CARDIOGENESIS CORP /CA
Form 10KSB
March 29, 2007

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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, 2006

Commission file number: 0-28288

Cardiogenesis Corporation
(Name of small business issuer in its charter)

California	**77-0223740**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
11 Musick, Irvine, CA	**92618**
(Address of principal executive offices)	*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 (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 þ No o

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. þ

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

Yes o No þ

State issuer s revenues for its most recent fiscal year: $17,117,000

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: $13,412,190 as of February 28, 2007.

State the number of shares outstanding of each of the issuer s classes of equity as of the latest practicable date: 45,273,701 shares of common stock, no par value, outstanding as of February 28, 2007.

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 o No þ

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PART I

Item 1. *Description of Business.*

This Annual Report on Form 10-KSB contains forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. 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) and through the transvascular approach of percutaneous myocardial channeling (PMC). The PMC procedure/system was formerly referred to by the Company and others as percutaneous myocardial revascularization (PMR). TMR and PMC are laser-based heart treatments in which 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. PMC is performed by an interventional cardiologist in a catheter-based femoral artery approach procedure which requires only conscious sedation for the patient. Prospective, randomized, multi-center controlled clinical trials have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with Cardiogenesis TMR and PMC systems (plus medications), when compared with patients who received medications alone.

In May 1997, we received CE Mark approval for our TMR system and in April 1998 we received CE Mark approval for our PMC 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.

We completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a pre market approval (PMA) application in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval for PMC. 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 decided to devote resources to our core business and other shorter term product development opportunities rather than to pursue FDA approval for PMC at

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this time. 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.

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, and PMC, which bears the CE Marking and for which we are not currently

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pursuing FDA approval for use in the U.S. (but may elect to do so in the future), offer potential relief to a large population of patients with advanced cardiovascular disease.

The TMR and PMC Procedures

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.

PMC is an interventional procedure performed by a cardiologist. PMC is based upon the same principles as TMR, but the procedure is much less invasive. The procedure is performed under local anesthesia and the patient is treated through a catheter inserted in the femoral artery at the top of the leg. A laser transmitting catheter is threaded up into the heart chamber, where channels are created in the inner portion of the myocardium (i.e. heart muscle). PMC has received the CE Marking approving its use within the European Union. See our discussion below under the caption Regulatory Status and above under the caption Business Overview, for the status of our PMA application with the FDA.

Business Strategy

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

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 and related co-morbidities of patients being referred today to cardiovascular surgery. We are committed to growing the TMR business with the Advanced TMR Plus platform which includes two new minimally invasive handpieces for thoracoscopic and robotic assisted TMR. These new products were developed with key clinical champions to expand the TMR market. We are also committed to identifying potential new products in the cardiovascular arena. These two new products are currently under IDE clinical study in support of the PMA applications with the FDA.

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. We also currently intend to expand our marketing efforts in Europe and to the rest of the world through the establishment of direct international sales and support and third party distributors and agents. In addition, we continue to advance and improve our comprehensive training program to assist physicians in acquiring the expertise necessary to utilize our products and procedures.

Leverage Proprietary Technology. We believe that our significant expertise in laser and catheter-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. and foreign patent applications pending relating to various aspects

of cardiovascular related devices and therapies.

Products and Technology

TMR System

Our TMR system consists of a holmium 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

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of the surgical handpiece. The compact base unit occupies a small amount of operating room floor space, operates on standard 110-volt or 220-volt power supply, and is light enough to move within the operating room or among operating rooms in order to use operating room space efficiently. Moreover, the flexible fiberoptic assembly used to deliver the laser energy to the patient enables ready access to the patient and to various sites within 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.

SolarGen 2100s laser system. SolarGen 2100s, approved in December 2004, generates 2.1 micron wavelength laser light by photoelectric excitation of a solid state holmium crystal. The holmium laser, because it uses a solid state crystal as its source, is compact, reliable and requires minimal maintenance. The systems specifications are as follows: size (21 L x 14 W x 36 H), weight (120 Lbs.), and power compatibility (115V and 230V for international customers).

