales of our MTWA Module and Micro-V Alternans Sensors exceed our projected levels, the Company may have sufficient resources to fund its operations beyond the end of 2011. Conversely, if we encounter material deviations from our plan including, but

not limited to, lower than expected level of sales to Cardiac Science, lower than expected sales of our HearTwave II Systems and Micro-V Alternans Sensors, or if we decide to expand the level of activity in R&D and/or SG&A beyond our initial plans, our ability to fund our operations will be negatively impacted. While the proceeds from the December 2010 Private Placement and the exercise of common stock warrants in 2010 provided the Company with financing to fund the Company's operations for a period of time, the Company anticipates that it will need to raise additional capital through the sale of equity or debt securities and/or the exercise of outstanding common stock warrants issued in connection with the December 2010 Private Placement to fund operations beyond 2011. However, there can be no assurance that such capital will be available at all, or if available, that the terms of such financing will not be dilutive to other stockholders. Similarly, there can be no assurance that holders of our common stock warrants issued in connection with the December 2010 Private Placement will elect to exercise their warrants when the capital is needed, or at all.

If we are unable to generate adequate cash flows or obtain sufficient additional funding when needed, we may have to 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, 2010 are included in the table below.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Capital Lease Obligations	$ 33,712	$ 5,009	$ 15,619	$13,084	$ —
Operating Lease Obligations	$912,630	$384,803	$527,827	$ —	$ —
Purchase Obligations	$ 30,000	$ 10,000	$ 20,000	$ —	$ —
Total	$976,342	$399,812	$563,446	$13,084	$ —

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 current 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 is reduced 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 $100,000 reduction began in 2010. The landlord for the property was responsible for paying for the costs of construction for the interior of the space 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, 2010. In addition, monthly royalty under the Company's consulting and technology agreement was $4,568.

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

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.

In January 2010, the FASB issued an Accounting Standards Update which improves disclosures about fair value measurements. More specifically, the update requires the 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 did not have an impact on the Company's 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.

During 2010, 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 interest 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.

Item 8. Financial Statements and Supplementary Data

CAMBRIDGE HEART, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Cambridge Heart, Inc. as of December 31, 2010, and the related statements of operations, changes in stockholders' deficit, and cash flows for the year 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit 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 audit provides 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, 2010, and the results of its operations and its cash flows for the year 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/ McGladrey & Pullen, LLP

Boston, Massachusetts
March 22, 2011

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Cambridge Heart, Inc. as of December 31, 2009, and the related statements of operations, changes in stockholders' deficit, and cash flows for the year 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit 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 audit provides a reasonable basis for our opinion.

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/s/ Caturano and Company, P.C.

Boston, Massachusetts
March 31, 2010

CAMBRIDGE HEART, INC.

BALANCE SHEET

	December 31, 2009	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 3,159,468	$ 4,188,215
Restricted cash, current portion	100,000	100,000
Accounts receivable, net of allowance for doubtful accounts of $171,515 and $174,650 at December 31, 2009 and 2010, respectively	458,887	480,658
Inventory, net	1,152,620	686,264
Prepaid expenses and other current assets	118,312	95,237
Total current assets	4,989,287	5,550,374
Fixed assets, net	239,970	190,294
Restricted cash, net current portion	400,000	300,000
Other assets	42,655	50,138
Total Assets	$ 5,671,912	$ 6,090,806
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 383,768	$ 421,670
Accrued expenses	1,116,663	1,025,975
Current portion of capital lease obligation	13,571	5,009
Total current liabilities	1,514,002	1,452,654
Capital lease obligation, net of current portion	13,551	28,703
Total liabilities	1,527,553	1,481,357
Commitments and contingencies (Note 13)		
Convertible Preferred Stock, $.001 par value; 2,000,000 shares authorized at December 31, 2009 and 2010, respectively; 6,852 shares issued and outstanding at December 31, 2009 and 2010, respectively. Liquidation preference and redemption value of $14,352,000 as of December 31, 2009 and 2010, respectively	12,870,613	12,870,613
	12,870,613	12,870,613
Stockholders' deficit:		
Common Stock, $.001 par value; 150,000,000 shares authorized; 64,904,955 and 97,494,185 and shares issued and outstanding at December 31, 2009 and 2010, respectively	64,905	97,494
Additional paid-in capital	87,201,360	92,801,870
Accumulated deficit	(95,992,519)	(101,160,528)
Total stockholders' deficit	(8,726,254)	(8,261,164)
Total Liabilities and Stockholders' Deficit	$ 5,671,912	$ 6,090,806

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

CAMBRIDGE HEART, INC.

STATEMENT OF OPERATIONS

	2009	2010
Revenue	$ 3,231,909	$ 2,819,243
Cost of goods sold	1,841,926	1,974,043
Gross profit	1,389,983	845,200
Costs and expenses:		
Research and development	380,840	575,960
Selling, general and administrative	8,380,199	5,432,703
Total costs and expenses	8,761,039	6,008,663
Loss from operations	(7,371,056)	(5,163,463)
Interest income	29,556	6,070
Interest expense	(6,926)	(10,616)
Net loss	(7,348,426)	(5,168,009)
Beneficial conversion feature (Note 8)	(107,342)	—
Net loss attributable to common stockholders	$ (7,455,768)	$ (5,168,009)
Net loss per common share-basic and diluted	$ (0.12)	$ (0.07)
Weighted average common shares outstanding-basic and diluted	64,574,536	72,457,014

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

CAMBRIDGE HEART, INC.

STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

	Common stock, $.001 par				
	Number of Shares	Par Value	Additional paid-in Capital	Accumulated deficit	Total stockholders' deficit
Balance at December 31, 2008	65,016,521	$65,017	$84,570,518	$ (88,644,093)	$(4,008,558)
Issuance of warrants to purchase common stock			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
Forfeiture 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)
Issuance of common stock through exercise of stock options	40,000	40	11,960		12,000
Issuance of common stock through December 2010 Private Placement, net issuance costs	14,500,000	14,500	2,499,990		2,514,490
Issuance of common stock through exercises of warrants	18,068,297	18,068	2,152,387		2,170,455
Compensation related to employee granted restricted stock			20,316		20,316
Forfeiture of restricted stock	(19,067)	(19)	19		—
Compensation related to employee stock options granted			781,887		781,887
Compensation related to non-employee stock options granted			133,951		133,951
Net Loss				(5,168,009)	(5,168,009)
Balance at December 31, 2010	97,494,185	$97,494	$92,801,870	$(101,160,528)	$(8,261,164)

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

CAMBRIDGE HEART, INC.

