

CARDIOGENESIS CORP /CA

Form 10KSB

March 25, 2008

**Table of Contents**

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

**Form 10-KSB**

**ANNUAL REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2007**

**Commission file number: 0-28288**

**Cardiogenesis Corporation**

*(Name of small business issuer in its charter)*

**California**

*(State or other jurisdiction of  
incorporation or organization)*

**11 Musick, Irvine, CA**

*(Address of principal executive offices)*

**77-0223740**

*(I.R.S. Employer  
Identification Number)*

**92618**

*Zip Code*

**(949) 420-1800**

**(Issuer's telephone number)**

**Securities registered under Section 12(g) of the Exchange Act:**

**Common Stock, no par value**

*(Title of Class)*

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

State issuer's revenues for its most recent fiscal year: \$12,059,000

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the issuer computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days: \$14,852,984 as of February 29, 2008.

State the number of shares outstanding of each of the issuer's classes of equity as of the latest practicable date: 45,274,395 shares of common stock, no par value, outstanding as of February 29, 2008.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Certain portions of the following documents are incorporated by reference into Part III of this Form 10-KSB: The Registrant's Proxy Statement for the Annual Meeting of Shareholders.

Transitional Small Business Disclosure Format

Yes  No

---

**INDEX TO FORM 10-KSB**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>Item 1.</u>	<u>Description of Business</u> 1
<u>Item 2.</u>	<u>Description of Property</u> 21
<u>Item 3.</u>	<u>Legal Proceedings</u> 22
<b><u>PART II</u></b>	
<u>Item 5.</u>	<u>Market for Common Equity and Related Shareholder Matters and Small Business</u> 22
	<u>Issuer Purchases of Equity Securities</u> 23
<u>Item 6.</u>	<u>Management's Discussion and Analysis or Plan of Operation</u> 31
<u>Item 7.</u>	<u>Financial Statements</u> 31
<u>Item 8.</u>	<u>Changes In and Disagreements With Accountants on Accounting and Financial</u> 31
	<u>Disclosure</u> 31
<u>Item 8A(T)</u>	<u>Controls and Procedures</u> 31
<u>Item 8B.</u>	<u>Other Information</u> 32
<b><u>PART III</u></b>	
<u>Item 9.</u>	<u>Directors, Executive Officers, Promoters, Control Persons and Corporate</u> 32
	<u>Governance: Compliance With Section 16(a) of the Exchange Act</u> 32
<u>Item 10.</u>	<u>Executive Compensation</u> 32
<u>Item 11.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related</u> 32
	<u>Shareholder Matters</u> 32
<u>Item 12.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u> 32
<u>Item 13.</u>	<u>Exhibits</u> 32
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u> 35
<u>Signatures</u>	36
<u>Exhibit 21.1</u>	
<u>Exhibit 23.1</u>	
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	

---

**Table of Contents**

**PART I**

**Item 1. Description of Business.**

*This Annual Report on Form 10-KSB contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, that are based on the beliefs of our management as well as assumptions made by and information currently available to us. When we use the words believe, plan, will likely result, expect, intend, will continue, is anticipated, estimate, project, may, could, would, should, expressions in this Form 10-KSB as they relate to us or our management, we are intending to identify forward-looking information statements. These statements reflect our current views with respect to expected future plans, initiatives, operating conditions and other potential events and are subject to certain risks, assumptions, and uncertainties. The statements contained herein that are not purely historical are forward-looking statements including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. Such statements include information contained in this Form 10-KSB regarding pending legal proceedings and the results thereof as well as any statements regarding our future product development, governmental or other regulatory approval prospects and related matters. All forward-looking statements included in this document or incorporated by reference herein are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth in Risk Factors below.*

**Business Overview**

Cardiogenesis Corporation, incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of ischemia associated with advanced cardiovascular disease through laser myocardial revascularization. This therapeutic procedure can be performed surgically as transmyocardial revascularization ( TMR ). TMR is a laser-based heart treatment in which transmural channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis. TMR is performed by a cardiac surgeon through a small anterior thoracotomy incision in the chest while the patient is under general anesthesia. Prospective, randomized, multi-center controlled clinical trials have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with the Cardiogenesis TMR system (plus medications), when compared with patients who received medications alone.

In May 1997, we received CE Mark approval for our TMR system. We have also received CE Mark on our minimally invasive TMR platform PEARL (Port Enabled Angina Relief with Laser) and on our Phoenix Combination Delivery System in November 2005 and October 2006, respectively. The CE Mark allows us to commercially distribute these products within the European Community. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In February 1999, we received approval from the Food and Drug Administration ( FDA ) for the marketing of our TMR products for treatment of patients suffering from chronic, severe angina. Effective July 1999, the Centers for Medicare and Medicaid Services ( CMS ), formerly known as the Health Care Financial Administration ( HCFA ) implemented a national coverage decision for Medicare coverage for any TMR as a primary and secondary procedure. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on indicated Medicare patients.

In December 2004, we received FDA approval for the Solargen 2100s, the advanced laser console for TMR. In addition, in November 2007 we received FDA approval for the PEARL 5.0 robotic handpiece delivery system designed for delivering TMR therapy with surgical robotic systems. We are in the process of completing the

Investigational Device Exemption ( IDE ) trial for the PEARL 8.0 Thoracoscopic handpiece delivery system, and are supporting the initial clinical application of the Phoenix Combination Delivery System in Europe and other international locations.

## **Table of Contents**

### **Background**

According to the American Heart Association, cardiovascular disease is the leading cause of death and disability in the U.S. Coronary artery disease is the principal form of cardiovascular disease and is characterized by a progressive narrowing of the coronary arteries which supply blood to the heart. This narrowing process is usually due to atherosclerosis, which is the buildup of fatty deposits, or plaque, on the inner lining of the arteries. Coronary artery disease reduces the available supply of oxygenated blood to the heart muscle, potentially resulting in severe chest pain known as angina, as well as damage to the heart. Typically, the condition worsens over time and often leads to heart attack and/or death.

Based on standards promulgated by the Canadian Heart Association, angina is typically classified into four classes, ranging from Class 1, in which angina pain results only from strenuous exertion, to the most severe, Class 4, in which the patient is unable to conduct any physical activity without angina and angina may be present even at rest. Currently, the American Heart Association estimates that more than 7 million Americans experience angina symptoms, growing at a rate of 8% per year.

The primary therapeutic options for treatment of coronary artery disease are drug therapy, balloon angioplasty also known as percutaneous transluminal coronary angioplasty ( PTCA ) with stenting, other interventional techniques for percutaneous coronary intervention ( PCI ), and coronary artery bypass grafting or ( CABG ). The objective of each of these approaches is to increase blood flow through the coronary arteries to the heart.

Drug therapy may be effective for mild cases of coronary artery disease and angina either through medical effects on the arteries that improve blood flow without reducing the plaque or by decreasing the rate of formation of additional plaque (e.g., by reducing blood levels of cholesterol). Because of the progressive nature of the disease, however, many patients with angina ultimately undergo either PTCA or CABG.

Introduced in the early 1980s, PTCA is a less-invasive alternative to CABG in which a balloon-tipped catheter is inserted into an artery, typically near the groin, and guided to the areas of blockage in the coronary arteries. The balloon is then inflated and deflated at each blockage site, thereby rupturing the blockage and stretching the vessel. Although the procedure is usually successful in widening the blocked channel, the artery often re-narrows within six months of the procedure, a process called restenosis, often necessitating a repeat procedure. A variety of techniques for use in conjunction with PTCA have been developed in an attempt to reduce the frequency of restenosis, including stent placement and atherectomy. Stents are small metal frames delivered to the area of blockage using a balloon catheter and deployed or expanded within the coronary artery. The stent is a permanent implant intended to keep the channel open. The most recent version, the drug eluting stents ( DES ) have approved formulations imbedded on the stent for the purpose of inhibiting restenosis of the stent and artery. Atherectomy is a means of using mechanical, laser or other techniques at the tip of a catheter to cut or grind away plaque.

CABG is an open chest procedure developed in the 1960s in which conduit vessels are taken from elsewhere in the body and grafted to the blocked coronary arteries so that blood can bypass the blockage. CABG typically requires the use of a heart-lung bypass machine to render the heart inactive (to allow the surgeon to operate on a still, relatively bloodless heart) and involves prolonged hospitalization and patient recovery periods. Accordingly, it is generally reserved for patients with severe cases of coronary artery disease or those who have previously failed to receive adequate relief of their symptoms from PTCA or related techniques. Many bypass grafts fail within one to fifteen years following the procedure. Repeating the surgery ( re-do bypass surgery ) is possible, but is made more difficult because of scar tissue and adhesions that typically form as a result of the first operation. Moreover, for many patients CABG is inadvisable for various reasons, such as the severity of the patient's overall condition, the extent of coronary artery disease or the small size of the blocked arteries.

When these treatment options are exhausted, the patient is left with no viable surgical or interventional alternative other than, in limited cases, heart transplantation. Without a viable surgical alternative, the patient is generally managed with drug therapy, often with significant lifestyle limitations. TMR, which bears the CE Marking and has received FDA approval, offers potential relief to a significant population of patients with advanced cardiovascular disease.



## **Table of Contents**

### **The TMR Procedure**

TMR is a surgical procedure performed on the beating or non-beating heart, in which a laser device is used to create pathways through the myocardium directly into the heart chamber. The pathways are intended to supply blood to ischemic, or oxygen-deprived, regions of the myocardium and reduce angina in the patient. TMR can be performed using open chest surgery or minimally invasive surgery through a small incision between the ribs. TMR offers end-stage cardiac patients who have regions of ischemia not amenable to PTCA or CABG a means to alleviate their symptoms and improve their quality of life. We have received FDA approval for U.S. commercial distribution of our TMR laser system for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

### **Business Strategy**

Our objective is to become a recognized leader in providing clinically effective therapies for ischemic conditions. TMR is approved and recognized as an effective therapy for angina associated with myocardial ischemia. Our strategies to achieve this goal are as follows:

*Expand Market for our Products.* We are seeking to expand market awareness of our products among opinion leaders in the cardiovascular field, the referring physician community and the targeted patient population. To achieve this goal, we have expanded the number of sales territories and added clinical specialists to our sales force to increase awareness of TMR. We continue to expand our physician training programs, including training for our recently approved Robotic delivery system.

*Add Innovative New Technology to our Product Offering.* Our focus is to add innovative new tools to help address ischemia associated with advanced cardiovascular disease. We are committed to growing the TMR business with new product initiatives including our minimally invasive handpieces for robotic assisted and thoracoscopic TMR, and the Phoenix Combination Delivery System. The pre market approval ( PMA ) supplement for the PEARL 5.0 Robotic handpiece was approved by the FDA in November 2007. The IDE study for the 8.0 thoracoscopic handpiece is ongoing. The Phoenix Combination Delivery System combines the delivery of TMR with biologic or pharmacologic therapeutic agents. This advanced system is CE Mark approved.

*Leverage Proprietary Technology.* We believe that our significant expertise in laser and surgical based systems for the treatment of ischemia related to advanced cardiovascular disease and the proprietary technologies we have developed are important factors in our efforts to demonstrate the safety and effectiveness of our procedures. We are seeking to develop additional proprietary technologies and maintain multiple U.S. and foreign patents and have multiple U.S. patent applications pending relating to various aspects of cardiovascular related devices and therapies.

### **Products and Technology**

#### ***TMR System***

Our TMR system consists of a laser console and a line of fiber-optic, laser-based surgical tools. Each surgical tool utilizes an optical fiber assembly to deliver laser energy from the source laser base unit to the distal tip of the surgical handpiece. Our holmium: YAG laser platforms utilize a solid state crystal to generate 2.1 micron wavelength laser light by photoelectric excitation of a solid state holmium crystal. The flexible fiberoptic assembly used to deliver the laser energy to the patient enables direct access to all potential target regions of the heart.

Our TMR system and related surgical procedures are designed to be used without the requirement of the external systems utilized with certain competitive TMR systems. Our TMR system does not require electrocardiogram synchronization, which monitors the electrical output of the heart and times the use of the laser to minimize electrical disruption of the heart, or transesophageal echocardiography, which tests (monitors) each application of the laser to the myocardium during the TMR procedure to determine if the pathway has penetrated through the myocardium into the heart chamber.

## **Table of Contents**

*SolarGen 2100s laser system.* SolarGen 2100s, FDA approved in December 2004. This console implements advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 110V power capability. The systems specifications are as follows: size (21 L x 14 W x 36 H), weight (120 Lbs.), and power compatibility (110V and 230V for international customers).

*TMR 2000 laser system.* The original laser platform approved for TMR by the FDA in 1999, it is no longer distributed. Last manufactured in 2001, the company has notified its existing customers that it can no longer guarantee support of this model due to limited availability of key system components. The systems specifications are as follows: size (35 L x 28.5 W x 45 H), weight (450 Lbs.), and power compatibility (230V).

*SoloGrip III.* The single use SoloGrip handpiece system contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle. The SoloGrip III fiber-optic delivery system has an easy to install connector that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation.

*PEARL 5.0 Robotic handpiece.* The PEARL (Port Enabled Angina Relief using Laser) procedure is an advanced therapeutic technique for the treatment of chronic severe angina in patients who are not candidates for traditional revascularization. The PEARL Robotic 5.0 delivery systems received FDA approval in November 2007. The PEARL 5.0 handpiece utilizes a robotically assisted technique to provide the significant patient benefits of Holmium: YAG TMR via minimally invasive port access. This device and technique is designed to provide the benefits of TMR with reduced risk and morbidity associated with the traditional approach.

## ***New Product Pipeline***

*PEARL Thoracoscopic 8.0 Minimally Invasive Delivery System.* The PEARL (Port Enabled Angina Relief using Laser) procedure is an advanced therapeutic technique for the treatment of chronic severe angina in patients who are not candidates for traditional revascularization. The Thoracoscopic 8.0 Minimally Invasive Delivery System has received CE Mark and Health Canada approval, and are part of an FDA approved IDE study that is underway to validate the safety and feasibility of this advanced delivery system and the minimally invasive approach. The PEARL 8.0 handpiece utilizes a thoracoscopic technique in an FDA approved trial of advanced laser delivery systems to provide the significant patient benefits of Holmium: YAG TMR via minimally invasive port access. The trial is a single arm consecutive series (open label) validation study of the advanced port access delivery system.

*Phoenix Combination Delivery System.* This advanced delivery system combines the delivery of our Holmium: YAG TMR therapy with targeted and precise delivery of biologic or pharmacologic agents to optimize the overall physiologic and clinical response. The Phoenix Combination Delivery System (Phoenix) has received CE Mark approval for marketing in the European Union. Within this advanced combination delivery system, the pulsed Holmium: YAG energy delivered through our proprietary fiberoptic system stimulates the tissue surrounding the TMR channel with thermoacoustic energy. At the time of surgery, this initiates the body's own angiogenic response in the border zone surrounding the channels. It has been reported in the early clinical experience that delivery of biologics or pharmacologic materials to this stimulated myocardium can enhance the physiologic effect in tissue and contribute to improved regional and global ventricular mechanical function. We are currently performing basic research and supporting the initial clinical experience with Phoenix outside the United States to gain additional safety and efficacy data to support our domestic regulatory and commercialization strategy.

## ***PMC System***

The Percutaneous Myocardial Channeling or PMC procedure/system was formerly referred to by the Company and others as percutaneous myocardial revascularization (PMR). PMC is based upon the same principles as TMR, but the

procedure is much less invasive. PMC is performed by an interventional cardiologist in a catheter-based femoral artery approach procedure which requires only conscious sedation for the patient. A laser transmitting catheter is threaded up from the femoral artery at the top of the leg into the heart chamber, where channels are created in the inner portion of the heart muscle. In April 1998 we received CE Mark approval for our PMC system. We completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a

## **Table of Contents**

PMA application in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval for PMC. The Company is not currently pursuing FDA approval of the PMC platform, but may elect to do so in the future). For additional detail on the regulatory status of PMC, see the discussion under the caption Regulatory Status.

We expect to continue to sell and support the PMC product internationally, but we realize that without obtaining FDA approval, we will significantly limit the product's potential sales volume. The PMC system consists of the PMC Laser console and Axcis Catheter delivery system.

## **Regulatory Status**

*United States.* In February 1999, we received approval from the FDA for use of our TMR 2000 laser console and SoloGrip handpiece for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization. We received FDA approval of the SolarGen 2100s laser console in December 2004, and for the PEARL 5.0 Robotic Handpiece Delivery System in November 2007.

We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a PMA application in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel (MDDRP). In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial parameters. We came to agreement with the FDA on a final trial design and received formal FDA approval in January 2006. We have no immediate plans to initiate this trial or further address the regulatory status for PMC with the FDA. Considering the costs involved in carrying out the trials, we have decided to devote resources to our core business and other shorter term product development opportunities rather than to pursue FDA approval for PMC. We expect to continue to sell and support the PMC product internationally, but we realize that without obtaining FDA approval, we will significantly limit the product's potential sales volume.