TMR 2000 laser system. TMR 2000 generates 2.1 micron wavelength laser light by photoelectric excitation of a solid state holmium crystal. The holmium laser, because it uses a solid state crystal as its source, is compact, reliable and requires minimal maintenance. 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.

PMC System

Our PMC system is currently sold only outside the United States. The PMC system consists of the PMC Laser and ECG Monitor.

PMC Laser. Our holmium laser base unit generates 2.1 micron wavelength laser light in the mid-infrared spectrum. It provides a reliable source for laser energy with low maintenance.

Axcis Catheter System. Our Axcis catheter system is an over-the-wire system that consists of two components, the Axcis laser catheter and Axcis aligning catheter. Our Axcis catheter system is designed to provide controlled navigation and access to target regions of the left ventricle. The coaxial Axcis laser catheter system has an independent, extendible lens with radiopaque lens markers which show the location and orientation of the tip for optimal contact with the ventricle wall. The Axcis laser catheter also has nitinol petals at the laser-lens tip which are designed for safe penetration of the endocardium and to provide depth control. This delivery system consists of the Axcis laser catheter and a separate Ultra guide catheter.

New Product Pipeline

PEARL Robotic 5.0 and Thoracoscopic 8.0 Minimally Invasive Delivery Systems. 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. Both the PEARL Robotic 5.0 and Thoracoscopic 8.0 Minimally Invasive Delivery Systems have achieved 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 these advanced delivery systems and the minimally invasive approach. The PEARL 5.0 handpiece utilizes a robotically assisted 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. 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

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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 and around 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 pursuing the initial sites for Phoenix outside the United States to gain additional safety and efficacy data to support our regulatory and commercialization strategy.

Regulatory Status

United States. In February 1999, we received approval from the FDA for use of our TMR 2000 laser console and SoloGrip III 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 have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a Pre Market Approval (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 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.

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. The Phoenix Combination Delivery System has received CE Mark approval as well. In addition, the minimally invasive PEARL handpieces have 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.

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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 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, a TMR 2000 laser base unit at a current end user list price of $355,000 per unit, and the single use TMR handpiece at an end user unit list price of $3,995. 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 a direct sales and support organization and through distributors and agents. We currently intend to expand our marketing efforts in Europe and to the rest of the world through the establishment and expansion of direct international sales and support organizations and third party distributors and agents. We can not assure you, however, that we will be successful in increasing our international sales.

We have developed, in conjunction with several major hospitals using our products, a training program to assist physicians in acquiring the expertise necessary to utilize our products and procedures. This program includes a comprehensive one-day course including didactic training and hands-on performance of our products in vivo. Currently, over 1,750 cardiothoracic surgeons and residents have been trained on the Cardiogenesis TMR system.

We exhibit 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.

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 combination PHOENIX Delivery System and are supporting the initial clinical sites outside the United States in implementing this advanced technology. For the years ended December 31, 2006 and 2005, we incurred research and development expenses of $1,474,000 and $1,725,000, respectively.

We believe our future success will depend, in part, upon the success of our research and development programs. 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 competitor is PLC Systems, Inc. (PLC) which markets FDA-approved TMR products in the U.S. and abroad. Other competitors may also enter the market, including large

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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.

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. Edwards Lifesciences, a well known publicly traded provider of products and technologies to treat cardiovascular disease, 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 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 than we currently can.

We believe that the factors which will be critical to maximizing our market development success include: the timing of receipt of requisite regulatory approvals, 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 Pre Market Approval (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 Investigational Device Exemption (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

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often occur over a significantly longer period and may include requests for additional information or extensive additional 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 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. 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. 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

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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 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 manufacturing facility. 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. 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. 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.

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 there under 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

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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 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. We have limited experience to date ascertaining the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. Private insurance and private health plans may not approve reimbursement for TMR. 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 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.