STATEMENT OF CASH FLOWS

	Year ended December 31,	
	2009	2010
Cash flows from operating activities:		
Net loss	$(7,348,426)	$(5,168,009)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	91,888	54,626
Inventory provision	26,983	124,476
Stock based compensation expense	2,026,058	936,154
Provisions for allowance for bad debts	33,404	(7,630)
Gain on sale of fixed assets	—	(6,589)
Changes in operating assets and liabilities:		
Change in restricted cash	—	100,000
Accounts receivable	274,588	(14,141)
Inventory	309,380	363,429
Prepaid expenses and other current assets	4,768	11,644
Accounts payable and accrued expenses	(250,269)	(52,786)
Net cash used for operating activities	(4,831,626)	(3,658,826)
Cash flows from investing activities:		
Purchases of fixed assets	(1,889)	(5,894)
Net cash used in investing activities	(1,889)	(5,894)
Cash flows from financing activities:		
Redemption of common stock warrants	—	2,170,455
Payments for the redemption of common and convertible preferred stock warrants	(681)	—
Proceeds from issuance of common stock through exercise of stock options	—	12,000
Proceeds from issuance of common stock and warrants net of issuance costs	—	2,514,490
Proceeds from issuance of preferred stock and warrants, net of issuance costs	1,797,724	—
Principal payments on capital lease obligations	(11,134)	(3,478)
Net cash provided by financing activities	1,785,909	4,693,467
Net (decrease) increase in cash and cash equivalents	(3,047,606)	1,028,747
Cash and cash equivalents, beginning of year	6,207,074	3,159,468
Cash and cash equivalents, end of year	$ 3,159,468	$ 4,188,215

Supplemental Disclosure of Cash Flow Information

During 2009 and 2010, the Company paid $6,926 and $10,616 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 operates as one reportable segment and 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, 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 $5,163,463 for the years ended December 31, 2009 and 2010, respectively. 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has evaluated its future cash flow assuming that revenue from its base business remains relatively consistent with 2010 results, that sales of the MTWA Module and Micro-V Alternans Sensors to Cardiac Science improve in 2011 and that operating expenses are in accordance with our plans. 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 related to the HearTwave II System in 2011. Based on these expectations, the Company believes that its existing resources and currently projected financial results from operations are only sufficient to fund its operations through approximately December 31, 2011. To the extent that sales of the MTWA Module and Micro-V Alternans Sensors exceed the projected levels, the Company may have sufficient resources to fund its operations beyond the end of 2011. Conversely, if the Company encounters material deviations from its plan including, but not limited to, lower than expected level of sales to Cardiac Science, lower than expected sales of the HearTwave II Systems and Micro-V Alternans Sensors, or if the Company decides to expand the level of activity in R&D and/or SG&A beyond its initial plans, its ability to fund

operations will be negatively impacted. While the proceeds from the December 2010 Private Placement and the exercise of common stock warrants in 2010 will provide the Company with financing to fund the Company's operations for a period of time, the Company anticipates that it will need to raise additional capital through the sale of equity or debt securities and/or the exercise of outstanding common stock warrants issued in connection with the December 2010 Private Placement to fund operations beyond 2011. However, there can be no assurance that such capital will be available at all, or if available, that the terms of such financing will not be dilutive to other stockholders. Similarly, there can be no assurance that holders of our common stock warrants issued in connection with the December 2010 Private Placement will elect to exercise their warrants when the capital is needed, or at all.

If the Company is unable to generate adequate cash flows or obtain sufficient additional funding when needed, the Company may have to cut back its operations, sell some or all of its assets, license potentially valuable technologies to third parties, and/or cease some or all of its 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 and December 31, 2010, respectively, $3,152,042 and $4,184,124 of the Company's cash and cash equivalent were in a transaction account. At December 31, 2010, this transaction account was covered by Federal Deposit Insurance Coverage ("FDIC") in the amount of $250,000. At December 31, 2009, the account was fully covered by the FDIC under the Temporary Liquidity Guarantee Program. At December 31, 2009 and 2010, the Company classified investments in money market funds totaling $7,426 and $4,091, 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 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 began in 2010. The Company has recorded this letter of credit as restricted cash on its balance sheets. During 2009 and 2010, we invested our cash in money market funds. At December 31, 2009 and 2010 the Company's investments consisted solely of money market funds classified as 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 $260,564 at December 31, 2010 ($302,573 at December 31, 2009) 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 2009 and 2010 was $145,465 and $23,244, respectively. At December 31, 2009 and 2010, the allowance for doubtful accounts was $171,515 and $174,650, 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:

	2009	2010
Dividend Yield	0.0%	0.0%
Expected Volatility	134%	162%
Risk Free Interest Rate	1.39%	1.50%
Expected Option Terms (in years)	5	3

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 2009 and 2010, the impact of options to purchase 5,928,367 and 9,816,545 shares of common stock, Short-Term Warrants to purchase 11,292,686 and 0 shares of common stock, Long-Term Warrants to purchase 6,775,611 and 0 shares of common stock, 5,000 shares of Series C-1 Convertible Preferred Stock, 1,852 shares of Series D Convertible Preferred Stock, warrants issued in connection with the December 2010 Private Placement to purchase 0 and 15,660,000 shares of common stock, and 293,800 and 49,867 restricted shares, respectively, have been excluded from the calculation of diluted weighted average share amounts as their inclusion would have been anti-dilutive as of December 31, 2009 and 2010, respectively.

Comprehensive Loss

For the years ended December 31, 2009 and 2010, the Company had no elements of other comprehensive loss.

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 2009, the Company recorded a provision of $967,148 for excess inventory built up in connection with our contractual obligation as part of the co-marketing agreement with St. Jude Medical. 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. The agreement with St. Jude Medical ended on November 5, 2008. Pursuant to the terms of the co-marketing agreement, we were contractually obligated to build up our inventory for HearTwave II Systems. Consequently, the level of our inventory exceeds our current sales projections of the HearTwave II System for the next 12 months. The provision is based on the uncertainty of realizing the value of the excess inventory. As of December 31, 2009 and 2010, the Company's inventory reserve totaled $967,148 and $1,091,624, respectively. 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, or from the date of in-service at the end-user site as it relates to the MTWA Module. 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.

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, 2009 and 2010 was $42,577 and $38,629, 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

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 did not have an impact on the Company's financial position or results of operations.

3. Inventory

Inventories consisted of the following at December 31, 2009 and 2010, respectively:

	December 31,	
	2009	2010
Raw materials	$ 379,423	$119,914
Work in process	3,818	14,284
Finished goods	769,379	552,066
	$1,152,620	$686,264

4. Fixed Assets

Fixed assets consisted of the following at December 31, 2009 and 2010, respectively:

	Estimated useful lives (years)	December 31,	
		2009	2010
Computer equipment	3-5	$ 916,451	$ 902,216
Manufacturing equipment	5	424,670	424,670
Office furniture	7	130,395	130,395
Sales demonstration and clinical equipment	3-5	1,174,163	1,159,202
Leasehold Improvements	Life of Lease	47,204	47,204
		2,692,883	2,663,687
Less-accumulated depreciation		2,452,913	2,473,393
		$ 239,970	$ 190,294

The Company recorded depreciation expense of $86,698 and $50,678 for the years ended December 31, 2009 and 2010, respectively.