We have received approvals for our new PEARL Robotic and Thoracoscopic delivery systems from Health Canada and CE Mark approval for marketing to the participating European Union countries. In addition, the PEARL 8.0 Thoracoscopic handpiece has been included in applications to the FDA and to other international health authorities, and we are currently working with these respective agencies toward approvals. We have also received CE Mark approval for our Phoenix Combination Delivery Systems for marketing to European Union countries.

*European Union.* We have obtained approval to affix the CE Marking to substantially all of our products, which enables us to commercially distribute our TMR and PMC products throughout the European Union.

## **Sales and Marketing**

We have received FDA approval for our surgical TMR laser system. In July 1999, the Centers for Medicare and Medicaid Services announced its coverage policy for TMR equipment and procedures. We are promoting market awareness of our approved surgical products among opinion leaders in the cardiovascular field and are recruiting

physicians and hospitals to use our TMR products. Our ability to generate sales depends on the level of sales force interaction with customers and on the geographic coverage of our sales force. We are a smaller company and therefore, are faced with challenges in recruiting and retaining sales personnel.

We work closely with our clinical practitioners and scientific experts in advancing the clinical and scientific understanding and awareness through ongoing clinical and basic research initiatives. Our investment in this critical

## **Table of Contents**

area supports the presentation of new and interesting clinical and scientific information about our products and therapy at scientific symposia and medical meetings, and ultimately published in related peer reviewed journals.

In the United States, we currently offer the SolarGen 2100s laser system at a current end user list price of \$395,000, and the single use SoloGrip III TMR handpiece at an end user unit list price of \$3,995. The recently approved PEARL 5.0 Robotic Handpiece is priced at \$5,395. In addition to sales of lasers to hospitals outright, we offer a range of leasing and financial options to our prospective customers.

Internationally, we sell our TMR and PMC products through distributors and agents. We are currently supporting the initial clinical application of our advanced delivery systems at international sites in support of our overall regulatory and commercialization strategy.

We continue to advance our physician training programs to assist physicians in acquiring the expertise necessary to utilize our products and procedures, including the recently approved PEARL 5.0 Robotic handpiece. Over 1,840 cardiothoracic surgeons and fellows have been trained on the Cardiogenesis TMR system.

We exhibit and promote our products at major meetings of cardiovascular medicine practitioners. Evaluators of our products have made presentations at meetings around the world, describing their results. Abstracts and articles have been published in peer-reviewed publications and industry journals to present the results of our clinical trials and experience.

## **Research and Development**

We believe that focusing our research efforts and product offerings is essential to our ability to stimulate growth and maintain our market leadership position. Our ongoing research and product development efforts are focused on the development of new and enhanced lasers and fiber-optic handpieces for TMR and additional applications in the treatment of ischemic disease. In 2006, we performed the IDE trials for the handpieces for our minimally invasive and robotic assisted TMR platforms. We also developed and validated our initial Phoenix Combination Delivery System and are supporting the initial clinical sites outside the United States in implementing this advanced technology. For the years ended December 31, 2007 and 2006, we incurred research and development expenses of \$681,000 and \$1,474,000, respectively.

We believe our future success will depend, in part, upon the success of our research and development programs. Our research and product development initiatives are supported by in-house research and development personnel and third-party research and development providers. There can be no assurance that we will realize financial benefit from these efforts or that products or technologies developed by others will not render our products or technologies obsolete or non-competitive.

## **Manufacturing**

We outsource the manufacturing and assembly of our handpiece systems to a single contract manufacturer. We also outsource the manufacturing of our laser systems to a different single contract manufacturer.

Certain components of our laser units and fiber-optic handpieces are generally acquired from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Although we have identified alternative vendors, the qualification of additional or replacement vendors for certain components or services is a lengthy process. Any significant supply interruption would have a material adverse effect on the ability to manufacture our products and, therefore, would harm our business. We intend to continue to qualify multiple sources for components that are presently single sourced.

## **Competition**

At this point in time, we believe our only direct competitive technology is manufactured by PLC Systems, Inc. ( PLC ) which directly markets FDA-approved TMR products outside the U.S. Other competitors may also enter the market, including large companies in the laser and cardiac surgery markets. Many of these companies have or may have significantly greater financial, research and development, marketing and other resources than we do.



## **Table of Contents**

PLC is a publicly traded corporation which uses a CO(2) laser and an articulated mechanical arm in its TMR products. PLC obtained a Pre Market Approval for TMR in 1998. PLC has received the CE Marking, which allows sales of its products commercially in all European Union countries. PLC has been issued patents for its apparatus and methods for TMR. Novadaq, a Canadian company publicly traded on the Toronto Stock Exchange, has assumed full sales and distribution responsibility in the U.S. for PLC's TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in March 2007.

We believe that the factors which will be critical to maximizing our market development success include: the timing of receipt of requisite regulatory approvals, favorable reimbursement for the procedure, effectiveness and ease of use of the TMR products and applications, breadth of product line, system reliability, brand name recognition, effectiveness of distribution channels and cost of capital equipment and disposable devices.

Our products also compete with other methods for the treatment of cardiovascular disease, including drug therapy, PTCA, DES, PCI, and CABG. Even with the FDA approval of our TMR system in patients for whom other cardiovascular treatments are not likely to provide relief, and when used in conjunction with other treatments, we cannot assure you that our products will be accepted and adopted by cardiovascular professionals. Moreover, technological advances in other therapies for cardiovascular disease such as pharmaceuticals or future innovations in cardiac surgery techniques could make such other therapies more effective or lower in cost than our TMR procedure and could render our technology obsolete. We cannot assure you that physicians will use our TMR procedure to replace or supplement established treatments, or that our TMR procedure will be competitive with current or future technologies. Such competition could harm our business.

Our TMR laser system and any other product developed by us that gains regulatory approval will face competition for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, the relative pace at which we can develop products, complete clinical testing, achieve regulatory approval, gain reimbursement acceptance and supply commercial quantities of the product to the market are important competitive factors. In the event a competitor is able to obtain a PMA for its products prior to our doing so, we may not be able to compete successfully. We may not be able to compete successfully against current and future competitors even if we obtain a PMA prior to our competitors.

## **Government Regulation**

Laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through TMR are considered medical devices, and as such are subject to regulation in the U.S. by the FDA and outside the U.S. by comparable international regulatory agencies. Our devices require the rigorous PMA process for approval to market the product in the U.S. and must bear the CE Marking for commercial distribution in the European Community.

To obtain a PMA for a medical device, we must file a PMA application that includes clinical data and the results of preclinical and other testing sufficient to show that there is a reasonable assurance of safety and effectiveness of the product for its intended use. To begin a clinical study, an IDE must be obtained and the study must be conducted in accordance with FDA regulations. An IDE application must contain preclinical test data demonstrating the safety of the product for human investigational use, information on manufacturing processes and procedures, and proposed clinical protocols. If the FDA clears the IDE application, human clinical trials may begin. The results obtained from these trials are accumulated and, if satisfactory, are submitted to the FDA in support of a PMA application. Prior to U.S. commercial distribution, premarket approval is required from the FDA. In addition to the results of clinical trials, the PMA application must include other information relevant to the safety and effectiveness of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. By law, the FDA has 180 days to review a PMA application. While the FDA has responded to PMA applications within the

allotted time frame, reviews more often occur over a significantly longer period and may include requests for additional information or extensive additional clinical trials. There can be no assurance that we will not be required to conduct additional trials which may result in substantial costs and delays, nor can there be any assurance that a PMA will be obtained for each product in a timely manner, if at all. In addition, changes in existing regulations or the adoption of new regulations or policies could prevent or delay regulatory approval of our products. Furthermore, even if a PMA is granted, subsequent modifications of the approved device or the

**Table of Contents**

manufacturing process may require a supplemental PMA or the submission of a new PMA which could require substantial additional clinical efficacy data and FDA review. After the FDA accepts a PMA application for filing, and after FDA review of the application, a public meeting is frequently held before an FDA advisory panel in which the PMA is reviewed and discussed. The panel then issues a favorable or unfavorable recommendation to the FDA or recommends approval with conditions which, subsequently, is issued as a conditional approval or an approvable letter by the FDA. Although the FDA is not bound by the panel's recommendations, it tends to give such recommendations significant weight. In February 1999, we received a PMA for our TMR laser system for use in certain indications. As discussed above under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States and further informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMC system. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We came to agreement with the FDA on a final trial design and received formal FDA approval in January 2006. Considering the costs involved in carrying out the trials, we have decided that at this time it is more important to devote resources to our core business and other shorter term product development opportunities rather than to pursue FDA approval for PMC. We will continue to sell and support the PMC product internationally, but we realize that without obtaining FDA approval, we will significantly limit the product's potential sales volume. Based on this decision, we evaluated the carrying value of the PLC license. On January 5, 1999, we entered into an Agreement (the PLC agreement) with PLC Systems, Inc. (PLC), which granted us a non-exclusive worldwide use of certain PLC patents. In return, we agreed to pay PLC a fee totaling \$2,500,000 over an approximately forty-month period. The present value of these payments of \$2,300,000 was recorded as a prepaid asset, included in other assets, and was being amortized over the life of the underlying patents. The patents covered in the PLC agreement are valuable to the Company's Percutaneous Myocardial Channeling (PMC) product line. The PMC product line is not approved for sale in the United States but is sold internationally.

Based on our analysis of the related undiscounted cash flows, the Company determined that the asset was fully impaired at December 31, 2006, and we recorded an impairment charge of \$730,000 included in selling, general and administrative expense related to the write-off of the PLC license in December 2006.

Products manufactured or distributed by us pursuant to a PMA will be subject to pervasive and continuing regulation by the FDA, including, among other things, post market surveillance and adverse event reporting requirements. Upon approval of the PMA for the Cardiogenesis TMR system in 1999, the FDA required the Company to complete a Post Market Approval Study with the device. The Company continues to provide updates on its progress in completing the study in its annual reports to the FDA on the approved TMR system. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, suspensions or delays of approvals, seizures or recalls of products, operating restrictions or criminal prosecutions. The Federal Food, Drug and Cosmetic Act requires us to manufacture our products in registered establishments and in accordance with Good Manufacturing Practices (GMP) regulations and to list our devices with the FDA. Furthermore, as a condition to receipt of a PMA, our facilities, procedures and practices will be subject to additional pre-approval GMP inspections and thereafter to ongoing, periodic GMP inspections by the FDA. These GMP regulations impose certain procedural and documentation requirements upon us with respect to manufacturing and quality assurance activities. Labeling and promotional activities are subject to scrutiny by the FDA. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses (also known as off-label indications). Changes in existing regulatory requirements or adoption of new requirements could harm our business. We may be required to incur significant costs to comply with laws and regulations in the future and current or future laws and regulations may harm our business.

We are also regulated by the FDA under the Radiation Control for Health and Safety Act, which requires laser products to comply with performance standards, including design and operation requirements, and manufacturers to certify in product labeling and in reports to the FDA that our products comply with all such standards. The law also requires laser manufacturers to file new product and annual reports, maintain manufacturing, testing and sales records,

and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product. In addition, we are subject to California regulations governing the

## **Table of Contents**

manufacture of medical devices, including an annual licensing requirement. Our facilities are subject to ongoing, periodic inspections by the FDA and California regulatory authorities.

Sales, manufacturing and further development of our systems also may be subject to additional federal regulations pertaining to export controls and environmental and worker protection, as well as to state and local health, safety and other regulations that vary by locality and which may require obtaining additional permits. We cannot predict the impact of these regulations on our business.

Sales of medical devices outside of the U.S. are subject to foreign regulatory requirements that vary widely by country. In addition, the FDA must approve the export of devices to certain countries. To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with appropriate ISO quality standards (e.g. ISO 13485) and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies. We have achieved International Standards Organization and European Union certification for our external manufacturing facilities. In addition, we have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere.

## **Intellectual Property Matters**

Our success depends, in part, on our ability to obtain patent protection for our products, preserve our trade secrets, and operate without infringing the proprietary rights of others. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business, as well as collaborate with and license technology from academic institutions. We have and maintain multiple U.S. and foreign patents and have multiple U.S. and foreign patent applications pending relating to various aspects of cardiovascular related devices and therapies. Our patents or patent applications may be challenged, invalidated or circumvented in the future or the rights granted may not provide a competitive advantage. We intend to vigorously protect and defend our intellectual property while also maintaining a defensive, strategic patent position. We do not know if patent protection will continue to be available for surgical methods in the future. Costly and time-consuming litigation brought by us may be necessary to enforce our patents and to protect our trade secrets and know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Our patent rights will also eventually expire, as will those of our competitors, which will thus allow others to exploit certain intellectual property that is currently proprietary.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We typically require our employees, consultants and advisors to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting, or advisory relationships with us. If any of these agreements are breached, we may not have adequate remedies available to protect our intellectual property or we may incur substantial expenses enforcing our rights. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our proprietary technology, or we may not be able to meaningfully protect our rights in unpatented proprietary technology.

The medical device industry in general, and the industry segment that includes products for the treatment of cardiovascular disease in particular, have been characterized by substantial competition and litigation regarding patent and other intellectual property rights. In this regard, our competitors have been issued a number of patents related to TMR and PMC. There can be no assurance that claims or proceedings will not be initiated against us by competitors

or other third parties in the future. In particular, the introduction in the United States market of our PMC technology, should we pursue that option, may create new exposures to claims of infringement of third party patents. Any such claims in the future, regardless of whether they have merit, could be time-consuming and expensive to respond to and could divert the attention of our technical and management personnel. We may be

## **Table of Contents**

involved in litigation to defend against claims of our infringement, to enforce our patents, or to protect our trade secrets. If any relevant claims of third party patents are upheld as valid and enforceable in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or we could be required to obtain licenses from the patent owners of each such patent or to redesign our products or processes to avoid infringement.

We cannot assure that our current and potential competitors and other third parties have not filed or in the future will not file patent applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights that will prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or internationally. In this regard, we note that the Company has recently been named as a defendant in a patent infringement lawsuit that is more fully described in Part I, Item 3 Legal Proceedings below. In the event we were to require licenses to patents issued to third parties, such licenses may not be available or, if available, may not be available on terms acceptable to us. In addition, we cannot assure you that we would be successful in any attempt to redesign our products or processes to avoid infringement or that any such redesign could be accomplished in a cost-effective manner. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would harm our business.

## **Third Party Reimbursement**

We expect that sales volumes and prices of our products will continue to depend significantly on the availability of reimbursement for surgical procedures using our products from third party payors such as governmental programs, private insurance and private health plans. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. Reimbursement rates from third party payors vary depending on the third party payor, the procedure performed and other factors. Moreover, third party payors, including government programs, private insurance and private health plans, have in recent years been instituting increasing cost containment measures designed to limit payments made to healthcare providers by, among other measures, reducing reimbursement rates, limiting services covered, negotiating prospective or discounted contract pricing and carefully reviewing and increasingly challenging the prices charged for medical products and services.

Medicare reimburses hospitals on a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis, and reimburses physicians on a prospectively determined fixed amount based on the procedure performed, regardless of the actual costs incurred by the hospital or physician in furnishing the care and unrelated to the specific devices used in that procedure. Medicare and other third party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. In addition, Medicare traditionally has considered items or services involving devices that have not been approved or cleared for marketing by the FDA to be precluded from Medicare coverage. In July 1999, Centers for Medicare and Medicaid Services began coverage of FDA approved TMR systems for any manufacturer's TMR procedures. In October of 1999, CMS further clarified its coverage policy to include coverage of TMR when performed as an adjunctive to CABG. In July 2004, CMS convened a Medicare Coverage Advisory Committee Meeting to review the new available data relating to its 1999 published coverage decision on TMR as a primary and secondary treatment. In September 2004, we confirmed that CMS had no current intention to initiate any changes in the current national coverage decision and related memoranda regarding TMR. As of the date of this filing, there have been no changes to the coverage decision as a result of the public hearing.

In contrast to Medicare which covers a significant portion of the patients who are candidates for TMR, private insurers and health plans each make any individual decision whether or not to provide reimbursement for TMR and, if so, at what reimbursement level. While our experience with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans has generally been positive, private insurance and private health plans may

choose to not approve reimbursement for TMR in the future. The lack of private insurance and health plans reimbursement may harm our business. Based on physician feedback, we believe many private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/Blue Shield's Technology Evaluation Center ( TEC ) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC



**Table of Contents**

decisions are not binding, many Blue Cross/Blue Shield plans and other third-party payers use the center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

In foreign markets, reimbursement is obtained from a variety of sources, including governmental authorities, private health insurance plans and labor unions. In most foreign countries, there are also private insurance systems that may offer payments for alternative therapies. Although not as prevalent as in the U.S., health maintenance organizations are emerging in certain European countries. We may need to seek international reimbursement approvals, and we may not be able to attain these approvals in a timely manner, if at all. Failure to receive foreign reimbursement approvals could make market acceptance of our products in the foreign markets in which such approvals are sought more difficult.