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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, 2006 we had 30 employees, of which 13 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, 2007:

Name	Age	Position
Richard P. Lanigan	47	President
William R. Abbott	50	Senior Vice President, Chief Financial Officer, Secretary and Treasurer
Charles J. Scarano	45	Senior Vice President of Marketing and Business Development
Gerard A. Arthur	48	Senior Vice President of Operations
John P. McIntyre	41	Vice President of Scientific and Regulatory Affairs

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

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U.S. Navy where he completed six years of service as Lieutenant in the Supply Corps. Mr. Lanigan has a Bachelor 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, Abbott was Controller of McKesson Water Products Company. Prior to that, 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.

Charles J. Scarano joined Cardiogenesis in June 2004 as the Director of Marketing and became Vice President, General Manager of the International Business Unit in January 2005. He was promoted to Senior Vice President, Worldwide Marketing in November 2005 and took over responsibilities of Business Development in July 2006. Prior to joining Cardiogenesis, Mr. Scarano served as Executive Vice President of OroPro, Inc., directing the business development, branding and strategic marketing efforts. Before OroPro he was Vice President of Marketing at Optimize, Inc. and prior to that he served as Vice President of Sales for Gabriel Medical. Prior to joining Gabriel Medical, Mr. Scarano spent several years with Stryker Endoscopy and Allergan Pharmaceuticals in sales and marketing management positions. Mr. Scarano received his B.A in Communications from Arizona State University.

Gerard A. Arthur was promoted to the position of Senior Vice President of Operations in January 2007. Prior to January 2007, Mr. Arthur had served as Vice President, General Manager of the Worldwide Service Division since December 2003. From 1993 to December 2003, Mr. Arthur was Director of Worldwide Service. Prior to Cardiogenesis, from 1991 to 1993, Mr. Arthur served as Service Manager at Intelligent Surgical Lasers, Inc. From 1990 to 1991, he served as Manager, Laser Services at National Instrument Service Corporation. From 1986 to 1990, he served as Service Manager, Medical Lasers at Carl Zeiss, Inc. Mr. Arthur has worked in the medical laser field for over twenty years. He is a graduate of the School of Marine Radio & Radar, Limerick, Ireland.

John P. McIntyre was promoted to the position of Vice President of R&D in March 2005 from the position of Director of Product Development & Quality. Mr. McIntyre has over 15 years experience in the medical device industry. Prior to joining Cardiogenesis, Mr. McIntyre worked in the Cardio Vascular and Vascular Divisions of Edwards Lifesciences Corporation (formerly Baxter Healthcare Corporation) and Innercool Therapies, Inc. in positions of increasing responsibility for both R&D Engineering and Regulatory Affairs. Mr. McIntyre received his B.S. in Bioengineering, graduating Magna Cum Laude from University of California-San Diego and his M.S. in Biomedical Engineering from University of California-Davis as a National Science Foundation Graduate Research Fellowship Stipend Winner.

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.

We have incurred significant losses since inception. For example, for the fiscal years 2006 and 2005 we incurred net losses of $1,979,000 and $1,857,000, respectively. We will have a continuing need for new infusions of cash if we continue to incur losses in the future. We plan 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

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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 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 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. Although we expect to seek international reimbursement approvals, any such approvals may not be obtained in a timely manner, if at all. Failure

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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 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 and robotically assisted handpieces.

Both the PEARL Robotic 5.0 and Thoracoscopic 8.0 Minimally Invasive Delivery Systems have achieved 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 these advanced delivery systems and the minimally invasive approach. The PEARL 5.0 handpiece utilizes a robotically assisted 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. 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. We will not be able to derive any revenue from the sale of our new minimally invasive and robotically assisted handpieces in the United States until such time, if any, that the FDA approves these devices. Such inability to realize revenue from sales of these devices in the United States may have an adverse effect on our results of operations.

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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 fail to comply with applicable FDA or other regulatory requirements, we can be subject to:

fines, 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.

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

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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.

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.

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.

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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.