5. Other Assets

Other assets consisted of the following at December 31, 2009 and 2010, respectively:

	Estimated useful lives (years)	December 31,	
		2009	2010
Capitalized software development costs	3	$1,482,728	$1,482,728
Patents	5	228,548	228,548
Other assets		78	11,509
		1,711,354	1,722,785
Less-accumulated amortization		1,668,699	1,672,647
		$ 42,655	$ 50,138

The Company recorded amortization expense of $5,190 and $3,948 for the years ended December 31, 2009 and 2010, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following at December 31, 2009 and 2010, respectively:

	December 31,	
	2009	2010
Accrued employee compensation	321,227	270,706
Deferred revenue	302,573	260,564
Deferred rent	129,216	102,029
Accrued product warranty costs	29,384	14,609
Accrued professional fees	171,236	185,921
Accrued other	163,027	192,146
	$1,116,663	$1,025,975

7. Capital Lease

The Company is the lessee of office equipment under a capital lease expiring in 2015. 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 and 2010.

Following is a summary of property held under capital leases as of December 31, 2009 and 2010, respectively:

	December 31,	
	2009	2010
Office equipment	$ 56,000	$37,190
Accumulated amortization	(28,878)	(3,478)
	$ 27,122	$33,712

Minimum future lease payments under capital leases as of December 31, 2010, were as follows:

	Amount
2011	14,239
2012	14,239
2013	14,239
2014	14,239
2015	1,186
Net minimum lease payments	58,142
Amount representing interest	(24,430)
Present value of net minimum lease payments	$ 33,712

Interest rate on capital leases is 29% 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.

8. Convertible Preferred Stock

The Company's authorized capital stock includes 2,000,000 shares of $0.001 par value preferred stock. The preferred stock may be issued at the discretion of our Board of Directors (without further stockholder approval)

with such designations, rights and preferences as the Board of Directors may determine from time to time. This preferred stock may have dividend, liquidation, redemption, conversion, voting or other rights, which may be more expansive than the rights of the holders of the common stock.

Total shares of Convertible Preferred Stock issued and outstanding at December 31, 2009 and 2010, respectively, are as follows:

	December 31,	
	2009	2010
Series C-1 Convertible Preferred		
Shares issued and outstanding	5,000	5,000
Liquidation preference and redemption value	$12,500,000	$12,500,000
Series D Convertible Preferred		
Shares issued and outstanding	1,852	1,852
Liquidation preference and redemption value	$ 1,852,000	$ 1,852,000
Total Convertible Preferred		
Shares issued and outstanding	6,852	6,852
Liquidation preference and redemption value	$14,352,000	$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 Preferred Stock at a purchase price of $4.42 per share providing gross proceeds of $3,079,966. Each share of Series A Preferred 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 holders 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 Emerging Issues Task Force ("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.

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 of proceeds, 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-1 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 expired on December 23, 2010, entitled 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 were issuable under the Short-Term Warrants. The exercise price of the Short-Term Warrants was $0.107 per share, which is 150% of the Closing Price. In May 2010, certain of the investors exercised their Short-Term Warrants, resulting in the issuance of 4,268,294 shares of common stock of the Company. In December 2010, the remaining outstanding Short-Term Warrants were exercised resulting in the issuance of 7,024,392 shares of common stock of the Company. 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 were issuable under the Long-Term Warrants. The exercise price of the Long-Term Warrants was $0.142 per share, or 200% of the Closing Price. Pursuant to the terms of the Long-Term Warrant, the Company called the Long-Term Warrants in May 2010 resulting in the issuance of 6,775,611 shares of common stock of the Company.

An analysis was performed on the exercise and settlement provisions of the Long-Term and Short-Term Warrants as of December 23, 2009. As a result, it was determined that they were not considered derivative instruments under American Standards Codification ("ASC") 815—*Derivatives and Hedging* as they met the scope exception since they are both indexed to the Company's own stock and are classified in stockholders' 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 of 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:

	Short-Term	Long-Term
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.

9. Stockholders' Equity

Common Stock

The Company's Board of Directors has authorized 150,000,000 shares of the Company's $0.001 par value common stock. At December 31, 2009, the Company had 64,904,955 common shares outstanding. In December 2010, the Company completed the December 2010 Private Placement. The transaction raised gross proceeds of $2.9 million and consisted of Units that were comprised of one share of common stock and a warrant to purchase one share of common stock. The Company sold 14,500,000 Units at a price of $0.20 per Unit. The Company filed a Registration Statement covering the resale of the common stock and the shares of common stock issuable upon the exercise of the warrants in connection with the offering in January 2011. At March 23, 2011, the Company had 97,494,185 common shares outstanding.

Warrants

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. During 2010, all of the Short-Term and Long-Term Warrants were exercised.

In December 2010, the Company completed the December 2010 Private Placement. The transaction consisted of Units that were comprised of one share of common stock and a warrant to purchase one share of common stock. Each warrant included in the Unit entitles the holder to purchase one share of common stock for $0.25 for a period of five years from the date of issuance. In addition, the Company issued 1,160,000 warrants to purchase common stock to the selling agent in the December 2010 Private Placement. An analysis was performed on the exercise and settlement provisions of the warrants issued in connection with the December 2010 Private Placement as of December 31, 2010. 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. In addition, under GAAP, proceeds from the sale of securities are to be allocated to each financial instrument based on their relative fair market value. In this regard, we allocated the proceeds from the sale of the common stock based on the relative fair market value of the common stock and warrants using the Company's closing common stock price as of December 20, 2010 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:

	December 20, 2010
Dividend Yield	0.0%
Expected Volatility	146%
Risk Free Interest Rate	2.06%
Expected Option Terms (in years)	5

Based on this allocation, the relative fair values of the common stock and the warrants were $1,535,142 and $1,364,858, respectively.

The Company filed a Registration Statement covering the resale of the common stock and the shares of common stock issuable upon the exercise of the warrants in connection with the December 2010 Private Placement in January 2011.

At December 31, 2010, there were 15,660,000 warrants to purchase shares of common stock outstanding.

10. Stock Plans

1993 and 1996 Stock Option Plans

During 1993, the Company adopted the 1993 Incentive and Non-Qualified Stock Option Plan (the "1993 Plan") and in 1996 the Board of Directors authorized the 1996 Equity Incentive Plan (the "1996 Plan"). The Plans provide for the grant of incentive and non-qualified stock options to management, other key employees, consultants and directors of the Company. 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. 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. No shares of restricted stock were granted under the 2001 Plan in 2009 or 2010.