We believe that reimbursement in the future will be subject to increased restrictions such as those described above, both in the U.S. and in foreign markets. We also believe that the escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services, including products offered by us. Third party reimbursement and coverage may not be available or adequate in U.S. or foreign markets, current levels of reimbursement may be decreased in the future and future legislation, regulation, or reimbursement policies of third party payors may reduce the demand for our products or our ability to sell our products on a profitable basis. Fundamental reforms in the healthcare industry in the U.S. and Europe that could affect the availability of third party reimbursement continue to be proposed, and we cannot predict the timing or effect of any such proposal. If third party payor coverage or reimbursement is unavailable or inadequate, our business may suffer.

**Product Liability and Insurance**

We maintain insurance against product liability claims in the amount of \$10 million per occurrence and \$10 million in the aggregate. We may not be able to obtain additional coverage or continue coverage in the amount desired or on terms acceptable to us, and such coverage may not be adequate for liabilities actually incurred. Any uninsured or underinsured claim brought against us or any claim or product recall that results in a significant cost to or adverse publicity against us could harm our business.

**Employees**

As of December 31, 2007 we had 32 employees, of which 15 employees were in sales and marketing. None of our employees are covered by a collective bargaining agreement and we have not experienced any work stoppages to date.

**Executive Officers**

The following gives certain information regarding our executive officers and significant employees as of March 1, 2008:

Name	Age	Position
Richard P. Lanigan	48	President
William R. Abbott	51	Senior Vice President, Chief Financial Officer, Secretary and Treasurer

*Richard P. Lanigan* has been our President since November 2006. Prior to November 2006, Mr. Lanigan served in a variety of different capacities. From November 2005 to October 2006, Mr. Lanigan served as the Senior Vice

President of Operations. From November 2003 to October 2005, Mr. Lanigan was Senior Vice President of Marketing. From March 2001 to October 2003, Mr. Lanigan was Vice President of Government Affairs and Business Development. From March 2000 to February 2001, Mr. Lanigan served as Vice President of Sales and Marketing and from 1997 to 2000 he was the Director of Marketing. From 1992 to 1997, Mr. Lanigan served in various positions, most recently Marketing Manager, at Stryker Endoscopy. From 1987 to 1992, Mr. Lanigan served in Manufacturing and Operations management at Raychem Corporation. From 1981 to 1987, he served in the U.S. Navy where he completed six years of service as Lieutenant in the Supply Corps. Mr. Lanigan has a Bachelor

## **Table of Contents**

of Business Administration from the University of Notre Dame and a Masters of Science in Systems Management from the University of Southern California.

*William R. Abbott* joined us as Senior Vice President & Chief Financial Officer, Secretary and Treasurer in May 2006. From 1997 to 2005, Mr. Abbott served in several financial management positions at Newport Corporation most recently as Vice President of Finance and Treasurer. From 1993 to 1997, Mr. Abbott served as Vice President and Corporate Controller of Amcor Sunclipse North America. From 1991 to 1992, Abbott served as Director of Financial Planning for the Western Division of Coca-Cola Enterprises, Inc. From 1988 to 1991, Mr. Abbott was Controller of McKesson Water Products Company. Prior to that, Mr. Abbott spent 6 years in management positions at PepsiCo, Inc. and began his career with PricewaterhouseCoopers, LLP. Mr. Abbott has a Bachelor of Science degree in accounting from Fairfield University and a Masters in Business Administration degree from Pepperdine University.

## **Risk Factors**

The following is a description of some of the principal risks inherent in our business. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, could negatively impact our results of operations or financial condition in the future.

***Our ability to maintain current operations is dependent upon achieving profitable operations or obtaining financing in the future.***

Prior to 2007, we had incurred significant operating losses for several years and at December 31, 2007 we had an accumulated deficit of \$169,535,000. We will have a continuing need for new infusions of cash if we incur losses or fail to generate sufficient cash from operations in the future. We plan to attempt to increase our revenues through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations, including our sales and marketing efforts and research and development. If we are required to significantly reduce our operations, our business will be harmed.

Changes in our business, financial performance or the market for our products may require us to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, there is a risk that we may be unsuccessful in obtaining financing in the future on terms acceptable to us and that we will not have sufficient cash to fund our continued operations.

***Our ability to maintain revenues and operating income and achieve growth in sales and operating income in the future is dependent upon commercial acceptance of our products by healthcare providers.***

Our ability to maintain current sales levels and/or increase our revenues and operating income will be dependent upon acceptance of our products and services by surgeons, cardiologists, hospitals and other healthcare providers in the United States. Our revenues and operating income may be constrained:

- if commercial adoption of our TMR laser systems by healthcare providers in the United States declines;
- if we are unable to achieve approval and commercialization of additional new products or therapies; and
- for an uncertain period of time after such approvals are obtained.

***We may not be able to successfully market our products if third party reimbursement for the procedures performed with our products is not available for our health care provider customers.***

Few individuals are able to pay directly for the costs associated with the use of our products. In the United States, hospitals, physicians and other healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, to reimburse all or part of the cost of the procedure in which the medical

**Table of Contents**

device is being used. Effective July 1, 1999, the Centers for Medicare and Medicaid Services ( CMS ), formerly the Health Care Financing Administration, commenced Medicare coverage for TMR procedures performed with FDA approved devices. Hospitals and physicians are eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. If CMS were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation could be harmed.

In July 2004, CMS convened the Medicare Advisory Committee ( MCAC ) to review the clinical evidence regarding laser myocardial revascularization as a treatment option for Medicare patients. The MCAC meeting was a non-binding public hearing to consider the body of scientific evidence concerning the safety and efficacy of laser myocardial revascularization and to provide advice and recommendations to the CMS on clinical issues. The MCAC reviewed more than six years of clinical evidence on laser myocardial revascularization and heard testimony from a group of leading physicians regarding TMR. Subsequent to that public hearing, CMS has not initiated a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS had no current intention to initiate any changes in the current national coverage decision and related memoranda regarding TMR. As of the date of this filing, there have been no changes to the coverage decision as a result of the public hearing.

As PMC has not been approved by the FDA, the CMS has not approved reimbursement for PMC. If we seek to obtain FDA approval for PMC in the future and CMS does not provide reimbursement, our ability to successfully market and sell our PMC products may be affected.

Even though Medicare beneficiaries appear to account for a majority of all patients treated with the TMR procedure, the remaining patients are beneficiaries of private insurance and private health plans. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. If private insurance and private health plans do not provide reimbursement, our business will suffer.

If we obtain the necessary foreign regulatory registrations or approvals for our products, market acceptance in international markets would be dependent, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. A hospital is more inclined to purchase new equipment if third-party reimbursement can be obtained. Reimbursement and health care payment systems in international markets vary significantly by country. They include both government sponsored health care and private insurance. International reimbursement approvals may not be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals could hurt market acceptance of our products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

***If we pursue FDA approval of our PMC laser system, we may fail to obtain required regulatory approvals in the United States to market our PMC laser system.***

The FDA has not approved our PMC laser system for any marketing application in the United States. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel ( MDDRP ). In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved.

In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial

parameters. We came to agreement with the FDA on a final trial design and received formal FDA approval in January 2006. Considering the costs involved in carrying out the trials, we have decided that at this time it is more important to devote resources to our core business rather than to pursue FDA approval for PMC. We will continue to sell the PMC product internationally, but we realize that without obtaining FDA approval, we will significantly limit the product's potential sales volume.

Based on this decision, we evaluated the carrying value of the PLC license. On January 5, 1999, we entered into an Agreement ( the PLC agreement ) with PLC Systems, Inc. ( PLC ), which granted us a non-exclusive

**Table of Contents**

worldwide use of certain PLC patents. In return, we agreed to pay PLC a fee totaling \$2,500,000 over an approximately forty-month period. The present value of these payments of \$2,300,000 was recorded as a prepaid asset, included in other assets, and was being amortized over the life of the underlying patents. The patents covered in the PLC agreement are valuable to the Company's Percutaneous Myocardial Channeling ( PMC ) product line. The PMC product line is not approved for sale in the United States but is sold internationally.

Based on our analysis of the related undiscounted cash flows, the Company determined that the asset was fully impaired at December 31, 2006, and we recorded an impairment charge of \$730,000 included in selling, general and administrative expense related to the write-off of the PLC license in December 2006.

In addition, we will not be able to derive any revenue from the sale of our PMC system in the United States until such time, if any, that the FDA approves the device. Such inability to realize revenue from sales of our PMC device in the United States may have an adverse effect on our results of operations.

***We may fail to obtain required regulatory approvals in the United States to market our new minimally invasive Thoracoscopic handpiece.***

The PEARL 8.0 Thoracoscopic Handpiece Delivery Systems has achieved CE Mark and Health Canada approval, and is under an FDA approved IDE study that is underway to validate the safety and feasibility of this advanced delivery system and the minimally invasive approach. The PEARL 8.0 handpiece utilizes a thoracoscopic technique in an FDA approved trial of this advanced laser delivery system to provide the significant patient benefits of Holmium: YAG TMR via minimally invasive port access. The trial is a single arm consecutive series (open label) validation study of the advanced port access delivery system. We will not be able to derive any revenue from the sale of our new PEARL Thoracoscopic minimally invasive handpieces beyond the participating investigative sites in the United States until such time, if any, that the FDA approves these devices. Such inability to realize incremental revenue from sales of this device in the United States may have an adverse effect on our results of operations.

***In the future, the FDA could restrict the current uses of our TMR product and thereby restrict our ability to generate revenues.***

We currently derive approximately 99% of our revenues from our TMR product. The FDA has approved this product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. If we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, although we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians in the United States, such as restricting TMR's use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be materially and adversely affected.

***We must comply with FDA manufacturing standards or face fines or other penalties including suspension of production.***

We are required to demonstrate compliance with the FDA's current good manufacturing practices regulations if we market devices in the United States or manufacture finished devices in the United States. The FDA inspects manufacturing facilities on a regular basis to determine compliance. If we, or our contract manufacturers, fail to comply with applicable FDA or other regulatory requirements, we can be subject to:

finances, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

The impact on us of any such failure to comply would depend on the impact of the remedy imposed on us.



**Table of Contents**

***We may fail to comply with international regulatory requirements and could be subject to regulatory delays, fines or other penalties.***

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. In addition, the FDA must approve the export of devices to certain countries. The occurrence and related impact of the following factors would harm our business:

delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with the appropriate quality assurance provisions of the International Standards Organization and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies.

We have completed CE Mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer. Noncompliance with international regulatory requirements could result in enforcement action such as prohibitions against us marketing our products in the European Union, which would significantly reduce international revenue.

***We may not be able to meet future product demand on a timely basis and may be subject to delays and interruptions to product shipments because we depend on single source third party suppliers and manufacturers.***

We purchase certain critical products and components for lasers and disposable handpieces from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of our products to third parties. We may experience harm to our business if we cannot timely provide lasers to our customers or if our outsourcing suppliers have difficulties supplying our needs for products and components.

In addition, we do not have long-term supply contracts. As a result, our sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our laser systems were to increase rapidly or significantly. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months. However, if demand for our TMR laser is greater than we currently anticipate and there is a delay in obtaining production capacity, unless we are able to obtain lasers originally placed through our loaned laser program and no longer utilized by a hospital, we may not be able to meet the demand for our TMR laser. In addition, any defect or malfunction in the laser or other products provided by our suppliers and manufacturers could cause delays in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

if materials and products obtained from outside suppliers and manufacturers will always be available in adequate quantities to meet our future needs; or

whether replacement suppliers and/or manufacturers can be qualified on a timely basis if our current suppliers and/or manufacturers are unable to meet our needs for any reason.

**Table of Contents**

***Expansion of our business may put added pressure on our management and operational infrastructure affecting our ability to meet any increased demand for our products and possibly having an adverse effect on our operating results.***

Our administrative and other resources are limited. To the extent we are successful in expanding our business, such growth may place a significant strain on our limited resources, staffing, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

the dependence on the growth of the market for our currently approved and reimbursed products;

our ability to successfully expand sales to potential customers and increasing clinical adoption of the TMR procedure;

domestic and international regulatory developments;

rapid technological change;

the highly competitive nature of the medical devices industry; and

the risk of entering emerging markets in which we have limited or no direct experience.

Shortfalls in projections of sales growth as it is related to the increased up front expenses required to support the essential resources, may result in the need to obtain additional funding. If there are significant shifts in the competitive, regulatory or reimbursement environments the ability to achieve the desired operating results could be impacted.

***Our operating results are expected to fluctuate and quarter-to-quarter comparisons of our results may not indicate future performance.***

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to continue to fluctuate significantly from quarter-to-quarter in future periods. We believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Due to the emerging nature of the markets in which we compete, forecasting operating results is difficult and unreliable. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts that may cover our stock and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs in the future, the price of our common stock may fall again, perhaps substantially.

***Potential acquisitions or strategic relationships may be more costly or less profitable than anticipated and may adversely affect the price of our company stock.***

We may pursue acquisitions or strategic relationships that could provide new technologies, products, or service offerings. Future acquisitions or strategic relationships may negatively impact our results of operations as a result of operating losses incurred by the acquired entity, the use of significant amounts of cash, potentially dilutive issuances of equity or equity-linked securities, incurrence of debt, or amortization or impairment charges. Furthermore, we may incur significant expenses pursuing acquisitions or strategic relationships that ultimately may not be completed. Moreover, to the extent that any proposed acquisition or strategic relationship that is not favorably received by shareholders and others in the investment community, the price of our stock could be adversely affected.

***Our stock is currently listed on the Pink Sheets which may have an unfavorable impact on our stock price and liquidity.***

In May of 2006, our common stock was delisted from the OTC Bulletin Board as a result of our failure to timely file our periodic reports. The Pink Sheets and the OTC Bulletin Board are significantly more limited markets in comparison to other larger trading markets such as the NASDAQ. The listing of our shares on the Pink Sheets results in a relatively illiquid market available for existing and potential stockholders to trade shares of our common stock, which could ultimately depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

**Table of Contents**

***Penny stock regulations may impose certain restrictions on marketability of our stock.***

The Securities and Exchange Commission has adopted regulations which generally define a penny stock to be any equity security that has a market price (as defined) of less than \$5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require delivery, prior to the transaction, of a risk disclosure document mandated by the Commission relating to the penny stock market. The broker-dealer must also disclose the commission payable to both the broker-dealer and the registered representative, current quotations for the securities and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Consequently, the penny stock rules may restrict the ability of broker-dealers to sell the Company's securities and may affect the ability of purchasers in this Offering to sell the Company's securities in the secondary market and the price at which such purchasers can sell any such securities.

***The price of our common stock may fluctuate significantly, which may result in losses for investors.***

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended February 29, 2008, the closing prices of our common stock as reported on the Pink Sheets ranged from a high of \$0.42 per share to a low of \$0.18 per share. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

- actual or anticipated variations in our quarterly operating results;
- the timing and amount of conversions and subsequent sales of common stock issuable upon exercise of outstanding options and warrants;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements relating to strategic relationships or acquisitions;
- additions or terminations of coverage of our common stock by securities analysts;
- statements by securities analysts regarding us or our industry;
- conditions or trends in the medical device industry;
- the lack of liquidity in the market for our common stock; and
- changes in the economic performance and/or market valuations of other medical device companies.

The prices at which our common stock trades will affect our ability to raise capital, which may have an adverse effect on our ability to fund our operations.

***We face competition from products of our competitors which could limit market acceptance of our products and render our products obsolete.***

The market for TMR laser systems is competitive. We currently compete with PLC Systems, a publicly traded company which uses a CO(2) laser and an articulated mechanical arm in its TMR products. Edwards Lifesciences, a well known, publicly traded provider of products and technologies to treat cardiovascular disease, has assumed full sales and marketing responsibility in the U.S. for PLC's TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in January 2001. Through its significantly greater financial and human resources, including a well-established and extensive sales representative network, we believe Edwards has the potential to market to a greater number of hospitals and doctors that we currently can. If PLC, or

**Table of Contents**

any new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business may suffer.

The market for TMR laser systems is characterized by rapid technical innovation. Our current or future competitors may succeed in developing TMR products or procedures that:

- are more effective than our products;
- are more effectively marketed than our products; or
- may render our products or technology obsolete.