Until May 2006, our stock was listed on the OTC Bulletin Board and is currently listed on the Pink Sheets which, in either case, may have an unfavorable impact on our stock price and liquidity.

Effective April 3, 2003 our common stock was delisted from The NASDAQ SmallCap Market and became quoted on the OTC Bulletin Board on the same day. 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 the Nasdaq SmallCap Market. The listing of our shares on the OTC Bulletin Board or the Pink Sheets will likely result in a significantly less liquid market available for existing and potential stockholders to trade shares of our common stock, could ultimately further 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.

We expect to seek reinstatement of our common stock for trading on the OTC Bulletin Board in the near future. However, there can be no assurance that we will be able to successfully obtain or maintain such a listing. To the extent we are no able to obtain or maintain a listing on the OTC Bulletin Board, the liquidity and trading price of our common stock and our ability to raise capital in the future would be adversely affected.

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-dealers 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

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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 trading prices of many high technology companies, and in particular medical device companies, have been volatile which may result in large fluctuations in the price of our common stock.

The stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of many of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results.

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 March 1, 2007, the closing prices of our common stock as reported on the OTC Bulletin Board or Pink Sheets ranged from a high of $0.61 per share to a low of $0.16 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 conversion of outstanding convertible promissory notes 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 affect 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 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;

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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.

Costly litigation may be necessary to protect 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.

Defending and prosecuting intellectual property suits, United States Patent and Trademark Office interference proceedings and 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;

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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

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.

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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 the continued contributions of our 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 our institutional knowledge held by our existing senior management team and could impair our ability to effectively operate and grow our business. For example, in April 2006, Christine G. Ocampo, our former Chief Financial Officer, resigned, in July 2006 we terminated the employment of Michael J. Quinn, our former Chief Executive Officer, President and Chairman of the Board and in November 2006, we eliminated the Senior Vice President of Domestic Sales position then occupied by Henry R. Rossell. 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.

We sell our products internationally which subjects us to specific risks of transacting business in foreign countries.

In future quarters, international sales may become a significant portion of our revenue if our products become more widely used outside of the United States. Our international revenue is subject to the following risks, the occurrence of any of which could harm our business:

- foreign currency fluctuations;
- economic or political instability;
- foreign tax laws;
- shipping delays;
- various tariffs and trade regulations;
- restrictions and foreign medical regulations;

customs duties, export quotas or other trade restrictions; and

difficulty in protecting intellectual property rights.

If an event of default occurs under the convertible note issued to Laurus, it could seriously harm our operations.

On October 26, 2004, we issued a $6,000,000 secured convertible term note to Laurus Funds, of which $835,000 remained outstanding as of March 1, 2007. Pursuant to the terms of the note, an event of default includes a suspension of trading of our common stock on the OTC Bulletin Board which remains uncured within thirty (30) days of notice of the suspension. To the extent that the delisting of our stock in May 2006 is deemed a

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suspension of trading, the Company could be deemed to be in default of its obligations under the note. If an event of default occurs under the note, interest on the note would accrue at the default rate which is the then current prime rate plus 12% per annum until the default is cured. In addition, the holder of the note will have the right to accelerate and declare it immediately due and payable and exercise its rights as a secured creditor under applicable law and the security agreement with us, including the right to foreclose upon our assets that secure the note, which constitute substantially all of our assets.

In addition to the requirements that we maintain listing on the OTC Bulletin Board, the note and related agreements contain numerous events of default which include:

A failure to pay interest and principal payments when due;

a breach by us of any material covenant or term or condition of the note or any agreement made in connection therewith;

a breach by us of any material representation or warranty made in the note or in any agreement made in connection therewith;

if we make an assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;

any form of bankruptcy or insolvency proceeding is instituted by or against us and is not dismissed within 60 days;

any money judgment entered or filed against us for more than $50,000 and remains unresolved for 30 days;

our failure to timely deliver shares of common stock when due upon conversions of the note;

we experience an event of default under any other debt obligations; and

we experience a loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than $100,000 and is not timely mitigated.