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. At December 31, 2010, the Company had 5,188,858 non-plan stock options outstanding which were granted in 2010 to senior executives, board members, and consultants. 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 no new restricted stock grants issued for the years ended December 31, 2009 and 2010. On December 31, 2009 and 2010, 1,120,217, and 1,139,283 shares of restricted stock were available for future grant. Included in the Company's statement of operations was $253,493 and $29,468 of compensation expense related to restricted stock for the year ended December 31, 2009 and 2010, respectively. Unvested restricted stock activity for the years ended December 31, 2009 and 2010 was as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Nonvested balance as of December 31, 2008	473,500	$1.62
Granted	—	—
Vested	(68,133)	0.46
Forfeited	(111,567)	0.48
Nonvested balance as of December 31, 2009	293,800	$2.32
Granted	—	—
Vested	(224,866)	2.89
Forfeited	(19,067)	0.48
Nonvested balance as of December 31, 2010	49,867	$0.45

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 were 2,186,110 options available for future grant.

At December 31, 2010, 9,816,545 shares of common stock were reserved for issuance upon exercise of the options issued under the Company's stock option plans and there were 2,678,855 options available for future grant.

Stock option transactions under all of the Company's equity incentive plans during the years ended December 31, 2009 and 2010 summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
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	5,928,367	$1.47	7.21	$ —
Exerciseable at December 31, 2009	4,562,199	$1.59	6.85	$ —
Vested and expected to vest at December 31, 2009	5,928,367	$1.47	7.21	$ —
Outstanding at January 1, 2010	5,928,367	$1.47		
Granted	7,138,512	0.16		
Exercised	(40,000)	0.30		
Canceled/Forfeited	(3,210,334)	1.91		
Outstanding and expected to vest at December 31, 2010	9,816,545	$0.58	8.50	$516,169
Exerciseable at December 31, 2010	5,046,596	$0.58	7.86	$175,517
Vested and expected to vest at December 31, 2010	9,816,545	$0.58	8.50	$516,169

The fair value of the options granted in 2010 was $1,136,062 with a per share weighted average fair value of $0.159. The fair value of options granted in 2009 was $5,880, with a per share weighted average fair value of $0.078. 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, 2010, there was $497,168 of total unrecognized compensation cost related to approximately 5,078,273 unvested outstanding stock options. The expense is anticipated to be recognized over a weighted average period of 3 years. There were 0 and 40,000 stock option shares exercised during 2009 and 2010, respectively.

The following table summarizes information about stock options outstanding under all of the Company's stock option plans at December 31, 2010:

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	7,723,509	9.16	0.16	3,024,563	9.15	0.16
$0.20 – $0.50	1,143,336	5.82	0.31	1,115,000	5.75	0.31
$0.51 – $1.00	155,000	6.77	0.65	112,333	6.52	0.65
$1.01 – $2.50	420,000	5.92	2.19	420,000	5.55	2.19
$2.51 – $4.00	339,700	6.81	2.80	339,700	6.81	2.80
$4.01 – $9.38	35,000	6.46	4.35	35,000	6.46	4.35
	9,816,545	8.50	$0.58	5,046,596	7.86	$0.58

The Company recognized the full impact of its share-based payment plans in the statement of operations for 2009 and 2010 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:

	2009	2010
Cost of goods sold	$ 2,417	$ 8,791
Research and development	32,807	7,034
Selling, general and administrative	1,990,834	920,328
Stock-based compensation expense	$2,026,058	$936,154

The Company has recorded compensation expense related to options granted to non-employee consultants for services rendered, totaling $2,860 in 2009 and $133,952 in 2010 based on the fair value of our common stock.

11. Income Taxes

There is no provision for income taxes because the Company has experienced recurring losses. The reported amount of income tax expense for each year differs from the amount that would result from applying federal statutory tax rates to pretax losses primarily because of the changes in the valuation allowance. Significant components of the Company's deferred tax assets at December 31, 2009 and 2010 are as follows:

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

	2009	2010
Net operating loss carryforwards	15,592,027	17,275,641
Research and development tax credit carryforwards	310,311	342,194
Capitalized research and development	859,141	556,558
Stock-based compensation	1,116,136	1,836,625
Other	1,539,001	722,387
Gross deferred tax assets	19,416,615	20,733,405
Capitalized software	(99,843)	—
Fixed assets	14,154	(13,274)
Patent costs	(14,748)	(15,026)
	19,316,178	20,705,105
Deferred tax asset valuation allowance	(19,316,178)	(20,705,105)
Net deferred tax assets	—	—

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 2010, the valuation allowance increased by $1,388,927, 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 for the years ended December 31, 2009 and 2010 primarily due to the following:

Summary

	2009	2010
Statutory US federal tax rate	(34)%	(34)%
State taxes, net of federal benefit	(3.7)%	8.4%
Non-deductible expenses	8.0%	5.0%
Other	3.9%	(6.3)%
Valuation allowance	25.8%	26.9%
Effective tax rate	0.0%	0.0%

As of December 31, 2010, the Company has approximately $47,429,000 federal and $29,506,000 state net operating loss carryforwards and $31,000 and $471,000 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 2011 to 2030.

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 fair value immediately prior to the ownership change. The Company 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, 2010 approximately $28,235,000 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 $9,600,000. The Company has also estimated that as of December 31, 2010 approximately $1,018,000 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 $1,018,000. 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, 2010 and 2009, 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 years ended December 31, 2009 and 2010 is as follows:

	2009	2010
Balance beginning January 1	$166,000	$166,000
Inc/Dec for tax positions related to prior years	—	—
Inc/Dec for tax positions related to current year	—	—
Settlements	—	—
Reductions for Expiration of Statue of Limitations	—	—
Balance ending December 31	$166,000	$166,000

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, 2007, 2008, 2009 and 2010 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.

12. Savings Plan

In January 1995, the Company adopted a retirement savings plan for all employees pursuant to Section 401(k) of the Internal Revenue Code. Employees become eligible to participate on the first day of the calendar quarter following their hire date. Employees may contribute any whole percentage of their salary, up to a maximum annual statutory limit. The Company is not required to contribute to this plan. The Company made no contributions to this plan in 2009 or 2010.

13. Commitments and Contingencies

Guarantor Arrangements

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 $29,384 and $14,609 of accrued warranties at December 31, 2009 and 2010, respectively.

	December 31,	
	2009	2010
Balance at beginning of period	$ 39,076	$ 29,384
Provision for warranty for units sold	55,575	51,318
Cost of warranty incurred	(65,267)	(66,093)
Balance at end of period	$29,384	$14,609

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 $347,400 for the years ended December 31, 2009 and 2010. At December 31, 2010, future minimum rental payments under the non-cancelable leases are $384,803, $395,019, and $132,808 for fiscal years 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 $30,000 of such minimum license maintenance fees subsequent to December 31, 2010 as the technology is used. License maintenance fees paid during 2009 and 2010 amounted to $10,000 each year. The future minimum license maintenance fee commitments at December 31, 2010 are approximately as follows:

2011	$10,000
2012	10,000
2013	10,000
Total	$30,000

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.