If we pursue FDA approval for our PMC laser system and we are successful at obtaining it, we will face competition for market acceptance and market share for that product. Our ability to compete may depend in significant part on the timing of introduction of competitive products into the market, and will be affected by the pace, relative to competitors, at which we are able to:

- develop products;
- complete clinical testing and regulatory approval processes;
- obtain third party reimbursement acceptance; and
- supply adequate quantities of the product to the market.

***Third party intellectual property rights may limit the development and protection of our intellectual property, which could adversely affect our competitive position.***

Our success is dependent in large part on our ability to:

- obtain patent protection for our products and processes;
- preserve our trade secrets and proprietary technology; and
- operate without infringing upon the patents or proprietary rights of third parties.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Certain competitors and potential competitors of ours have obtained United States patents covering technology that could be used for certain of our procedures and potential new applications. We do not know if such competitors, potential competitors or others have filed and hold international patents covering our procedures and potential new applications. In addition, international patents may not be interpreted the same as any counterpart United States patents.

While we periodically review the scope of our patents and other relevant patents of which we are aware, the question of patent infringement involves complex legal and factual issues. Any conclusion regarding infringement may not be consistent with the resolution of any such issues by a court.

***We have been named as a defendant in a patent infringement lawsuit and costly litigation may be necessary to protect or defend our intellectual property rights.***

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of others. In addition, we may become subject to patent infringement claims or litigation, or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions. In this regard, we have recently been named as a defendant in a patent infringement lawsuit. See Part I, Item 3 Legal Proceedings below for a description of this lawsuit.

Defending and prosecuting intellectual property suits, including the pending lawsuit described elsewhere in this Annual Report on Form 10-KSB, United States Patent and Trademark Office interference proceedings and



**Table of Contents**

related legal and administrative proceedings are both costly and time-consuming. We may be required to litigate further to:

enforce our issued patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Any litigation or interference proceedings will result in substantial expense and significant diversion of effort by technical and management personnel. If the results of such litigation or interference proceedings are adverse to us, then the results may:

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

prevent us from selling our products in certain markets or at all; or

require us to modify our products.

Although patent and intellectual property disputes regarding medical devices are often settled through licensing and similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all.

Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products. This would harm our business.

The United States patent laws have been amended to exempt physicians, other health care professionals, and affiliated entities from infringement liability for medical and surgical procedures performed on patients. We are not able to predict if this exemption will materially affect our ability to protect our proprietary methods and procedures.

***We rely on patent and trade secret laws, which are complex and may be difficult to enforce.***

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. An issued patent or patents based on pending patent applications or any future patent application may not exclude competitors or may not provide a competitive advantage to us. In addition, patents issued or licensed to us may not be held valid if subsequently challenged and others may claim rights in or ownership of such patents.

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

will not design around any patents issued to or licensed by us.

Because patent applications in the United States are maintained in secrecy until the patents are issued, we cannot be certain that:

others did not first file applications for inventions covered by our pending patent applications; or

we will not infringe any patents that may issue to others on such applications.

***We may suffer losses from product liability claims if our products cause harm to patients.***

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death. We are not aware of any material side effects or adverse events arising from the use of our TMR product. However, if we pursue FDA approval of the PMC product, we would have to respond to the FDA's

**Table of Contents**

Circulatory Devices Panel's recommendation against approval because of concerns over the safety of the device and the data regarding adverse events in the clinical trials. We believe there are no material side effects or adverse events arising from the use of our PMC product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. In light of this, we believe that the difference in the rates of complications between the treated groups and the control groups in the clinical trials for our PMC product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMC product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the FDA's good manufacturing practices or other regulations could hurt our ability to defend against product liability lawsuits.

***Our insurance may be insufficient to cover product liability claims against us.***

Our product liability insurance may not be adequate for any future product liability problems or continue to be available on commercially reasonable terms, or at all.

If we were held liable for a product liability claim or series of claims in excess of our insurance coverage, such liability could harm our business and financial condition. We maintain insurance against product liability claims in the amount of \$10 million per occurrence and \$10 million in the aggregate.

We may be required to increase our product liability coverage if sales of approved products increase and if additional products are commercialized. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all.

***We depend heavily on key personnel and turnover of key employees and senior management could harm our business.***

Our future business and results of operations depend in significant part upon our ability to identify, hire and retain key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer. Significant turnover in our senior management could significantly deplete the institutional knowledge held by our existing senior management team and could impair our ability to effectively operate and grow our business. We depend on the skills and abilities of our key management level employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover. To the extent we are unable to identify or retain suitable management personnel, our business and prospects could be adversely affected.

***Future sales of our common stock could lower our stock price.***

If our shareholders sell substantial amounts of our common stock, including shares issuable upon exercise of options or warrants or shares issued in previous financings, in the public market, the market price of our common stock could decline. If these sales were to occur, we may also find it more difficult to sell equity or equity-related securities in the future at a time and price that we deem appropriate and desirable.

In the future, we may issue additional shares in public or private offerings. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of our common stock would have

on the market price of our common stock.

***Provisions of our certificate of incorporation as well as our rights agreement could discourage potential acquisition proposals and could deter or prevent a change of control.***

Our articles of incorporation authorize our board of directors, subject to any limitations prescribed by law, to issue shares of preferred stock in one or more series without shareholder approval. On August 17, 2001 we adopted a shareholder rights plan, as amended, and under the rights plan, our board of directors declared a dividend

## **Table of Contents**

distribution of one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Pursuant to the Rights Agreement, in the event (a) any person or group acquires 15% or more of our then outstanding shares of voting stock (or 21% or more of our then outstanding shares of voting stock in the case of State of Wisconsin Investment Board), (b) a tender offer or exchange offer is commenced that would result in a person or group acquiring 15% or more of our then outstanding voting stock, (c) we are acquired in a merger or other business combination in which we are not the surviving corporation or (d) 50% or more of our consolidated assets or earning power are sold, then the holders of our common stock are entitled to exercise the rights under the Rights Plan, which include, based on the type of event which has occurred, (i) rights to purchase preferred shares from us, (ii) rights to purchase common shares from us having a value twice that of the underlying exercise price, and (iii) rights to acquire common stock of the surviving corporation or purchaser having a market value of twice that of the exercise price. The rights expire on August 17, 2011, and may be redeemed prior thereto at \$0.001 per right under certain circumstances. The Board's ability to issue preferred stock without shareholder approval while providing desirable flexibility in connection with financings, acquisitions and other corporate purposes, and the existence of the rights plan might discourage, delay or prevent a change in the ownership of our company or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock.

### ***Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges.***

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. To the extent that such interpretations or changes in policies negatively impact our reported financial results, our results of stock price could be adversely affected.

### ***Our internal controls over financial reporting may not be effective, which could have a significant and adverse effect on our business.***

Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Securities and Exchange Commission, which we collectively refer to as Section 404, require us to evaluate our internal controls over financial reporting to allow management to report on those internal controls as of the end of each year beginning in fiscal 2007. Section 404 will also require our independent registered public accounting firm to attest to the effectiveness of our internal controls over financial reporting in future periods. Effective internal controls are necessary for us to produce reliable financial reports and are important in our effort to prevent financial fraud. In the course of our Section 404 evaluations, we may identify conditions that may result in significant deficiencies or material weaknesses and we may conclude that enhancements, modifications or changes to our internal controls are necessary or desirable. Implementing any such matters would divert the attention of our management, could involve significant costs, and may negatively impact our results of operations.

We note that there are inherent limitations on the effectiveness of internal controls, as they cannot prevent collusion, management override or failure of human judgment. If we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, and it could harm our financial condition and results of operations, result in a loss of investor confidence and negatively impact our share price.

## **Item 2. Description of Property**

Our headquarters, located in Irvine, California, are comprised of approximately 7,800 square feet of leased space. The lease expires in November 2011. We believe our facilities are adequate to meet our foreseeable requirements. There can be no assurance that additional facilities will be available to us on favorable terms, if and when needed, thereafter.

**Table of Contents****Item 3. *Legal Proceedings.***

We have been notified that on February 19, 2008, Cardiofocus, Inc. ( Cardiofocus ) filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1.08-cv-10285) against us and a number of other companies. In the complaint, Cardiofocus alleges that we and the other defendants have violated patent rights allegedly held by Cardiofocus. The complaint does not identify specific alleged monetary damages. Although we have not completed our analysis of the claims, we intend to vigorously defend ourselves. However, any litigation involves risks and uncertainties and the likely outcome of the case cannot be determined at this time. In addition, litigation involves significant expenses and distraction of management resources which may have an adverse effect on our results of operations.

Except as described above, the Company is not a party to any material legal proceeding.

**PART II****Item 5. *Market for Common Equity and Related Shareholder Matters.***

Our common stock was traded on the OTC Bulletin Board under the symbol CGCP.OB through May 30, 2006. As we previously disclosed, trading of our common stock on the OTC Bulletin Board was suspended due to our prior failure to timely file required periodic reports. Our common stock is currently quoted on the Pink Sheets under the symbol CGCP.PK.

For the periods indicated, the following table presents the range of high and low bid quotations for the common stock as reported by the OTC Bulletin Board and Pink Sheets for the respective market on which our common stock was listed during the quarter being reported. Prices below reflect inter-dealer prices, without retail write-up, write-down or commission and may not represent actual transactions.

<b>2006</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 0.61	\$ 0.33
Second Quarter	\$ 0.59	\$ 0.16
Third Quarter	\$ 0.50	\$ 0.35
Fourth Quarter	\$ 0.45	\$ 0.27
<b>2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 0.41	\$ 0.25
Second Quarter	\$ 0.35	\$ 0.21
Third Quarter	\$ 0.31	\$ 0.17
Fourth Quarter	\$ 0.38	\$ 0.21

As of February 29, 2008 shares of our common stock were held by 221 shareholders of record.

We have never paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future, as we intend to retain our earnings, if any, for general corporate purposes.





**Table of Contents****Equity Compensation Plan Information**

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans as of December 31, 2007, including the 1996 Stock Option Plan, as amended, and the 1996 Director Stock Option Plan, as amended.

<b>Plan Category</b>	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>	<b>(d)</b>
	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>	<b>Total of Securities Reflected in Columns (a) and (c)</b>
Stock Option Plans Approved by Shareholders(1)	3,076,000	\$ 0.81	5,237,000	8,313,000
Employee Stock Purchase Plan Approved by Shareholders(2)			267,743	267,743
Equity Compensation Plans Not Approved by Shareholders(3)	6,015,000	\$ 0.94	N/A	6,015,000
<b>Total</b>	<b>9,091,000</b>	<b>\$ 0.88</b>	<b>5,504,743</b>	<b>14,595,743</b>

- (1) Consists of the Cardiogenesis Corporation Stock Option Plan and Director Stock Option Plan.
- (2) Consists of the Cardiogenesis Corporation Employee Stock Purchase Plan. The Employee Stock Purchase Plan enables employees to purchase the Company's common stock at a 15% discount to the lower of market value at the beginning or end of each six month offering period. As such, the number of shares that may be issued pursuant to the Employee Stock Purchase Plan during a given six month period and the purchase price of such shares cannot be determined in advance.
- (3) Consists of 275,000 shares of common stock subject to warrants having exercise prices ranging from \$0.35 to \$0.44 per share issued to a lender in connection with a canceled credit facility, 3,100,000 shares of common stock subject to warrants having an exercise price of \$1.37 issued to investors in connection with a private equity offering, and 2,640,000 shares of common stock subject to warrants having an exercise price of \$0.50 per share issued to a lender in connection with a secured convertible note financing transaction.

For a complete description of the Company's equity compensation plans, please refer to Note 9 of our audited financial statements as of December 31, 2007, which are filed herein.

**Item 6. *Management's Discussion and Analysis or Plan of Operation.***

Management's Discussion and Analysis or Plan of Operation contains certain statements relating to future results, which are forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, and similar expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based on the beliefs of management, as well as assumptions and estimates based on information available to us as of the dates such assumptions and estimates are made, and are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated, depending on a variety of factors, including those factors discussed in Risk Factors in Part I, Item 1. Should one or more of those risks or uncertainties materialize adversely, or should underlying assumptions or estimates prove incorrect, actual results may vary materially from those described. Those events and uncertainties are difficult or impossible to predict accurately and many are beyond our control. Except as may be required by applicable law, we assume no obligation to publicly release the result of any revisions that may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements. The following discussion should be read in conjunction with our financial statements and notes thereto included in this Annual Report on Form 10-KSB.

## **Table of Contents**

### **Overview**

Cardiogenesis Corporation, incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of ischemia associated with advanced cardiovascular disease through laser myocardial revascularization. This therapeutic procedure can be performed surgically as transmyocardial revascularization ( TMR ). TMR is a laser-based heart treatment in which transmural channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis. TMR is performed by a cardiac surgeon through a small anterior thoracotomy incision in the chest while the patient is under general anesthesia. Prospective, randomized, multi-center controlled clinical trials have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with the Cardiogenesis TMR system (plus medications), when compared with patients who received medications alone.

In May 1997, we received CE Mark approval for our TMR system. We have also received CE Mark on our minimally invasive TMR platform PEARL (Port Enabled Angina Relief with Laser) and on our Phoenix Combination Delivery System in November 2005 and October 2006, respectively. The CE Mark allows us to commercially distribute these products within the European Community. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In February 1999, we received approval from the Food and Drug Administration ( FDA ) for the marketing of our TMR products for treatment of patients suffering from chronic, severe angina. Effective July 1999, the Centers for Medicare and Medicaid Services ( CMS ), formerly known as the Health Care Financial Administration ( HCFA ) implemented a national coverage decision for Medicare coverage for any TMR as a primary and secondary procedure. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on indicated Medicare patients.

In December 2004, we received FDA approval for the Solargen 2100s, the advanced laser console for TMR. In addition, in November 2007 we received FDA approval for the PEARL 5.0 robotic handpiece delivery system designed for delivering TMR therapy with surgical robotic systems. We are in the process of completing the IDE trial for the PEARL 8.0 Thoracoscopic handpiece delivery system, and are supporting the initial clinical application of the Phoenix combination delivery system in Europe and other international locations.

As of December 31, 2007, we had an accumulated deficit of \$169,535,000. Although we have achieved operating income during the year ended December 31, 2007, we do not have a history of operating income. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

### **Results of Operations**

#### ***Year Ended December 31, 2007 Compared to Year Ended December 31, 2006***

##### *Net Revenues*

We generate our revenues primarily through the sale of our TMR laser base units, related handpieces, and related services. The handpieces are a single use product and are considered to be disposable units. In addition, we frequently loan lasers to hospitals in accordance with our loaned laser programs. Under certain loaned laser programs we charge the customer an additional amount over the stated list price on our handpieces in exchange for the use of the laser or we collect an upfront deposit that can be applied towards the purchase of a laser.

Net revenues of \$12,059,000 for the year ended December 31, 2007 decreased \$5,058,000, or 30%, when compared to net revenues of \$17,117,000 for the year ended December 31, 2006. The decrease in net revenues was due to a decrease in handpiece revenues of \$3,251,000 and laser revenues of \$1,927,000, partially offset by a \$120,000 increase in service and other revenues.

For the year ended December 31, 2007, domestic laser sales decreased by \$1,922,000 compared to the year ended December 31, 2006 primarily due to a decrease in unit sales.

The decrease in domestic handpiece revenue of \$3,228,000 was attributed primarily to a decrease in unit sales. Domestic handpiece revenue for the year ended December 31, 2007 consisted of \$895,000 in sales to customers

## **Table of Contents**

operating under our loaned laser program as compared to \$2,026,000 in sales of product to customers operating under our loaned laser program in 2006. In the years ended December 31, 2007 and 2006, sales of product to customers not operating under our loaned laser program were \$7,211,000 and \$9,308,000, respectively.

International sales of \$353,000, accounted for approximately 3% of total sales for the year ended December 31, 2007, a decrease of approximately \$23,000 from the prior year when international sales were \$376,000 and accounted for 2% of total sales. The decrease in international sales occurred primarily as a result of a \$23,000 decrease in handpiece revenues as a result of a decrease in unit sales and average handpiece unit sales price.

We believe that in fiscal 2007 our revenues were adversely affected by sales force turnover, which resulted in a lack of consistent customer coverage for the year. Our sales can vary depending on the level of sales force interaction with customers and can also be influenced by the amount of turnover that is experienced within the physician community using our products.

### *Gross Profit*

Gross profit decreased to 76% of net revenues for the year ended December 31, 2007 as compared to 79% of net revenues for the year ended December 31, 2006. Gross profit in absolute dollars decreased by \$4,363,000, or 32%, to \$9,110,000 for the year ended December 31, 2007, as compared to \$13,473,000 for the year ended December 31, 2006. The overall decrease in gross margin for the year ended December 31, 2007 resulted primarily from inventory obsolescence charges totaling approximately \$533,000. Of this amount, \$271,000 was related to the TMR 2000 laser product line. In the fourth quarter of 2007, we announced to our customers that since our TMR 2000 component inventory on hand was limited and no longer being manufactured, we would no longer be able to guarantee component availability to service and support the TMR 2000 laser. Therefore, we recorded an impairment charge for the TMR 2000 laser finished goods and excess parts used to maintain and service TMR 2000 lasers. In addition, \$221,000 of the inventory obsolescence charges were related to expired product associated with the PMC product line.