14. 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 agreed 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 received a reduced Monthly Royalty payment of $5,811 per month for the period beginning on January 1, 2010 and ending on December 31, 2010. Dr. Cohen did not receive any additional compensation for the Base Consulting Services.

Under the Consulting Agreement, the Company has 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 Consulting 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 $178,202 and $106,366 during fiscal 2009 and 2010, respectively.

Series D Convertible Preferred Stock 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 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, who served as director through December 30, 2009 and Jeffrey Wiggins, who serves as director, 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, 2009 and 2010. During the years ended December 31, 2009 and 2010, international sales accounted for 14% and 20% of the total revenue, respectively. Company policy does not require collateral on accounts receivable balances.

17. Subsequent Event

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, 2010. 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, 2010, 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 year ended December 31, 2010 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, 2010.

Item 9B. Other Information

Not applicable.

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 executive officers 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, and the year of the commencement of his term as a director or executive officer. Additionally, for each director, included below is the information regarding 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. No director or executive officer is related by blood, marriage or adoption to any other director or executive officer. Except as otherwise disclosed below, no director was selected as a director or nominee pursuant to any arrangement or understanding.

Directors

RODERICK DE GREEF

Director since 2008

Age: 50

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. Mr. de Greef's employment agreement provides that he has a right to be nominated to the Board of Directors. 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: 51

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 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 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 has a right to be nominated to the Board of Directors pursuant to the terms of his employment agreement. 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: 58

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 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: 64

Mr. McGuire is retired and currently serves as a consultant to various biomedical companies. 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: 55

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.

Executive Officers who are not Directors

VINCENZO LICAUSI

Officer since 2007

Age: 37

Mr. LiCausi 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, Massachusetts.

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, 2010, the Reporting Persons complied with all Section 16(a) filing requirements, except that Luis Martins reported the exercise of warrants on May 18, 2010 in a Form 4 filed on June 11, 2010 and Saba Malak reported the exercise of warrants on June 1, 2010 in a Form 4 filed on June 9, 2010.

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. 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. 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, 2009 and 2010 concerning the compensation paid to each person (i) serving as the Company's Chief Executive Officer or Chief

Financial Officer or acting in a similar capacity during the last completed fiscal year and (ii) each other executive officer of the Company whose total compensation in the last completed fiscal year exceeded $100,000 (the "Named Executive Officers").

Summary Compensation Table For 2009 and 2010

Name and Principal Position	Year	Salary ($)(1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	Total ($)
Ali Haghighi-Mood	2010	275,000	221,614	55,000	551,614
President and Chief Executive Officer	2009	275,000	1,032,545	77,000	1,384,545
Vincenzo LiCausi	2010	93,000	76,001	11,160	180,161
Vice President Finance and Administration, Chief Financial Officer	2009	155,000	245,958	26,040	426,998
Roderick de Greef	2010	120,000	13,634		133,633
Chairman of the Board	2009	120,000	55,176		175,176

(1) For 2010, includes the base salary paid to the Named Executive Officers and the base salary foregone by the Named Executive Officers. Effective March 1, 2010, Dr. Haghighi-Mood, Mr. LiCausi and Mr. de Greef agreed to a 10% reduction in their base salaries for 2010. In recognition of the reduction of their salaries, the Compensation Committee in March 2010 granted to Dr. Haghighi-Mood, Mr. LiCausi and Mr. de Greef options to purchase 198,949, 67,281 and 86,814 shares of common stock, respectively, in lieu of $22,917, $7,750 and $10,000 in base salary. See "2010 Management Stock Option Awards" for a description of the terms of the stock options.

(2) Reflects the compensation cost related to all outstanding awards recognized in 2009 and 2010 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, 2010, included in this Annual Report on Form 10-K.

(3) 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 "2010 Management Stock Option Awards" for a description of the terms of the stock options. For 2010, represents the cash bonuses earned pursuant to non-equity incentive plan awards.

Severance Arrangements with Named Executive Officers

The Company has entered into agreements with Dr. Haghighi-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. Haghighi-Mood.

In the event that Dr. Haghighi-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. Haghighi-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. Haghighi-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. Haghighi-Mood's consent; and (ii) any failure by the Company to nominate and recommend to stockholders that they reelect Dr. Haghighi-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. Haghighi-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. Haghighi-Mood as the Company's President and Chief Executive Officer and elected him as a director of the Company. Dr. Haghighi-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. Haghighi-Mood.

Under the terms of the employment agreement, Dr. Haghighi-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."

Under the terms of the employment agreement, Dr. Haghighi-Mood will have the opportunity to earn an annual performance bonus in the amount, and contingent upon the achievement by the Company or Dr. Haghighi-Mood, as the case may be, of performance goals to be agreed upon by Dr. Haghighi-Mood and the Board of Directors or the Compensation Committee. See "Senior Management Bonus Plan for 2010" for a description of the 2010 performance bonus criteria for Dr. Haghighi-Mood.

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

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.

Pursuant to Mr. de Greef's employment agreement, he was awarded 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 Grant Date, subject to acceleration upon the occurrence of certain performance goals further described under "Outstanding Equity Awards At Fiscal Year-end For 2010." The option will expire on the tenth anniversary of the Grant Date. As of December 31, 2010, two of the three performance goals had been achieved.

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 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 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.

Effective March 1, 2010, Mr. de Greef agreed to a 10% reduction in his base salary for 2010. See "2010 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.

Senior Management Bonus Plan for 2010

Dr. Haghighi-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 2010 (the "2010 Bonus

Plan"). The objective of the 2010 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 2010 Bonus Plan for Dr. Haghighi-Mood and Mr. LiCausi was 50% and 30% of annual base pay, respectively.

Rewards under the 2010 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 Dr. Haghighi-Mood. The performance goals under the 2010 Bonus Plan consisted of four separate goals each weighted between 20% and 40% relating to:

- the achievement of revenue goals for the year ending December 31, 2010;
- the execution of a material distribution agreement or partnership approved by the Board of Directors;
- the launch of the MTWA Module by September 30, 2010; and
- the enrollment of a minimum number of patients in the ischemia pilot study.

The Compensation Committee determined that performance goals related to the launch of the MTWA Module by September 30, 2010 and the enrollment of a minimum number of patients in the ischemia pilot study had been achieved, and the other performance goals had not been achieved. Based on the foregoing, the Compensation Committee determined that the bonus amounts earned by Dr. Haghighi-Mood and Mr. LiCausi under the 2010 Bonus Plan were $55,000 and $11,160, respectively.

2010 Management Stock Option Awards

On March 11, 2010, the Compensation Committee of the Board of Directors of the Company approved the grant of stock option awards (the "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 plan (the "Non-Plan Awards"). The remaining 2,039,654 options were granted under the Company's 2001 Stock Incentive Plan (the "Plan Awards"). 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. The terms of each of the awards is more fully described below. In connection with the approval of certain of the Non-Plan Awards, 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.

The Non-Plan Awards consisted of (i) Option Awards to purchase an aggregate of 461,562 shares of common stock of the Company granted to senior management in recognition of each senior management member's agreement to a reduction in salary; (ii) Option Awards to purchase an aggregate of 338,574 shares of common stock granted to the non-employee directors of the Company in recognition of a reduction in the cash fees paid to the non-employee directors; (iii) Option Awards to purchase an aggregate of 605,389 shares of common stock granted to a consultant to the Company in lieu of the payment of approximately $70,000, or 50%, of the fees otherwise payable to him in 2010 under his consulting agreement with the Company; and (iv) Option Awards to purchase an aggregate of 2,983,333 shares of common stock granted to senior management in connection with the termination of certain previously awarded out-of-the-money stock options. The following is a summary of the material terms of the Non-Plan Awards granted to the senior management team and directors of the Company.

Effective March 1, 2010, the senior management team of the Company agreed to a 10% reduction in their base salaries for 2010. 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 became exercisable in nine equal monthly installments beginning on April 11, 2010, and 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.

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 Plan Awards consisted of (i) Option Awards to purchase an aggregate of 1,164,871 shares of common stock of the Company awarded to the senior management team in lieu of a 2010 cash bonus; (ii) Option Awards to purchase an aggregate of 400,000 shares of common stock awarded to the non-employee directors and the Chairman of the Company's Scientific Advisory Board; and (iii) Option Awards to purchase an aggregate of 474,783 shares of common stock of the Company awarded to non-management employees.

Each of the members of the senior management team of the Company (other than Mr. de Greef) was eligible to receive a cash bonus for 2009 based upon the achievement of certain criteria. The Compensation Committee determined that in accordance with the Senior Management Bonus Plan for 2009, Messrs. Haghighi-Mood and LiCausi were entitled to receive cash bonuses of $77,000 and $26,040, respectively. On March 11, 2010, the Compensation Committee awarded, and each of the members of senior management team has agreed to accept, stock options granted under and subject to the Company's 2001 Stock Incentive Plan in lieu of a cash bonus for 2009 (the "Bonus Replacement Option Awards"). Mr. Haghighi-Mood received a Bonus Replacement Option Award to purchase 668,468 shares of common stock, and Mr. LiCausi received a Bonus Replacement Option Award to purchase 226,064 shares of common stock. The number of shares covered by each Bonus Replacement Option Award was determined based on the amount of the bonus for each recipient and the fair value of the Bonus Replacement 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 Bonus Replacement Option Awards were 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.

On March 11, 2010, the Compensation Committee also approved the grant of Option Awards to purchase an aggregate of 474,783 shares of common stock of the Company under the 2001 Stock Incentive Plan to non-management employees of the Company. The options awarded to non-management employees become exercisable in three equal annual installments beginning on the one-year anniversary of the date of grant.

The following table sets forth certain information concerning stock options held by the Named Executive Officers as of December 31, 2010.

Outstanding Equity Awards At Fiscal Year-end For 2010

Name	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.	668,468(2)		$0.16	3/11/2020
Ali Haghighi-Mood, Ph.D.	198,949(3)		$0.16	3/11/2020
Ali Haghighi-Mood, Ph.D.		2,383,333	$0.16	3/11/2020
Vincenzo LiCausi	226,064(2)		$0.16	3/11/2020
Vincenzo LiCausi	67,281(3)		$0.16	3/11/2020
Vincenzo LiCausi		450,000	$0.16	3/11/2020
Roderick de Greef	100,000(4)		$0.33	7/29/2018
Roderick de Greef	366,666	183,334(5)	$0.15	11/24/2018
Roderick de Greef	86,814(3)		$0.16	3/11/2020

(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) 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 "2010 Management Stock Option Awards" for a description of the terms of the stock options. These options became exercisable immediately on March 11, 2010.

(3) Effective March 1, 2010, Dr. Haghighi-Mood, Mr. LiCausi and Mr. de Greef agreed to a 10% reduction in their base salaries for 2010. In recognition of the reduction of their salaries, the Compensation Committee in March 2010 granted to Dr. Haghighi-Mood, Mr. LiCausi and Mr. de Greef options to purchase 198,949, 67,281 and 86,814 shares of common stock, respectively, in lieu of $$22,917, $7,750 and $10,000 in base salary. See "2010 Management Stock Option Awards" for a description of the terms of the stock options. These options become exercisable in nine equal monthly installments ending December 11, 2010.

(4) Option became exercisable as to 100% of the total number of shares upon the consummation of the Cardiac Science Agreement.

(5) 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. As of December 31, 2010, both the Financing Target and the Strategic Transaction Target had been achieved.

Director Compensation

At the start of fiscal year 2010, 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 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. Additionally, each of the Company's non-employee directors received an annual retainer of $15,000, payable in equal quarterly installments.

In order to allow the Company to conserve cash, in March 2010 the Board of Directors temporarily reduced the amount of cash compensation paid to the non-employee directors of the Company. Specifically, during the period from March 31, 2010 through December 31, 2010, all per meeting fees were eliminated and the cash annual retainer paid to non-employee directors was reduced from $15,000 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 became 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 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.

For fiscal year 2011, fees payable to the Board of Directors consist of a $25,000 annual retainer payable in equal quarterly installments.

The following table sets forth compensation actually paid, earned or accrued during 2010 by the Company's directors.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
John F. McGuire	17,000	77,883(2)	94,883
Jeffrey Wiggins	17,000	41,892(3)	58,892
Paul McCormick	17,000	24,832(4)	41,832

(1) Reflects the dollar amounts recognized for financial statement reporting purposes for the fiscal year ended December 31, 2010, 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 2010. 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, 2010, included in this Annual Report on Form 10-K.

(2) As of December 31, 2010, Mr. McGuire held options to purchase (a) 100,000 shares of Common Stock at an exercise price of $2.40 per share and (b) 212,858 shares of Common Stock at an exercise price of $0.16 per share.

(3) As of December 31, 2010, Mr. Wiggins held options to purchase (a) 100,000 shares of common stock at an exercise price of $0.63 per share and (b) 212,858 shares of Common Stock at an exercise price of $0.16 per share.

(4) As of December 31, 2010, Mr. McCormick held options to purchase (a) 100,000 shares of common stock at an exercise price of $0.63 per share and (b) 112,858 shares of Common Stock at an exercise price of $0.16 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, 2010.