### *Research and Development*

Research and development expense represents expenses incurred in connection with the development of technologies and products including the costs of third party studies, salaries and stock based compensation associated with research and development personnel. Research and development expenditures of \$681,000 decreased \$793,000, or 54%, for the year ended December 31, 2007 as compared to \$1,474,000 for the year ended December 31, 2006. As a percentage of revenues, research and development expenditures were 6% for the year ended December 31, 2007 as compared to 9% for the prior year period. The decrease in expenditures as a percentage of revenue and in dollars was primarily due to a decrease in employee related expenses of approximately \$330,000 due to a reduction in headcount, a decrease of approximately \$306,000 related to the mechanism of action study completed in 2006, and an approximate \$161,000 additional reduction in expenses for other research and development projects.

### *Salaries and Employee Benefits*

Salaries and employee benefit expense represents expenses incurred in connection with the salaries, stock based compensation, commissions, taxes and benefits for employees, excluding expenses associated with research and development personnel which are included in research and development expense. For the year ended December 31, 2007, salaries and employee benefits of \$4,800,000 decreased \$2,984,000, or 38%, when compared to \$7,784,000 for the year ended December 31, 2006. As a percentage of revenues, salaries and employee benefits expenditures were 40% for the year ended December 31, 2007 as compared to 45% for the prior year period. The dollar and percentage decrease in salaries and employee benefits resulted primarily from a decrease in sales-based commissions of approximately \$1,527,000 and a reduction in salary expense of \$1,475,000 associated with both a lower average

headcount in 2007 as compared to 2006 and the \$682,000 of expense incurred in 2006 in connection with the legal settlement reached in 2006 with our former Chairman, Chief Executive Officer and President.

**Table of Contents***Sales, General and Administrative*

Sales, general and administrative expenditures represent all other operating expenses not included in research and development or salaries and employee benefits expenses. For the year ended December 31, 2007, sales, general and administrative expenditures ( SG&A ) totaled \$2,773,000, or 23% of net revenues, as compared to \$5,691,000, or 33% of net revenues for the year ended December 31, 2006. This represents a reduction of \$2,918,000, or 51%. The decrease in SG&A both in dollars and as a percentage of net revenues for the 2007 year end as compared to the 2006 period resulted primarily from a \$771,000 reduction in accounting, legal and miscellaneous outside services, a \$730,000 reduction related to the impairment charge recorded in 2006 for the PLC license described below and an additional \$195,000 related to the PLC license amortization during 2006, a \$442,000 reduction in employee related expenses due to the lower average headcount, a \$277,000 decrease in certain facility costs related to our move to the new corporate office in 2006, a \$178,000 decrease in bad debt expense and a \$108,000 reduction in depreciation expense.

In December 2006, we recorded an impairment charge of \$730,000 that was included in sales, general and administrative expense related to the write-off of the PLC license. On January 5, 1999, we entered into an Agreement ( the PLC agreement ) with PLC Systems, Inc. ( PLC ), which granted us a non-exclusive worldwide use of certain PLC patents. In return, we agreed to pay PLC a fee totaling \$2,500,000 over an approximately forty-month period. The present value of these payments of \$2,300,000 was recorded as a prepaid asset, included in other assets, and was being amortized over the life of the underlying patents. The patents covered in the PLC agreement are valuable to the Company's Percutaneous Myocardial Channeling ( PMC ) product line. The PMC product line is not approved for sale in the United States but is sold internationally.

In the fourth quarter of 2006, we evaluated the costs involved in carrying out the clinical trials to obtain FDA approval and decided to devote resources to our core business rather than to pursue this course of action. We will continue to sell the PMC product internationally, but without obtaining FDA approval, the product's potential sales volume will be significantly limited. Based on our analysis of the related undiscounted cash flows, we determined that the asset was fully impaired at December 31, 2006.

Prior to the write down of this asset, the patent was being amortized on a straight-line basis at a rate of \$195,000 per year through 2010 and the related amortization expense was included in sales, general and administrative expenses in the consolidated statements of operations included elsewhere in this annual report.

*Other Income (Expense)*

The following table reflects the components of other income (expense):

	<b>Years Ended December 31, 2007      2006 (\$ In thousands)</b>	
Interest expense    Secured Convertible Term Note	\$ (51)	\$ (241)
Interest expense    Secured Convertible Term Note prepayment penalty		(483)
Interest expense    other	(18)	(57)
Interest income	120	132
Gain on insurance settlement		70
Loss on disposal of assets	(2)	(111)

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

Non cash interest expense	Accretion of discount on Note	(72)	(667)
Non cash interest expense	Amortization of debt issuance costs relating to the Note	(17)	(164)
Change in fair value of derivatives		(376)	613
Change in fair value of warrants		151	407
Total other expense, net		\$ (265)	\$ (501)



## **Table of Contents**

For the year ended December 31, 2007, total other expense, net was \$265,000 as compared to total other expense, net of \$501,000 for the year ended December 31, 2006. The net other expense incurred in the year ended December 31, 2006 was primarily due to the recognition of a prepayment penalty and the acceleration of the amortization of the debt discount and debt issuance costs associated with the prepayment of the restricted cash balance on the Note in the prior year. During the year ended December 31, 2007, we incurred an expense of \$376,000 related to the change in fair value of the derivatives associated with the Laurus Note described in Liquidity and Capital Resources below. In addition, there was other income of \$151,000 in 2007 associated with the change in fair value of the warrants issued to Laurus (as described below).

## **Liquidity and Capital Resources**

Cash and cash equivalents were \$2,824,000 at December 31, 2007 compared to \$2,118,000 at December 31, 2006, an increase of \$706,000. Net cash provided by operating activities was \$1,908,000 for the twelve months ended December 31, 2007 primarily due to a decrease in accounts receivable as a result of the decrease in sales. Net cash provided by operating activities was \$1,887,000 for the twelve months ended December 31, 2006 primarily due to an increase in deferred revenue related to an increase in service contracts, an increase in inventory, and an increase in collections.

Cash used in investing activities during the twelve months ended December 31, 2007 was \$61,000 related to the acquisition of property and equipment. Cash used in investing activities during the twelve months ended December 31, 2006 was \$84,000 related to the acquisition of property and equipment offset by insurance proceeds received.

Cash used in financing activities for the year ended December 31, 2007 was \$1,141,000 primarily due to payments on the secured convertible term note. Cash used in financing activities for the year ended December 31, 2006 was \$1,528,000 primarily due to payments on the secured convertible term note and for insurance premiums.

In October 2004, we completed a financing transaction with Laurus Master Fund, Ltd, a Cayman Islands corporation ( Laurus ), pursuant to which we issued a Secured Convertible Term Note in the aggregate principal amount of \$6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of our common stock at a price of \$0.50 per share to Laurus in a private offering. Net proceeds to us from the financing, after payment of fees and expenses to Laurus and its affiliates, were \$5,752,500. Of this amount, we received \$2,875,250 which was deposited in a restricted cash account. In May 2006, we repaid \$2,417,000 of the Note's outstanding principal amount out of the restricted cash account created for the benefit of Laurus and us and related interest of \$314,000. In connection with the repayment, we were required to pay a prepayment penalty of \$483,000 out of our unrestricted cash. In October 2007, the Note matured and was paid in full.

Prior to 2007, we had incurred significant operating losses for several years and at December 31, 2007 we had an accumulated deficit of \$169,535,000. Our ability to maintain current operations is dependent upon maintaining our sales at least at the same levels achieved this year.

Currently, our primary goal is to sustain profitability at the operating level. Our actions have been guided by this initiative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of December 31, 2007, our projected cash flows from operations and actions we have taken to reduce sales, general and administrative expenses will be sufficient to meet our capital, debt and operating requirements through the next 12 months. We believe that if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our

operations until an appropriate solution is implemented.

We will have a continuing need for new infusions of cash if we incur losses or are otherwise unable to generate positive cash flow from operations in the future. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce

## **Table of Contents**

our operations. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and that we will not have sufficient cash to fund our operations.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The following presents a summary of our critical accounting policies and estimates, defined as those policies and estimates we believe are: (i) the most important to the portrayal of our financial condition and results of operations, and (ii) that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Our most significant estimates made in preparing the consolidated financial statements include (but are not limited to) the determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax assets, warranty reserve, the assessment of future cash flows in evaluating intangible assets for impairment and assumptions used in fair value determination of warrants, derivatives, and stock options.

#### ***Revenue Recognition:***

We recognize revenue on product sales upon shipment of the products when the price is fixed or determinable and when collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence of an arrangement, delivery has occurred, the sales price is fixed or determinable and collection of the sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

We frequently loan lasers to hospitals in accordance with our loaned laser programs. Under certain loaned laser programs we charge the customer an additional amount (the Premium) over the stated list price on our handpieces in exchange for the use of the laser or we collect an upfront deposit that can be applied towards the purchase of a laser.

These arrangements meet the definition of a lease and are recorded in accordance with Statement of Financial Accounting Standards No. 13, *Accounting for Leases*, ( SFAS No. 13 ) as they convey the right to use the lasers over the period of time the customers are purchasing handpieces. Based on the provisions of SFAS No. 13, the loaned lasers are classified as operating leases and are transferred from inventory to fixed assets upon commencement of the loaned laser program. In addition, the Premium is considered contingent rent under Statement of Financial Accounting Standards No. 29, *Determining Contingent Rentals*, ( SFAS No. 29 ) and therefore, such amounts allocated to the lease of the laser should be excluded from minimum lease payments and should be recognized as revenue when the contingency is resolved. In these instances, the contingency is removed upon the sale of the handpiece.

We enter into contracts to sell our products and services and, while the majority of our sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the contract value should be allocated

among the deliverable elements and when to recognize revenue for each element. We recognize revenue for such multiple element arrangements in accordance with Emerging Issues Task Force Issue ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

## **Table of Contents**

### ***Accounts Receivable:***

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product sales, reduced by reserves for the estimated amount deemed uncollectible due to bad debt. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review the allowance for doubtful accounts quarterly with the corresponding provision included in general and administrative expenses. Past due balances over 90 days and over a specified amount are reviewed individually for collectibility. All other balances are reviewed on a pooled basis by type of receivable. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

### ***Inventories:***

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value. We regularly monitor potential excess, or obsolete, inventory by analyzing the usage for parts on hand and comparing the market value to cost. When necessary, we reduce the carrying amount of our inventory to its market value.

### ***Valuation of Long-lived Assets:***

We review the recoverability of the carrying value of long-lived assets on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is determined based upon the forecasted undiscounted future net cash flows from the operations to which the assets relate, utilizing our best estimates, appropriate assumptions and projections at the time. These projected future cash flows may vary significantly over time as a result of increased competition, changes in technology, fluctuations in demand, consolidation of our customers and reductions in average selling prices. If the carrying value is determined not to be recoverable from future operating cash flows, the asset is deemed impaired and an impairment loss is recognized to the extent the carrying value exceeds the estimated fair market value of the asset.

### ***Income Taxes:***

We account for income taxes using the asset and liability method under which deferred tax assets or liabilities are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

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

We account for equity issuances to non-employees in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 123, *Accounting for Stock Based Compensation*, and Emerging Issues Task Force ( EITF ) Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods and Services*. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the third-party performance is complete or the date on which it is probable that performance will occur.

Prior to January 1, 2006, we accounted for stock-based compensation issued to employees using the intrinsic value method of accounting prescribed by Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued*

*to Employees* and related pronouncements. Under this method, compensation expense was recognized over the respective vesting period based on the excess, on the date of grant, of the fair value of our common stock over the grant price, net of forfeitures. There was no stock-based compensation expense for the year ended December 31, 2005.

**Table of Contents**

On January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors related to our Amended and Restated 2000 Equity Incentive Plan based on estimated fair values. We adopted SFAS No. 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our consolidated financial statements as of and for the years ended December 31, 2007 and 2006 reflect the impact of adopting SFAS No. 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R). The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our consolidated statement of operations. As stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rate for the years ended December 31, 2007 and 2006 was based on historical forfeiture experience and estimated future employee forfeitures. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

**Recently Issued Accounting Standards**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after December 15, 2007. We plan to adopt SFAS No. 157 beginning in the first quarter of 2008. We are currently evaluating the impact, if any, that adoption of SFAS No. 157 will have on our operating income (loss) or net income (loss).

On February 15, 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* Including an Amendment of FASB Statement No. 115 ( SFAS No. 159 ). SFAS No. 159 permits an entity to choose to measure many financial instruments and certain other items at fair value. Most of the provisions in SFAS No. 159 are elective; however, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The fair value option established by SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided that the entity makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of FASB Statement No. 157, *Fair Value Measurements*. The adoption of this pronouncement is not expected to have a material effect on our consolidated financial statements.

In June 2007, the FASB ratified a consensus opinion reached on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF Issue No. 07-3 ). The guidance in EITF Issue No. 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue No. 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning

after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue No. 07-3 is also not permitted. We intend to adopt EITF Issue No. 07-3 effective January 1, 2008. The impact of



## **Table of Contents**

applying this consensus will depend on the terms of our future research and development contractual arrangements entered into on or after December 15, 2007.

Other recent accounting pronouncements issued by the FASB (including the EITF) and the American Institute of Certified Public Accountants did not or are not believed by management to have a material impact on our present or future consolidated financial statements.

### **Item 7. *Financial Statements***

The information required by Item 7 is included on pages F-1 to F-24 immediately following the signature page.

### **Item 8. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

### **Item 8A(T). *Controls and Procedures.***

#### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

#### **Management's Report 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 Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 based on the criteria set forth in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we engaged our independent registered public accounting firm to perform, an audit on our internal control over financial reporting pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations on Internal Control**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can

**Table of Contents**

provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple errors. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Item 8B. *Other Information.***

None.

**PART III**

**Item 9. *Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance With Section 16(a) of the Exchange Act.***

Information required under Item 9 will be presented in the Company's 2008 definitive proxy statement which is incorporated herein by this reference.

**Item 10. *Executive Compensation.***

Information required under Item 10 will be presented in the Company's 2008 definitive proxy statement which is incorporated herein by this reference.

**Item 11. *Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.***

Information required under Item 11 will be presented in the Company's 2008 definitive proxy statement which is incorporated herein by this reference.

**Equity Compensation Plan Information**

See Part II, Item 5 of this Form 10-KSB for certain information regarding the Company's equity compensation plans.

**Item 12. *Certain Relationships and Related Transactions, and Director Independence***

Information required under Item 12 will be presented in the Company's 2008 definitive proxy statement which is incorporated herein by this reference.

**Item 13. *Exhibits.***

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1.1(1)	Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996
3.1.2(2)	Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001

- 3.1.3(3) Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
- 3.1.4(4) Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
3.2(5)	Amended and Restated Bylaws
4.1(6)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A.
4.2(7)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.3(8)	First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.4(9)	Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.5(10)	Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
4.6(11)	Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
4.7(12)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share
4.8(13)	Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.9(14)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.10(15)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(16)*	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(17)*	Stock Option Plan, as amended and restated July 2005
10.3(18)*	Director Stock Option Plan, as amended and restated July 2005
10.4(19)*	Employee Stock Purchase Plan, as amended and restated July 2005
10.5(20)	Lease for the Company's executive offices in Irvine, California
10.6(21)*	401(k) Plan, as restated January 1, 2005
10.8(22)*	Description of the Stock Option Plan
10.9(23)*	Description of the Director Stock Option Plan
10.10(24)*	Form of Stock Option Agreement for Executive Officers under the Stock Option Plan
10.11(25)*	Form of Grant Notice under the Stock Option Plan
10.12(26)*	Form of Stock Option Agreement for Directors under the Director Stock Option Plan
10.13(27)*	Form of Grant Notice under the Director Stock Option Plan
10.14(28)*	Settlement Agreement and General Release between the Registrant and Michael J. Quinn, dated October 24, 2006
10.15(29)*	Summary of Director Compensation
10.16(30)*	Employment Agreement between the Registrant and Richard Lanigan
10.17(31)*	Employment Agreement between the Registrant and William Abbott
21.1(32)	List of Subsidiaries
23.1(32)	Consent of KMJ Corbin & Company LLP
31.1(32)	Certification of the President pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
31.2(32)	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1(32)	Certifications of the President and 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, compensatory plan or arrangement	
(1)	Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1/A (File No. 33-03770), filed May 21, 1996
(2)	Incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 14, 2001
(3)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on August 20, 2001
(4)	Incorporated by reference to Exhibit 3.1.4 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
(5)	Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
(6)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(7)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 26, 2004
(8)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 18, 2002
(9)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed August 20, 2001
(10)	Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(11)	Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(12)	Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(13)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(14)	Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(15)	Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(16)	Incorporated by reference to the Company's Registration Statement on Form S-1 (File No. 333-03770), as amended, filed April 18, 1996

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

- (17) Incorporated by reference to Exhibit 10.2 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
- (18) Incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
- (19) Incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
- (20) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 10-K filed August 25, 2006
- (21) Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed March 31, 2005
- (22) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 4, 2005

**Table of Contents**

- (23) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (24) Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (25) Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (26) Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (27) Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (28) Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-KSB filed on March 29, 2007
- (29) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-QSB filed on August 14, 2007
- (30) Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on August 1, 2007
- (31) Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K filed on August 1, 2007
- (32) Filed herewith

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

Incorporated by reference to the portions of the Definitive Proxy Statement entitled "Independent Registered Public Accounting Firm" and "Audit Committee Policy on Pre-Approval of Services of Independent Registered Public Accounting Firm."



**Table of Contents**

**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.**

CARDIOGENESIS CORPORATION

By: /s/ RICHARD P. LANIGAN  
Richard P. Lanigan  
*President*

Date: March 25, 2008

**Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the date indicated.**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ RICHARD P. LANIGAN Richard P. Lanigan	President <i>(Principal Executive Officer)</i>	March 25, 2008
/s/ WILLIAM R. ABBOTT William R. Abbott	Senior Vice President, Chief Financial Officer, Secretary and Treasurer <i>(Principal Financial and Accounting Officer)</i>	March 25, 2008
/s/ GARY S. ALLEN, M.D. Gary S. Allen, M.D.	Director	March 25, 2008
/s/ PAUL J. MCCORMICK Paul J. McCormick	Director	March 25, 2008
/s/ ROBERT L. MORTENSEN Robert L. Mortensen	Director	March 25, 2008
/s/ MARVIN J. SLEPIAN, M.D. Marvin J. Slepian, M.D.	Director	March 25, 2008
/s/ GREGORY D. WALLER Gregory D. Waller	Director	March 25, 2008



**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated balance sheet at December 31, 2007</u>	F-3
<u>Consolidated statements of operations for the years ended December 31, 2007 and 2006</u>	F-4
<u>Consolidated statements of shareholders' equity for the years ended December 31, 2007 and 2006</u>	F-5
<u>Consolidated statements of cash flows for the years ended December 31, 2007 and 2006</u>	F-6
<u>Notes to consolidated financial statements</u>	F-7

F-1

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders  
Cardiogenesis Corporation and Subsidiaries

We have audited the accompanying consolidated balance sheet of Cardiogenesis Corporation and subsidiaries (the Company ) as of December 31, 2007 and the related consolidated statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cardiogenesis Corporation and subsidiaries as of December 31, 2007 and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

As described in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based compensation to adopt Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

/s/ KMJ Corbin & Company LLP  
KMJ Corbin & Company LLP

Irvine, California  
March 24, 2008

**Table of Contents**

**CARDIOGENESIS CORPORATION**  
**CONSOLIDATED BALANCE SHEET**  
**December 31, 2007**

	<b>(In thousands)</b>
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	\$ 2,824
Accounts receivable, net of allowance for doubtful accounts of \$28	1,763
Inventories	1,602
Prepays and other current assets	486
<b>Total current assets</b>	<b>6,675</b>
Property and equipment, net	457
Other assets	27
<b>Total assets</b>	<b>\$ 7,159</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>	
Current liabilities:	
Accounts payable	\$ 169
Accrued liabilities	1,458
Deferred revenue	1,210
Current portion of capital lease obligation	12
<b>Total current liabilities</b>	<b>2,849</b>
Capital lease obligation, less current portion	19
<b>Total liabilities</b>	<b>2,868</b>
Commitments and contingencies	
Shareholders' equity:	
Preferred stock:	
no par value; 5,000 shares authorized; none issued and outstanding	
Common stock:	
no par value; 75,000 shares authorized; 45,274 shares issued and outstanding	173,826
Accumulated deficit	(169,535)
<b>Total shareholders' equity</b>	<b>4,291</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 7,159</b>

Table of Contents**CARDIOGENESIS CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For the Years Ended December 31, 2007 and 2006**

	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except per share amounts)</b>	
Net revenues	\$ 12,059	\$ 17,117
Cost of revenues	2,949	3,644
Gross profit	9,110	13,473
Operating expenses:		
Research and development	681	1,474
Salaries and employee benefits	4,800	7,784
Sales, general and administrative	2,773	5,691
Total operating expenses	8,254	14,949
Operating income (loss)	856	(1,476)
Other income (expense):		
Interest expense	(69)	(781)
Interest income	120	132
Gain on insurance settlement		70
Loss on disposal of fixed assets	(2)	(111)
Non-cash interest expense	(89)	(831)
Change in fair value of derivatives and warrants	(225)	1,020
Total other expense, net	(265)	(501)
Income (loss) before income taxes	591	(1,977)
Tax provision	13	2
Net income (loss)	\$ 578	\$ (1,979)
Net income (loss) per share:		
Basic	\$ 0.01	\$ (0.04)
Diluted	\$ 0.01	\$ (0.04)
Weighted average shares outstanding:		
Basic	45,274	45,274
Diluted	45,274	45,274



Table of Contents**CARDIOGENESIS CORPORATION****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY****For the Years Ended December 31, 2007 and 2006**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>(In thousands)</b>			
Balances, December 31, 2005	45,102	173,000	(168,134)	4,866
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	56			
Issuance of common stock for option exercises	116	37		37
Vesting of share-based awards		364		364
Net loss			(1,979)	(1,979)
Balances, December 31, 2006	45,274	\$ 173,401	\$ (170,113)	\$ 3,288
Vesting of share-based awards		77		77
Reclassification of warrants fair value to equity		348		348
Net income			578	578
Balances, December 31, 2007	45,274	\$ 173,826	\$ (169,535)	\$ 4,291

F-5



**Table of Contents****CARDIOGENESIS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the Years Ended December 31, 2007 and 2006**

	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Cash flows from operating activities:		
Net income (loss)	\$ 578	\$ (1,979)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Derivative and warrant fair value adjustments	225	(1,020)
Amortization related to discount on notes payable	72	667
Impairment of PLC license		730
Loss on disposal of fixed assets	2	111
Depreciation and amortization	464	667
Provision for doubtful accounts	62	183
Interest income on restricted cash		(39)
Stock-based compensation expense	77	364
Amortization of other assets		195
Amortization of debt issuance costs	17	164
Gain on insurance settlement		(70)
Changes in operating assets and liabilities:		
Accounts receivable	502	557
Inventories	382	189
Prepays and other current assets	(65)	280
Other assets	19	20
Accounts payable	(157)	(751)
Accrued liabilities	(148)	681
Deferred revenue	(122)	938
Net cash provided by operating activities	1,908	1,887
Cash flows from investing activities:		
Acquisition of property and equipment	(61)	(154)
Insurance proceeds received		70
Net cash used in investing activities	(61)	(84)
Cash flows from financing activities:		
Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan		37
Payments on short term borrowings	(89)	(308)
Repayments on secured convertible term note	(1,041)	(1,251)
Repayments of capital lease obligations	(11)	(6)
Net cash used in financing activities	(1,141)	(1,528)

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

Net increase in cash and cash equivalents	706	275
Cash and cash equivalents at beginning of year	2,118	1,843
Cash and cash equivalents at end of year	\$ 2,824	\$ 2,118
Supplemental schedule of cash flow information:		
Interest paid	\$ 54	\$ 146
Taxes paid	\$ 35	\$ 30
Supplemental schedule of noncash investing and financing activities:		
Financing of insurance premiums	\$	\$ 381
Financing of fixed assets	\$	\$ 31
Repayment of restricted cash portion of secured convertible term note and accrued interest	\$	\$ 2,547
Reclassification of warrants fair value to equity	\$ 348	\$
Reclassification of inventories to property and equipment	\$ 247	\$ 306

F-6

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Operations:**

Cardiogenesis Corporation ( Cardiogenesis or the Company ) was founded in 1989 to design, develop, and distribute surgical lasers and accessories for the treatment of cardiovascular disease. Currently, Cardiogenesis emphasis is on the development of products used for transmyocardial revascularization ( TMR ) and percutaneous myocardial channeling ( PMC ), which are cardiovascular procedures. PMC was formerly referred to as percutaneous myocardial revascularization ( PMR ). The new name PMC more literally depicts the immediate physiologic tissue effect of the Cardiogenesis PMC system to ablate precise, partial thickness channels into the heart muscle from the inside of the left ventricle.

Cardiogenesis markets its products for sale primarily in the U.S., Europe and Asia. Cardiogenesis operates in a single segment.

These consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Although Cardiogenesis has achieved operating income during the year ended December 31, 2007, it does not have a history of operating income. Management believes its cash and cash equivalents as of December 31, 2007 and expected results of operations is sufficient to meet the Company s capital and operating requirements for the next 12 months.

Cardiogenesis may require additional financing in the future. There can be no assurance that Cardiogenesis will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to Cardiogenesis stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the execution of the Company s business plan, operating results or financial condition. Cardiogenesis long term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the execution of the Company s business plan, operating results or financial condition.

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

These consolidated financial statements include accounts of the Company and its wholly owned subsidiaries, which are all inactive. All material intercompany accounts have been eliminated in consolidation.

***Use of Estimates:***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made in preparing the consolidated financial statements include (but are not limited to) the determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax assets, warranty reserve, the assessment of future cash flows in evaluating intangible assets for impairment and assumptions used in fair value determination of warrants, derivatives, and stock options.

***Reclassification:***

Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

***Cash and Cash Equivalents:***

All highly liquid instruments purchased with a maturity of three months or less at the time of purchase are considered cash equivalents.

F-7

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

***Accounts Receivable:***

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product sales, reduced by reserves for the estimated amount deemed uncollectible due to bad debt. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company reviews the allowance for doubtful accounts quarterly with the corresponding provision included in general and administrative expenses. Past due balances over 90 days and over a specified amount are reviewed individually for collectibility. All other balances are reviewed on a pooled basis by type of receivable. Account balances are charged off against the allowance when the Company feels it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to its customers.

***Inventories:***

Inventories are stated at the lower of cost (principally at actual cost determined on a first-in, first-out basis) or market value. The Company regularly monitors potential excess or obsolete inventory by analyzing the usage for parts on hand and comparing the market value to cost. When necessary, the Company reduces the carrying amount of inventory to its market value.

***Patent Expenses:***

Patent and patent related expenditures are expensed as general and administrative expenses as incurred.

***Property and Equipment:***

Property and equipment are stated at cost and depreciated on a straight-line basis over their estimated useful lives of two to seven years. Assets acquired under capital leases are amortized over the shorter of their estimated useful lives or the term of the related lease (generally three to five years). Amortization of leasehold improvements is based on the straight-line method over the shorter of the estimated useful life or the lease term.

***Accounting for the Impairment or Disposal of Long-Lived Assets:***

The Company assesses potential impairment of finite lived, intangible assets and other long-lived assets when there is evidence that recent events or changes in circumstances indicate that their carrying value may not be recoverable. Reviews are performed to determine whether the carrying value of assets is impaired based on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the asset's carrying value over its fair value. Events or changes in circumstances which may cause impairment include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

***Fair Value of Financial Instruments:***

The Company's financial instruments consist primarily of cash and cash equivalents, accounts receivable, trade accounts payable, accrued liabilities and capital lease obligations. The carrying amounts of certain Cardiogenesis

financial instruments including cash and cash equivalents, accounts receivable, trade accounts payable, accrued liabilities, and capital lease obligations approximate fair value due to their short maturities.

***Derivative Financial Instruments:***

In October 2004, the Company completed a financing transaction with Laurus Master Fund, Ltd., a Cayman Islands corporation ( Laurus ), pursuant to which the Company issued a Secured convertible term note (the Note ). Prior to the repayment of the Note in October 2007, the Company s derivative financial instruments

F-8

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

consisted of embedded derivatives related to the \$6,000,000 Note. These embedded derivatives included certain conversion features and variable interest features. The accounting treatment of derivatives required that the Company record the derivatives at their relative fair values as of the inception date of the agreement, and at fair value as of each subsequent balance sheet date until the Note was paid off. Any change in fair value was recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives was higher at the subsequent balance sheet date, the Company recorded a non-operating, non-cash charge. If the fair value of the derivatives was lower at the subsequent balance sheet date, the Company recorded non-operating, non-cash income. As a result of the repayment of the Note in October 2007, the Company does not have any derivative financial instruments, see Note 7.

***Revenue Recognition:***

Cardiogenesis recognizes revenue on product sales upon shipment of the products when the price is fixed or determinable and when collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence of an arrangement, delivery has occurred, the sales price is fixed or determinable and collection of the sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

The Company frequently loans lasers to hospitals in accordance with its loaned laser programs. Under certain loaned laser programs the Company charges the customer an additional amount (the Premium ) over the stated list price on its handpieces in exchange for the use of the laser or collects an upfront deposit that can be applied towards the purchase of a laser. These arrangements meet the definition of a lease and are recorded in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 13, *Accounting for Leases*, as they convey the right to use the lasers over the period of time the customers are purchasing handpieces. Based on the provisions of SFAS No. 13, the loaned lasers are classified as operating leases and are transferred from inventory to fixed assets upon commencement of the loaned laser program. In addition, the Premium is considered contingent rent under SFAS No. 29, *Determining Contingent Rentals*, and therefore, such amounts allocated to the lease of the laser should be excluded from minimum lease payments and should be recognized as revenue when the contingency is resolved. In these instances, the contingency is resolved upon the sale of the handpiece.

Cardiogenesis enters into contracts to sell its products and services and, while the majority of its sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the contract value should be allocated among the deliverable elements and when to recognize revenue for each element. The Company recognizes revenue for such multiple element arrangements in accordance with Emerging Issues Task Force Issue ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

***Shipping and Handling Costs and Revenues***

All shipping and handling costs are expensed as incurred and are recorded as a component of cost of sales. Amounts billed to customers for shipping and handling are included as a component of revenue.

***Research and Development:***

Research and development costs are charged to operations as incurred.

F-9

---



**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

***Warranties:***

Cardiogenesis laser products are generally sold with a one year warranty. Cardiogenesis provides for estimated future costs of repair or replacement which are reflected in accrued liabilities in the accompanying financial statements and approximate \$28,000 at December 31, 2007. There was no significant warranty activity during the years ended December 31, 2006 and 2007.

***Advertising:***

Cardiogenesis expenses all advertising as incurred. Cardiogenesis advertising expenses were \$135,000 and \$193,000 for 2007 and 2006, respectively. Advertising expenses include fees for website design and hosting, reprints from medical journals, promotional materials and sales sheets.

***Income Taxes:***

Cardiogenesis accounts for income taxes using the asset and liability method under which deferred tax assets or liabilities are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

***Stock-Based Compensation:***

On January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*, ( SFAS 123(R) ) which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, primarily focusing on accounting for transactions where an entity obtains employee services in share-based payment transactions. SFAS 123(R) requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant-date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) for periods beginning in fiscal 2006. In March 2005, the SEC issued SAB 107 relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's consolidated financial statements for the years ended December 31, 2007 and 2006 reflect the impact of SFAS 123(R).

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statements of operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). Under the intrinsic value method, stock-based compensation expense was recognized in the Company's consolidated statements of operations for option grants to employees and directors below the fair

market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company's consolidated statements of operations for the years ended December 31, 2007 and 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested, as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31,

F-10

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). As stock-based compensation expense recognized in the consolidated statements of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rate for the years ended December 31, 2007 and 2006 was based on historical forfeiture experience and expected future employee forfeitures.

SFAS 123(R) requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options to be classified as financing cash flows. There were no such tax benefits during the years ended December 31, 2007 and 2006. Prior to the adoption of SFAS 123(R) those benefits would have been reported as operating cash flows had the Company received any tax benefits related to stock option exercises.

***Description of Plans:***

The Company's stock option plans provide for grants of options to employees and directors of the Company to purchase the Company's shares at the fair value of such shares on the grant date (based on the closing price of the Company's common stock). The options vest immediately or up to four years beginning on the grant date and have a 10-year term. The terms of the option grants are determined by the Company's Board of Directors. As of December 31, 2007, the Company is authorized to issue up to 12,125,000 shares under these plans.

The Company's 1996 Employee Stock Purchase Plan (the ESPP) was adopted in April 1996. A total of 1,500,000 common shares are reserved for issuance under this plan, as amended. Future increases may occur on the first day of each year until 2015, in amounts that the Board of Directors determines. This plan permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. The ESPP has two offering periods, the first one from May 16 through November 15 and the second one from November 16 through May 15. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply.