Securities Authorized for Issuance Under Equity Compensation Plans

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a),(3)
Equity compensation plans approved by security holders (1)	4,627,687	$0.52	2,678,855
Equity compensation plans not approved by security holders (2)	5,188,858	$0.25	—
Total	9,816,545	$0.38	2,678,855

(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) a stock option to purchase 200,000 shares of Common Stock awarded to Jeffrey J. Langan, and (b) stock options to purchase an aggregate of 4,988,858 of Common Stock awarded to certain employees, directors and consultants of the Company. See "2010 Management Stock Option Awards" for further details.

(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, 2010, 1,139,283 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.

In 2010, the Compensation Committee of the Board of Directors approved the grant of 4,988,858 stock option awards to certain employees, directors and consultants outside of the Company's stock option plan (the "Non-Plan Awards"), as well as 2,039,654 stock option awards granted pursuant to the 2001 Stock Incentive

Plan. Each of the Non-Plan Awards has a term of 10 years and an exercise price of $0.16, which was the closing price of the Company's stock on the date of grant. The Non-Plan Awards consisted of (i) Option Awards to purchase an aggregate of 461,562 shares of common stock of the Company granted to senior management in recognition of each senior management member's agreement to a reduction in salary; (ii) Option Awards to purchase an aggregate of 338,574 shares of common stock granted to the non-employee directors of the Company in recognition of a reduction in the cash fees paid to the non-employee directors; (iii) Option Awards to purchase an aggregate of 605,389 shares of common stock granted to a consultant to the Company in lieu of the payment of approximately $70,000, or 50%, of the fees otherwise payable to him in 2010 under his consulting agreement with the Company; and (iv) Option Awards to purchase an aggregate of 2,983,333 shares of common stock granted to senior management in connection with the termination of certain previously awarded out-of-the-money stock options. The material terms of the Non-Plan Awards are set forth in Item 11 under the headings "2010 Management Stock Option Awards" and "Director Compensation" and are incorporated herein.

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, (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 March 1, 2011, 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
Directors						
Ali Haghighi-Mood, Ph.D.	1,661,861(3)	1.7%	—	—	—	—
Roderick de Greef	1,651,041(4)	1.7%	—	—	50	2.7%
Paul McCormick	212,858(5)	*	—	—	—	—
John McGuire	312,858(6)	*	—	—	—	—
Jeffrey Wiggins	6,864,892(7)	6.8%	—	—	300	16.2%
Named Executive Officers						
Ali Haghighi-Mood, Ph.D.	1,661,861(3)	1.7%	—	—	—	—
Roderick de Greef	1,651,041(4)	1.7%	—	—	50	2.7%
Vincenzo LiCausi	443,345(8)	*	—	—	—	—
All directors and executive officers as a group (6 persons)	11,146,855(9)	10.6%	—	—	350	18.9%
5% Stockholders						
Osiris Investment Partners, L.P.	8,176,830(10)	8.0%			270	14.6%
Vicente Madrigal	6,585,367(11)	6.5%	—	—	300	16.2%
Saba Malak	8,608,924(12)	8.5%	—	—	300	16.2%
Luis Martins	11,814,634(13)	11.5%	—	—	315	17.0%
St. Jude Medical, Inc.	4,180,602(14)	4.1%	5,000	100%	—	—

* 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 March 1, 2011 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 March 1, 2011 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 97,494,185 shares of Common Stock outstanding as of March 1, 2011.

(3) Consists of 1,661,861 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(4) Consists of (i) 487,805 shares of Common Stock, (ii) 609,756 shares of Common Stock issuable upon the conversion of 50 shares of Series D Preferred and (iii) 553,480 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(5) Consists of 212,858 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(6) Consists of 312,858 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(7) Consists of (i) 2,926,830 shares of Common Stock, (ii) 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 and (iii) 279,525 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(8) Consists of 443,345 shares of Common Stock that may be acquired under stock options that are presently exercisable or will be exercisable on April 30, 2011.

(9) See notes 2 through 8 above.

(10) Osiris Investment Partners, L.P., Osiris Partners, L.P. and Paul S. Stuka have shared voting power over 8,176,830 shares of Common Stock, including (i) 3,759,147 shares of Common Stock, (ii) 3,292,683 shares of Common Stock issuable upon conversion of 270 shares of Series D Preferred and (iii) 1,125,000 shares of Common Stock issuable on exercise of warrants to purchase Common Stock. The business address of Osiris Investment Partners, L.P. is c/o Osiris Partners, LLC, One Liberty Square, 5th Floor, Boston, Massachusetts, 02109. All shares of common stock (including any shares issuable pursuant to the exercise of warrants) reported herein for Osiris Investment Partners, L.P. (the "LP") are held of record and beneficially owned by the LP. Osiris Partners, LLC (the "LLC") serves as general partner of the LP, and as such, may be deemed to have investment and/or voting power with respect to the shares held by the LP. Mr. Paul Stuka serves as the managing member of the LLC, and as such, may also be deemed to have investment and/or voting power with respect to the shares held by the LP. Each of the LP, the LLC and Mr. Stuka disclaims beneficial ownership of the shares of common stock (including any shares issuable pursuant to the exercise of warrants) reported herein except to the extent of its or his pecuniary interest therein.

(11) 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. Mr. Madrigal's address is 79 East 79th Street, Apartment 12, New York, New York 10075.

(12) Saba Malak beneficially owns 8,608,924 shares of Common Stock, including (i) 4,950,387 shares of Common Stock and (ii) 3,658,537 shares of Common Stock issuable upon conversion of 300 Shares of Series D Preferred. Mr. Malak's address is 225 Commonwealth Avenue, Apartment 4, Boston, Massachusetts 02116.

(13) Luis Martins beneficially owns 11,814,634 share of Common Stock, including (i) 6,973,171 shares of Common Stock, (ii) 3,841,463 shares of Common Stock issuable upon conversion of 315 shares of Series D Preferred, and (iii) 1,000,000 shares of Common Stock issuable upon exercise of warrants to purchase Common Stock. Mr. Martins' address is 1886 Beacon Street, Waban/Newton, Massachusetts 02468.

(14) 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.

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, or any beneficial holder of more than 5% of the outstanding shares of Common Stock. 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.

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") at a purchase price of $1,000 per share 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"). 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 Series D Financing resulted in gross proceeds to the Company of $1,852,000. The total number of shares of Common Stock initially issuable upon conversion of the 1,852 shares of Series D Preferred was 22,585,366, or approximately 32.7% of the Company's issued and outstanding Common Stock on an as-converted basis.

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.

The Company also issued to the investors two types of warrants. The first warrant, which expired on December 23, 2010, entitled 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 had the right to 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.

In April 2010, Jeffery Wiggins exercised his Short-Term Warrants and Long-Term Warrants to purchase 1,829,269 and 1,097,561 shares, respectively, of the Company's common stock resulting in aggregate proceeds of $351,585.