The Company has treated the ESPP as a compensatory plan and has recorded compensation expense of approximately \$1,000 and \$87,000 during the year ended December 31, 2007 and 2006, respectively, in accordance with SFAS No. 123(R).

From November 15, 2006 to November 15, 2007, the Company suspended the ESPP. As of November 16, 2007, the ESPP has been reinstated. During the years ended December 31, 2007 and 2006, there were no purchases of shares under the ESPP.

***Summary of Assumptions and Activity***

The fair value of stock-based awards to employees and directors is calculated using the Black-Scholes option pricing model, even though the model was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which differ significantly from the Company's stock options. The Black-Scholes model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which

greatly affect the calculated values. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the term of the grant effective as of the date of the grant. The expected volatility is based on the historical volatility of the Company's stock price. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods.

F-11

---

Table of Contents**CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The weighted-average fair value of stock-based compensation is based on the single option valuation approach. Forfeitures are estimated and it is assumed no dividends will be declared. The estimated fair value of stock-based compensation awards to employees is amortized using the straight-line method over the vesting period of the options.

The Company's fair value calculations for stock-based compensation awards to employees under its stock option plans for the years ended December 31, 2007 and 2006 were based on the following assumptions:

	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Expected term	4 years	4 years
Expected volatility	94%	106%
Risk-free interest rate	3.1 - 5.1%	4.9%
Expected dividends		

Compensation expense under the ESPP is measured as the fair value of the employees' purchase rights during the look-back option period as calculated under the Black-Scholes option pricing model. The weighted average assumptions used in the model are outlined in the following table:

	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Expected term	0.50 years	0.50 years
Expected volatility	94%	106%
Risk-free interest rate	3.1 - 5.1%	4.9%
Expected dividends		

A summary of option activity as of December 31, 2007 and changes during the year then ended, is presented below:

	<b>Shares (In thousands)</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Options outstanding at December 31, 2006	3,491	\$ 0.89		

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

Options granted	1,048	\$	0.30		
Options exercised					
Options forfeited/canceled	(1,447)	\$	0.56		
Options expired	(16)	\$	7.58		
Options outstanding at December 31, 2007	3,076	\$	0.81	5.8	\$ 61,000
Vested or expected to vest	2,914	\$	0.83	5.6	\$ 52,000
Options exercisable at December 31, 2007	2,266	\$	0.98	4.5	\$ 13,000

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the quoted price of the Company's common stock for the approximately 943,000 outstanding and 245,000 exercisable stock options that were in-the-money at December 31, 2007.

The weighted average grant date fair value of options granted during the year ended December 31, 2007 was \$0.22 per option.

F-12

---

**Table of Contents****CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2007, there was approximately \$166,000 of total unrecognized compensation cost related to employee and director stock option compensation arrangements. That cost is expected to be recognized over the weighted average vesting period of 2.5 years. For the years ended December 31, 2007 and 2006, the amount of stock-based compensation expense related to stock options was approximately \$76,000 and \$277,000, respectively. For the years ended December 31, 2007 and 2006, the amount of stock-based compensation expense related to ESPP purchases was approximately \$1,000 and \$87,000, respectively.

The following table summarizes stock-based compensation expense related to stock options and ESPP purchases under SFAS 123(R) for the years ended December 31, 2007 and 2006 which was allocated as follows (in thousands):

	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Research and development	\$ 10	\$ 33
Sales, general and administrative	67	331
	<b>\$ 77</b>	<b>\$ 364</b>

***Net Income (Loss) Per Share:***

Basic earnings (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted income (loss) per share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of incremental shares issuable upon the exercise of stock options and warrants using the treasury stock method and, for the year ended December 31, 2006, dilutive potential common shares also include convertible notes payable using the as-if converted method.

For the year ended December 31, 2007, there were no potentially dilutive shares. For the year ended December 31, 2006, potentially dilutive shares of approximately 2,192,000 have been excluded from diluted loss per share as their effect would be antidilutive for the year then ended.

***Recently Issued Accounting Standards:***

In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after December 15, 2007. The Company plans to adopt SFAS No. 157 beginning in the first quarter of 2008. The Company is currently

evaluating the impact, if any, that adoption of SFAS No. 157 will have on its operating income (loss) or net income (loss).

On February 15, 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* Including an Amendment of FASB Statement No. 115 ( SFAS No. 159 ). SFAS No. 159 permits an entity to choose to measure many financial instruments and certain other items at fair value. Most of the provisions in SFAS No. 159 are elective; however, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The fair value option established by SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has



**Table of Contents****CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

been elected in earnings at each subsequent reporting date. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided that the entity makes that choice in the first 120 days of that fiscal year and also elects to apply the provisions of FASB Statement No. 157, Fair Value Measurements. The adoption of this pronouncement is not expected to have material effect on the Company's consolidated financial statements.

In June 2007, the FASB ratified a consensus opinion reached on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities ( EITF Issue No. 07-3 ). The guidance in EITF Issue No. 07-3 requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the Company would be required to expense the related capitalized advance payments. The consensus in EITF Issue No. 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue No. 07-3 is also not permitted. The Company intends to adopt EITF Issue No. 07-3 effective January 1, 2008. The impact of applying this consensus will depend on the terms of the Company's future research and development contractual arrangements entered into on or after December 15, 2007.

Other recent accounting pronouncements issued by the FASB (including the EITF) and the American Institute of Certified Public Accountants did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

**3. Inventories:**

Inventories consist of the following (*in thousands*)

	<b>December 31, 2007</b>
Raw materials	\$ 295
Work in process	96
Finished goods	1,211
	<b>\$ 1,602</b>

**4. Property and Equipment:**

Property and equipment consists of the following (*in thousands*):

**December 31,**

	<b>2007</b>
Computers and equipment	\$ 510
Manufacturing and demonstration equipment	293
Leasehold improvements	38
Loaned lasers	3,240
	4,081
Less accumulated depreciation and amortization	(3,624)
	\$ 457

Equipment under capital lease of \$59,000, net of accumulated amortization of \$30,000 at December 31, 2007, is included in property and equipment.

F-14

---

Table of Contents**CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In the year ended December 31, 2007, the Company recognized a loss on disposal of \$2,000. The total gross fixed assets of approximately \$125,000 and related accumulated depreciation of \$123,000 were written down to zero and the resulting loss was included in other expense.

**5. Other Assets:**

For the year ended December 31, 2006, the Company recorded an impairment charge of \$730,000 related to its PMC licensing fee. On January 5, 1999, Cardiogenesis entered into an Agreement ( the PLC agreement ) with PLC Systems, Inc. ( PLC ), which granted Cardiogenesis a non-exclusive worldwide use of certain PLC patents. In return, Cardiogenesis agreed to pay PLC a fee totaling \$2,500,000 over an approximately forty-month period. The present value of these payments of \$2,300,000 was recorded as a prepaid asset and was being amortized over the life of the underlying patents. The patents covered in the PLC agreement are valuable to the Company's PMC product line. The PMC product line is not approved for sale in the United States but is sold internationally.

In the fourth quarter of 2006, the Company evaluated the costs involved in carrying out the clinical trials to obtain FDA approval and decided to devote resources to its core business rather than to pursue this course of action. The Company will continue to sell the PMC product internationally, but without obtaining FDA approval, the product's potential sales volume will be significantly limited. Based on its analysis of the related undiscounted cash flows, the Company determined that the asset was fully impaired at December 31, 2006 and recorded an impairment charge of \$730,000 included in sales, general and administrative expense.

Prior to the write down of this asset, the patent was being amortized on a straight-line basis at a rate of \$195,000 per year and the related amortization expense was included in sales, general and administrative expenses in the accompanying consolidated statements of operations.

**6. Accrued Liabilities:**

Accrued liabilities consist of the following (*in thousands*):

	<b>December 31, 2007</b>
Accrued accounts payable and related expenses	\$ 28
Accrued vacation	119
Accrued salaries and commissions	473
Accrued accounting and tax fees	169
Legal settlement with former CEO(1)	319
Accrued other	350
	<b>\$ 1,458</b>

(1) See Note 8.

**7. Secured Convertible Term Note and Related Obligations:**

In October 2004, the Company completed a financing transaction with Laurus, pursuant to which the Company issued a Secured convertible term note (the Note ) in the aggregate principal amount of \$6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of the Company s common stock to Laurus in a private offering. Net proceeds to the Company from the financing, after payment of fees and expenses to Laurus, were \$5,752,500, \$2,875,250 of which was received by the Company and \$2,877,250 of which was deposited in a restricted cash account. In May 2006, the Company repaid the outstanding restricted cash balance of approximately \$2,417,000 including accrued interest of \$130,000 and a prepayment penalty of \$483,000. In October 2007, the Note matured and was paid in full.

F-15

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

The Note was convertible into shares of the Company's common stock at the option of Laurus and, in certain circumstances, at the Company's option and subject to certain trading volume limitations and certain limitations on Laurus' ownership percentage. The Note was collateralized by all of the Company's assets.

Under certain circumstances, the Note could have resulted in conversion of the Company's common stock at conversion prices that were low enough that the shares required would be in excess of the shares then authorized by the Company. If the Company was in a situation where the current shares authorized were not sufficient to cover the conversion amount, a cash payment would have been required. Since there was a possibility that a cash payment would be required, certain features of the Note as well as other equity related instruments were recorded as liabilities on the Company's consolidated balance sheet prior to the repayment of the Note.

The Note included certain features that were considered embedded derivative financial instruments, such as a variety of conversion options, a variable interest rate feature, events of default and a variable liquidated damages clause. As a result of the repayment of the Note in October 2007, these derivatives were not applicable at December 31, 2007. These features are described below, as follows:

The Note was convertible at the holder's option at any time at the fixed conversion price of \$.50 per share. This conversion feature had been identified as an embedded derivative and had been bifurcated and recorded on the Company's consolidated balance sheet at its fair value.

Beginning May 2005, the Company was required to make monthly principal payments of \$104,000 per month. The monthly payment as well as related accrued interest was required to be converted to common stock at the fixed conversion price of \$0.50 if the fair value of the Company's common stock was greater than \$0.55 per share for the 5 days preceding the payment due date. This conversion feature had been identified as an embedded derivative and has been bifurcated and recorded on the Company's balance sheet at its fair value.

Restricted cash must have been converted at a fixed conversion price of \$0.50 per share if the fair value of the Company's common stock had been greater than 125%, 150% or 175% (each threshold must meet higher trading volume limits) of the initial fixed conversion price of \$0.50 per share. This conversion feature had been identified as an embedded derivative and had been bifurcated and recorded on the Company's consolidated balance sheet at its fair value.

Annual interest on the Note was equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided that such annual rate of interest was not less than six and one-half percent (6.5%). For every 25% increase in the Company's common stock fair value above \$0.50 per share, the interest rate will be reduced by 2%. The interest rate could have never been reduced below 0%. Interest on the Note was payable monthly in arrears on the first day of each month during the term of the Note, beginning November 2004. The potential interest rate reduction due to future possible increases in the Company's stock price had been identified as an embedded derivative and had been bifurcated and recorded on the Company's consolidated balance sheet at its fair value.

The Note agreement included a liquidated damages provision based on any failure to meet registration requirements for shares issuable under the conversion of the note or exercise of the warrants by February 2005.

The Note agreement contained certain events of default including delinquency, bankruptcy, change in control and stop trade or trade suspension. In the event of default, Laurus had the right to call the debt at a 30% premium, increase the note rate to the stated rate, increase the note rate by an additional 12%, foreclose on the collateral, and/or seek other remedies. Laurus' right to increase the interest rate on the debt in the event of default represented an embedded derivative.

In conjunction with the Note, the Company issued a warrant to purchase 2,640,000 shares of common stock. The accounting treatment of the derivatives and warrant required that the Company record the derivatives and the

Table of Contents**CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

warrant at their relative fair value as of the inception date of the agreement, and at fair value as of each subsequent balance sheet date until the Note was repaid. Any change in fair value was recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives and warrants was higher at the subsequent balance sheet date, the Company recorded a non-operating, non-cash charge. If the fair value of the derivatives and warrants was lower at the subsequent balance sheet date, the Company recorded non-operating, non-cash income. During the years ended December 31, 2007 (through the date of the repayment of the Note) and 2006, the Company recorded other (expense) income of (\$376,000) and \$613,000, respectively, related to the change in fair market value of the embedded derivatives. The initial fair value assigned to the embedded derivatives was \$1,075,000 and the initial fair value assigned to the warrant was \$631,000, both of which were recorded as discounts to the Note and were recorded at fair market value at each balance sheet date.

In addition, the initial fair value assigned to the discount on the note payable was \$1,706,000 and the initial value of the debt issue costs was \$417,000, both of which were amortized to interest expense over the term of the debt, using the effective interest method. During the years ended December 31, 2007 and 2006, the Company recorded expense of \$72,000 and \$667,000, respectively, related to the discount on the Note. During the years ended December 31, 2007 and 2006, the Company recorded expense of \$17,000 and \$164,000, respectively, related to the amortization of debt issuance costs.

The following table presents a reconciliation between the principal amount of the Note and the full repayment of the Note:

	<b>December 31, 2007 (In thousands)</b>
Original Note balance	\$ 6,000
Principal conversions	(1,184)
Repayment of restricted cash balance	(2,417)
Cash payments	(2,399)
Total secured convertible term note	

During the years ended December 31, 2007 and 2006, the Company paid all required principal and interest amounts in cash and did not issue any shares of its common stock in connection with conversions of the Laurus debt.

**8. Commitments and Contingencies:*****Operating Lease***

Cardiogenesis entered into a non-cancelable operating lease for an office facility beginning October 1, 2006 extending through November 30, 2011. The minimum future rental payments are as follows (*in thousands*):

**Year Ending December 31,**

2008	105
2009	120
2010	126
2011	120
	\$ 471

Rent expense was approximately \$147,000 and \$328,000 for the years ended December 31, 2007 and 2006, respectively.

F-17

---



**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

***Litigation***

On July 12, 2006, Cardiogenesis terminated Michael Quinn as its Chairman, Chief Executive Officer and President in accordance with the terms of his employment agreement. At the time of termination, Mr. Quinn stated that he intended to bring claims against the Company relating to his termination, including claims for payment of severance he claimed was owed to him under the terms of his employment agreement.

On October 12, 2006, Cardiogenesis and Mr. Quinn entered into a Memorandum of Understanding (the MOU ) pursuant to which the parties agreed to settle certain disputes between them relating to Mr. Quinn's termination from employment.

Pursuant to the terms of the MOU, the Company will pay Mr. Quinn a total of approximately \$500,000 in 72 equal bi-monthly installments and also paid approximately \$51,000 to Mr. Quinn's counsel as attorney's fees. At December 31, 2006, the Company accrued the entire amount of approximately \$500,000, which included \$28,000 of related payroll taxes. At December 31, 2007 approximately \$319,000 is included in accrued liabilities, see Note 6. Mr. Quinn will be entitled to retain 689,008 previously issued stock options having the following exercise prices:

89,008 shares at \$0.32 per share  
150,000 shares at \$0.70 per share  
200,000 shares at \$0.54 per share  
250,000 shares at \$0.50 per share

The exercise period of these options has been extended so that each option shall terminate on October 12, 2009. For the year ended December 31, 2006, the Company recognized stock-based compensation expense, net of forfeitures, of \$103,000 related to the vesting of these options which is included in sales, general and administrative expenses, of which \$29,000 related to the modification of the original terms of these options.

In addition, Mr. Quinn will be entitled to statutory indemnification and any indemnification required by the Company's bylaws relating to his services on the Board of Directors of the Company. The MOU also provides that both parties will not disparage each other.

On October 24, 2006, the Company and Mr. Quinn entered into a Settlement Agreement and General Release that formalizes the settlement contemplated by the MOU and includes customary releases and other provisions.

The Company has been notified that on February 19, 2008, Cardiofocus, Inc. ( Cardiofocus ) filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1.08-cv-10285) against the Company and a number of other companies. In the complaint, Cardiofocus alleges that the Company and the other defendants have violated patent rights allegedly held by Cardiofocus. The complaint does not identify specific alleged monetary damages. Although the Company has not completed the analysis of the claims, it intends to vigorously defend itself. However, any litigation involves risks and uncertainties and the likely outcome of the case cannot be determined at this time. In addition, litigation involves significant expenses and distraction of management resources which may have an adverse effect on the Company's results of operations.

**9. Shareholders Equity:**

***Issuances of Common Stock:***

During the years ended December 31, 2007 and 2006, the Company did not issue any shares of its common stock in connection with conversions of the Note. See Note 7.

During the year ended December 31, 2007, the Company did not issue any shares of common stock related to stock option exercises. During the year ended December 31, 2006, the Company issued 116,000 shares of common stock for approximately \$37,000 in connection with the exercise of options.

F-18

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

During the years ended December 31, 2007 and 2006, the Company did not issue any shares of common stock in connection with purchases under the ESPP. However, the Company issued approximately 56,000 shares of its common stock during 2006, related to proceeds received in 2005.

***Warrants:***

During the year ended December 31, 2001, the Company issued warrants to purchase 75,000 shares of common stock at a price of \$1.63 per share in connection with a facilities lease agreement executed in 2001. The warrants were fair valued at \$94,000 using the Black-Scholes pricing model and were amortized over the five-year lease term. The warrants expired in May 2006. For the years ended December 31, 2007 and 2006, the Company recorded amortization charges to rent expense of \$0 and \$10,000, respectively, in connection with these warrants.

During the year ended December 31, 2003, the Company issued five-year warrants to purchase 275,000 shares of common stock at exercise prices ranging from \$0.35 to \$0.44 per share in connection with a credit facility that was executed in March 2003 and canceled in March 2004. The warrants were fair valued at \$75,000 using the Black-Scholes pricing model. The warrants were fully amortized in 2004 when the credit facility was cancelled. The warrants expire in March 2008 and were outstanding at December 31, 2007.

In January 2004, the Company sold 3,100,000 shares of common stock to private investors for a total price of \$2,700,000. The Company also issued a warrant to purchase 3,100,000 additional shares of common stock at a price of \$1.37 per share, which were fully vested upon issuance and expire in January 2009. The warrant is immediately exercisable and has a term of five years. In association with the repayment of the Note in October 2007, the warrant liability, which was valued at approximately \$40,000 at the date of repayment, was reclassified to equity.

In October 2004, Cardiogenesis issued a warrant to purchase an aggregate of 2,640,000 shares of the Company's common stock at a price of \$0.50 per share, with a term of 7 years, to Laurus Master Fund in connection with the secured convertible note agreement. In association with the repayment of the Note in October 2007, the warrant liability, which was valued at approximately \$308,000 at the date of repayment, was reclassified to equity. See Note 7.

During the years ended December 31, 2007 and 2006, no warrants were issued, exercised, forfeited or cancelled.

With the signing of the Laurus agreement in October 2004, the Company no longer had enough authorized shares to cover potential conversion of every equity instrument then outstanding. Under EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, it is assumed that there may be a circumstance that a cash payment may have to be made by the Company to compensate the holder of these instruments, if authorized shares are not available. Therefore, in October 2004, the Company recognized liabilities associated to the warrants to purchase approximately 3,100,000 shares and 2,640,000 shares of common stock. During the years ended December 31, 2007 (through the date of the repayment of the Note) and 2006, the Company recorded other income related to the warrants of \$151,000 and \$407,000, respectively, which was included in other non-cash income in the consolidated statements of operations.

***Options Granted to Employees:***

During the year ended December 31, 2007, the Company issued approximately 1,048,000 options to purchase shares of the Company's common stock to certain officers, directors, and employees with a weighted average exercise price of \$0.30, a 10 year expiration term, and vesting terms ranging from 1 to 4 years. During the year ended December 31, 2006, the Company issued approximately 1,268,000 options to purchase shares of the Company's common stock to certain officers, directors, and employees with a weighted average exercise price of \$0.49, a 10 year expiration term, and vesting terms ranging from immediate to 3 years.

F-19

---

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

***Shareholder Rights Plan:***

The Company's articles of incorporation authorize the board of directors, subject to any limitations prescribed by law, to issue shares of preferred stock in one or more series without shareholder approval. On August 17, 2001 the Company adopted a shareholder rights plan, as amended, and under the rights plan, the board of directors declared a dividend distribution of one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Pursuant to the Rights Agreement, in the event (a) any person or group acquires 15% or more of the Company's then outstanding shares of voting stock (or 21% or more of the Company's then outstanding shares of voting stock in the case of State of Wisconsin Investment Board), (b) a tender offer or exchange offer is commenced that would result in a person or group acquiring 15% or more of the Company's then outstanding voting stock, (c) the Company is acquired in a merger or other business combination in which the Company is not the surviving corporation or (d) 50% or more of the Company's consolidated assets or earning power are sold, then the holders of the Company's common stock are entitled to exercise the rights under the Rights Plan, which include, based on the type of event which has occurred, (i) rights to purchase preferred shares from the Company, (ii) rights to purchase common shares from the Company having a value twice that of the underlying exercise price, and (iii) rights to acquire common stock of the surviving corporation or purchaser having a market value of twice that of the exercise price. The rights expire on August 17, 2011, and may be redeemed prior thereto at \$0.001 per right under certain circumstances.

***Stock Option Plan:***

Cardiogenesis maintains a Stock Option Plan, which includes the Employee Program under which incentive and nonstatutory options may be granted to employees and the Consultants Program, under which nonstatutory options may be granted to consultants of the Company. As of December 31, 2007, Cardiogenesis had reserved a total of 11,100,000 shares of common stock for issuance under this plan. Under the plan, options may be granted at not less than fair market value, as determined by the Board of Directors. Options generally vest over a period of three years and expire ten years from date of grant. No shares of common stock issued under the plan are subject to repurchase.

***Directors' Stock Option Plan:***

Cardiogenesis maintains a Directors' Stock Option Plan which provides for the grant of nonstatutory options to directors who are not officers or employees of the Company. As of December 31, 2007, Cardiogenesis had reserved 1,025,000 shares of common stock for issuance under this plan. Under this plan, options are granted at the trading price of the common stock at the date of grant. Options generally can vest immediately or up to thirty-six months and expire ten years from date of grant. No shares of common stock issued under the plan are subject to repurchase.

***Employee Stock Purchase Plan:***

The Company's 1996 Employee Stock Purchase Plan (the "ESPP") was adopted in April 1996. As of December 31, 2007, a total of 1,500,000 common shares are authorized and reserved for issuance under this plan, as amended, and 267,743 shares remain available for issuance. Cardiogenesis adopted the ESPP in April 1996. The purpose of the ESPP is to provide eligible employees of Cardiogenesis with a means of acquiring common stock of Cardiogenesis through payroll deductions. Eligible employees are permitted to purchase common stock at 85% of the fair market value through payroll deductions of up to 15% of an employee's compensation, subject to certain limitations. During

fiscal years 2007 and 2006, no shares were sold through the ESPP. In addition, from November 15, 2006 to November 15, 2007, the Company suspended the ESPP. As of November 16, 2007, the ESPP has been reinstated.

F-20

---

Table of Contents**CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Option activity under the Stock Option Plan and the Directors Stock Option Plan is as follows (*in thousands, except per share amounts*):

	<b>Shares Available for Grant</b>	<b>Outstanding Options Number of Shares</b>	<b>Weighted Average Price per Share</b>
Balance, December 31, 2005	3,892	4,537	\$ 1.10
Options granted	(1,268)	1,268	\$ 0.49
Options forfeited	2,190	(2,190)	\$ 1.10
Options expired	8	(8)	\$ 11.00
Options exercised		(116)	\$ 0.32
Balance, December 31, 2006	4,822	3,491	\$ 0.89
Options granted	(1,048)	1,048	\$ 0.30
Options forfeited	1,447	(1,447)	\$ 0.56
Options expired	16	(16)	\$ 7.58
Options exercised			
Balance, December 31, 2007	5,237	3,076	\$ 0.81

The following table summarizes information about the Company's stock options outstanding and exercisable under the Stock Option Plan and the Director's Stock Option Plan at December 31, 2007:

<b>Exercise Prices</b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b>Number Outstanding (In thousands)</b>	<b>Weighted Average Remaining Contractual Life (In Years)</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable (In thousands)</b>	<b>Weighted Average Exercise Price</b>
\$0.23 - \$0.30	522	9.35	\$ 0.28	18	\$ 0.27
\$0.31 - \$0.43	451	6.67	\$ 0.34	249	\$ 0.33
\$0.48 - \$0.50	553	5.32	\$ 0.50	456	\$ 0.50
\$0.51 - \$0.54	367	4.18	\$ 0.54	362	\$ 0.54

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

\$0.56 - \$0.71	528	4.91	\$ 0.65	526	\$ 0.65
\$0.80 - \$0.91	189	4.85	\$ 0.86	189	\$ 0.86
\$1.01 - \$1.40	334	4.73	\$ 1.20	334	\$ 1.20
\$2.57 - \$3.88	43	3.22	\$ 2.88	43	\$ 2.88
\$6.06 - \$11.50	89	1.49	\$ 7.78	89	\$ 7.78
	3,076	5.76	\$ 0.81	2,266	\$ 0.98

**10. Employee Retirement Plan:**

Cardiogenesis maintains a 401(k) plan for its employees. The plan allows eligible employees to defer up to 15% of their earnings, not to exceed the statutory amount per year on a pretax basis through contributions to the plan. The plan provides for employer contributions at the discretion of the Board of Directors. For the years ended December 31, 2007 and 2006 employer contributions of \$80,000 and \$0, respectively, were made to the plan.

F-21

---



Table of Contents**CARDIOGENESIS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Segment Disclosures:**

The Company operates in one segment. The principal markets for the Company's products are in the United States. International sales occur in Europe, Canada and Asia and amounted to \$353,000 and \$376,000 for the years ended December 31, 2007 and 2006, respectively. The international sales represent 3% and 2% of total sales for the years ended December 31, 2007 and 2006, respectively. The majority of international sales are denominated in US Dollars. All of the Company's long-lived assets are located in the United States.

**12. Income Taxes:**

Significant components of Cardiogenesis' deferred tax assets are as follows (*in thousands*):

	<b>December 31, 2007</b>
Net operating losses	\$ 54,760
Credits	3,568
Research and development	599
Reserves	277
Accrued liabilities	548
Depreciation/Amortization	24
Net deferred tax asset	59,776
Less valuation allowance	(59,776)
Net deferred tax assets	\$

A reconciliation of income taxes computed at the federal statutory rate of 34% to the provision for income taxes is as follows for the years ended December 31:

	<b>2007</b>	<b>2006</b>
Statutory federal income tax rate	34%	34%
State income taxes, net of federal benefit		
Change in valuation allowance	(36)%	(33)%
Other	3%	(1)%
	1%	

The Company has established a valuation allowance to the extent of its deferred tax assets because it was determined by management that it was more likely than not at the balance sheet date that such deferred tax assets would not be realized. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced. As of December 31, 2007, the Company had federal and state net operating loss carryforwards of approximately \$157,000,000 and \$25,000,000, respectively, to offset future taxable income. In addition, the Company had federal and state credit carryforwards of approximately \$2,450,000 and \$1,490,000 available to offset future tax liabilities. The Company's net operating loss carryforwards, as well as federal credit carryforwards, will expire at various dates through 2024, if not utilized. Research and experimentation credits carry forward indefinitely for state purposes. The Company also has manufacturer's investment credits for state purposes of approximately \$21,000.

The Internal Revenue Code limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. The Company believes that the sale of common stock in its initial public offering and the merger with Cardiogenesis resulted in changes in ownership which could restrict the utilization of the carryforwards.

**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

The deferred tax assets as of December 31, 2007 include a deferred tax asset of \$36,223 representing net operating losses arising from the exercise of stock options by Cardiogenesis employees. To the extent the Company realizes any tax benefit for the net operating losses attributable to the stock option exercises, such amount would be credited directly to stockholders' equity.

Income tax expense for the year ended December 31, 2007 is comprised of state minimum taxes of \$2,400 and federal alternative minimum taxes of \$10,600. Income tax expense for the year ended December 31, 2006 represented current state minimum taxes of \$1,600.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. The Company adopted the provisions of FIN 48 as of January 1, 2007, and has analyzed filing positions in each of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions. The Company has identified the U.S. federal and California as its major tax jurisdictions. Generally, the Company remains subject to Internal Revenue Service examination of its 2004 through 2006 U.S. federal income tax returns, and remains subject to California Franchise Tax Board examination of its 2003 through 2006 California Franchise Tax Returns. However, the Company has certain tax attribute carryforwards which will remain subject to review and adjustment by the relevant tax authorities until the statute of limitations closes with respect to the year in which such attributes are utilized.

The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48. The Company's policy for recording interest and penalties associated with income-based tax audits is to record such items as a component of income taxes.

**13. Related Party Transaction:**

In June 2007, the Company provided an unrestricted educational grant of \$80,000 to the University of Arizona Sarver Heart Center to support the research of cardiovascular disease and stroke. Dr. Marvin Slepian, a member of the Company's board of directors, is also a member of the Sarver Heart Center. While the Company is not legally bound to provide any additional funding for such research, the Company may elect to provide an additional \$80,000 grant in the future.

**14. Risks and Concentrations:**

Cardiogenesis sells its products primarily to hospitals and other healthcare providers in North America, Europe and Asia. Cardiogenesis performs ongoing credit evaluations of its customers and generally does not require collateral. Although Cardiogenesis maintains allowances for potential credit losses that it believes to be adequate, a payment default on a significant sale could materially and adversely affect its operating results and financial condition. At December 31, 2007, three customers individually accounted for 22%, 17% and 11% of gross accounts receivable. For the years ended December 31, 2007 and 2006, no customer individually accounted for 10% or more of net revenues.



**Table of Contents**

**CARDIOGENESIS CORPORATION**

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

At December 31, 2007, the Company had amounts on deposit with financial institutions in excess of the federally insured limits of \$100,000, which approximated \$2,925,000.

The Company outsources the manufacturing and assembly of its handpiece systems to a single contract manufacturer. The Company also outsources the manufacturing of its laser systems to a different single contract manufacturer.

Certain components of laser units and fiber-optic handpieces are generally acquired from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Although the Company has identified alternative vendors, the qualification of additional or replacement vendors for certain components or services is a lengthy process. Any significant supply interruption would have a material adverse effect on the Company's ability to manufacture its products and, therefore, would harm its business. The Company intends to continue to qualify multiple sources for components that are presently single sourced.

F-24

---

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1.1(1)	Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996
3.1.2(2)	Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001
3.1.3(3)	Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
3.1.4(4)	Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004
3.2(5)	Amended and Restated Bylaws
4.1(6)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A.
4.2(7)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.3(8)	First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.4(9)	Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.5(10)	Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
4.6(11)	Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
4.7(12)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share
4.8(13)	Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.9(14)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.10(15)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(16)*	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(17)*	Stock Option Plan, as amended and restated July 2005
10.3(18)*	Director Stock Option Plan, as amended and restated July 2005
10.4(19)*	Employee Stock Purchase Plan, as amended and restated July 2005
10.5(20)	Lease for the Company's executive offices in Irvine, California
10.6(21)*	401(k) Plan, as restated January 1, 2005
10.8(22)*	Description of the Stock Option Plan
10.9(23)*	Description of the Director Stock Option Plan
10.10(24)*	Form of Stock Option Agreement for Executive Officers under the Stock Option Plan
10.11(25)*	Form of Grant Notice under the Stock Option Plan
10.12(26)*	Form of Stock Option Agreement for Directors under the Director Stock Option Plan
10.13(27)*	Form of Grant Notice under the Director Stock Option Plan
10.14(28)*	Settlement Agreement and General Release between the Registrant and Michael J. Quinn, dated October 24, 2006
10.15(29)*	Summary of Director Compensation
10.16(30)*	Employment Agreement between the Registrant and Richard Lanigan

10.17(31)*	Employment Agreement between the Registrant and William Abbott
21.1(32)	List of Subsidiaries
23.1(32)	Consent of KMJ Corbin & Company LLP

---

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
31.1(32)	Certification of the President pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2(32)	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1(32)	Certifications of the President and 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, compensatory plan or arrangement	
(1)	Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1/A (File No. 33-03770), filed May 21, 1996
(2)	Incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 14, 2001
(3)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on August 20, 2001
(4)	Incorporated by reference to Exhibit 3.1.4 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
(5)	Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
(6)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(7)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 26, 2004
(8)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 18, 2002
(9)	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed August 20, 2001
(10)	Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(11)	Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(12)	Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed January 22, 2004
(13)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(14)	Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(15)	Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed October 28, 2004
(16)	



Edgar Filing: CARDIOGENESIS CORP /CA - Form 10KSB

Incorporated by reference to the Company's Registration Statement on Form S-1 (File No. 333-03770), as amended, filed April 18, 1996

- (17) Incorporated by reference to Exhibit 10.2 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
  - (18) Incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
  - (19) Incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed on August 21, 2006
  - (20) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 10-K filed August 25, 2006
  - (21) Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed March 31, 2005
  - (22) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
  - (23) Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
-

**Table of Contents**

- (24) Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (25) Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (26) Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (27) Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on August 4, 2005
- (28) Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-KSB filed on March 29, 2007
- (29) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-QSB filed on August 14, 2007
- (30) Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on August 1, 2007
- (31) Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K filed on August 1, 2007
- (32) Filed herewith