In May 2010, the Company elected to exercise its right to call all outstanding Long-Term Warrants pursuant to the terms of the Long-Term Warrants. In connection with the Company's election to call the Long-Term Warrants, Roderick de Greef exercised his Long-Term Warrants to purchase 182,927 shares of Common Stock resulting in proceeds to the Company of $25,976. Additionally, four persons who are beneficial holder of more than 5% of the outstanding shares of Common Stock exercised their Long-Term Warrants. Osiris Investment Partners, L.P., Vicente Madrigal, Saba Malak and Luis Martins exercised Long-Term Warrants to purchase 987,805, 1,097,561, 1,097,561 and 1,152,439 shares of Common Stock, respectively, resulting in proceeds to the Company of $140,268, $155,854, $155,854 and $163,646, respectively.

In December 2010, Mr. de Greef exercised his Short-Term Warrants to purchase 304,878 shares of Common Stock resulting in proceeds to the Company of $32,619. Additionally, Osiris Investment Partners, L.P., Vicente Madrigal, Saba Malak and Luis Martins exercised Short-Term Warrants to purchase 1,646,342, 1,829,269, 1,829,269 and 1,920,732 shares of Common Stock, respectively, resulting in proceeds to the Company of $176,159, $195,732, $195,732 and $205,518, respectively.

Participation in Private Placement of Common Stock and Warrants

On December 20, 2010, the Company issued and sold 14,500,000 units (the "Units") for an aggregate purchase price of $2,900,000 (less fees and commissions), each Unit consisting of (i) one share of the Company's Common Stock and (ii) one five-year warrant to purchase one share of Common Stock, pursuant to the terms and conditions of a Securities Purchase Agreement, dated as of December 20, 2010, by and among the Company and certain accredited investors (the "December 2010 Private Placement"). The Units were offered and sold pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933. Among the investors who participated in the December 2010 Private Placement were Luis Martins and Osiris Investment Partners, L.P., each of whom is a "related person" as defined in Item 404 of Regulation S-K as a result of their ownership of 5% or more of a class of securities of the Company.

Mr. Martins purchased 1,000,000 Units, for an aggregate purchase price of $200,000, in connection with the 2010 Private Placement. Mr. Martins' investment represented approximately 7.6% of the aggregate net proceeds received by the Company in the December 2010 Private Placement.

Osiris Investment Partners, L.P. purchased 1,125,000 Units, for an aggregate purchase price of $225,000, in connection with the December 2010 Private Placement. The investment by Osiris Investment Partners, L.P. represented approximately 8.5% of the aggregate net proceeds received by the Company in the December 2010 Private Placement.

Director Independence

The Board has determined that Messrs. Wiggins, McGuire and McCormick are 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.

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 and Governance 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 McGladrey and Pullen, LLP and 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:

Fee Category	2010	2009
Audit Fees	$121,540	$137,250
Audit-Related Fees	$ —	$ —
Total Fees	$121,540	$137,250

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, 2010 that were not approved by the Audit Committee or its chairman.

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.

No other financial statement schedules are required by Regulation S-K.

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 23, 2011.

CAMBRIDGE HEART, INC.

By: /s/ ALI HAGHIGHI-MOOD
Ali Haghighi-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.

Signature	Title	Date
/s/ ALI HAGHIGHI-MOOD **Ali Haghighi-Mood**	President and Chief Executive Officer (Principal Executive Officer)	March 23, 2011
/s/ VINCENZO LICAUSI **Vincenzo LiCausi**	Vice President, Chief Financial Officer, Treasurer, Corporate Secretary	March 23, 2011
/s/ RODERICK DE GREEF **Roderick de Greef**	Chairman	March 23, 2011
/s/ PAUL MCCORMICK **Paul McCormick**	Director	March 23, 2011
/s/ JOHN MCGUIRE **John McGuire**	Director	March 23, 2011
/s/ JEFFREY WIGGINS **Jeffrey Wiggins**	Director	March 23, 2011

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 29, 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 29, 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 23, 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 23, 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 29, 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).

Exhibit No.	Description
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#+	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).
10.7	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).
10.8	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).
10.9	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).
10.10#	Severance Agreement dated September 17, 2003 between the Registrant and Ali Haghighi-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).
10.11#	Summary of Amendment dated December 14, 2006 to Severance Agreement dated September 17, 2003 between the Registrant and Ali Haghighi-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).
10.12#	Employment Agreement dated December 14, 2007 between the Registrant and Ali Haghighi-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
10.13#	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).
10.14#	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).
10.15#	Employment Agreement dated November 28, 2008 between the Registrant and Roderick de Greef is incorporated by reference to Exhibit 10.18 of the Registrant's Form 10-K for the fiscal year ended December 31, 2009 (File No. 0-20991).
10.16	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).

Exhibit No.	Description
10.17	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).
10.18	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).
10.19#	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).
10.20+	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).
10.21#	Summary of Non-Employee Director Fees
10.22#	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.
10.23#	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.
10.24+	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)
10.25	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).
10.26	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).
10.27	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).
10.28	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).
10.29#	Summary of Stock Option Awards for Certain Executive Officers, Non-Employee Directors and Consultants and Exchange Agreement with Certain Executive Officers is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
10.30#	Form of Incentive Stock Option Agreement in Lieu of Cash Bonus Granted Under 2001 Stock Incentive Plan dated March 11, 2010 between the Registrant and certain Executive Officers is incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.

Exhibit No.	Description
10.31#	Form of Stock Option Agreement Granted Outside 2001 Stock Incentive Plan (Monthly Vesting) dated March 11, 2010 is incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-165410).
10.32#	Form of Stock Option Agreement for Non-Employee Directors and Consultants Granted Outside 2001 Stock Incentive Plan (Monthly Vesting) dated March 11, 2010 is incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-165410).
10.33#	Form of Stock Option Agreement Granted Outside 2001 Stock Incentive Plan (Annual Vesting) dated March 11, 2010 is incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-165410).
10.34#	Form of Stock Option Agreement for Non-Employee Directors and Consultants Granted Under the 2001 Stock Incentive Plan dated March 11, 2010 between the Registrant and certain Non-Employee Directors and Consultants is incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
10.35#	Form of Exchange Agreement, between the Registrant and certain Executive Officers dated March 11, 2010 is incorporated herein by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
10.36#	Summary of Senior Management Bonus Plan for 2010 is incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
23.1	Consent of McGladrey & Pullen, LLP
23.2	Consent of Caturano and Company, Inc.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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

BOARD OF DIRECTORS

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 on June 24, 2011 at 8:30 a.m., local time, at the Corporate Office at 100 Ames Pond Drive, Tewksbury, Massachusetts 01876

INDEPENDENT ACCOUNTANTS

McGladrey & Pullen, LLP
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

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.0B