If we default on the note and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital and non current assets, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely affect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the note are secured by all of our assets. Failure to fulfill our obligations under the note and related agreements could lead to loss of these assets, which would be detrimental to our operations.

We may continue to incur significant non-operating, non-cash charges resulting from changes in the fair value of warrants and derivatives.

In October 2004, we entered into a Secured Convertible Term Note agreement with Laurus Funds. Pursuant to the Note agreement, a warrant totaling 2,640,000 shares was issued to Laurus. This warrant, along with multiple embedded derivatives in the agreement, have been recorded at their relative fair value at the inception date of the agreement, October 27, 2004, and will continue to be recorded at fair value at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our stock price in the

future.

The fair value of the warrant and derivatives is tied in large part to our stock price. If our stock price increases between reporting periods, the warrant and derivatives become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

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The restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.

The Laurus financing documents restrict us from obtaining additional debt financing, subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus s right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

Low market prices for our common stock would result in greater dilution to our shareholders, and could negatively impact our ability to convert the Laurus debt into equity

The market price of our common stock significantly impacts the extent to which we are permitted to convert the outstanding balance of the Laurus debt into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due on the outstanding balance of the debt. Because the market price of our common stock has been below certain thresholds, we have been unable to convert any such repayments of principal and interest into equity, and instead have been forced to make such repayments in cash. We currently expect that the remaining payments due under the Laurus debt will be made in cash rather than equity.

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

The sale of our common stock by the holders of the Laurus debt upon conversion of all or any portion of the Laurus debt could cause the market price of our common stock to decline. In addition, 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. We expect that Laurus will generally promptly sell any shares into which the Laurus indebtedness is converted, and that the market price of our common stock could decline as a result of such sales.

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 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

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$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 generally accepted accounting principles. 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.

Recent rulemaking by the Financial Accounting Standards Board requires us to expense equity compensation given to our employees and could significantly harm our operating results and may reduce our ability to effectively utilize equity compensation to attract and retain employees.

We historically have used stock options as a component of our employee compensation program in order to align employees interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. Beginning in the first quarter of 2006, the Financial Accounting Standards Board adopted changes requiring companies to record a charge to earnings for employee stock option grants and other equity incentives. This accounting change reduces our reported earnings and may require us to reduce the availability and amount of equity incentives provided to employees, which may make it more difficult for us to attract, retain and motivate key personnel. Each of these results could materially and adversely affect our business.

While we believe that we currently have adequate internal controls over financial reporting, we are exposed to risks from recent legislation requiring companies to evaluate those internal controls.

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control structure and procedures for financial reporting. We are developing a program to perform the system and process evaluation and testing necessary to comply with these requirements on a sustained basis. Companies do not have significant experience in complying with these requirements on an ongoing and sustained basis. As a result, we expect to continue to incur increased expense and to devote management resources to Section 404 compliance. In the event that our chief executive officer, chief financial officer or our independent registered public accounting firm determine that our internal controls over financial reporting are not effective as defined under Section 404, investor perceptions of Cardiogenesis may be adversely affected and could cause a decline in the market price of our stock.

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.

Item 3. ***Legal Proceedings.***

The Company is not a party to any material legal proceeding.

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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 sale prices 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.

2005	**High**	**Low**
First Quarter	$ 0.79	$ 0.48
Second Quarter	$ 0.64	$ 0.38
Third Quarter	$ 0.68	$ 0.44
Fourth Quarter	$ 0.51	$ 0.32

2006	**High**	**Low**
First Quarter	$ 0.61	$ 0.33
Second Quarter	$ 0.59	$ 0.16
Third Quarter	$ 0.50	$ 0.35
Fourth Quarter	$ 0.45	$ 0.27

As of March 1, 2007, shares of our common stock were held by 238 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. Moreover, certain restrictions contained in the terms of our financing transaction with Laurus prohibit us from paying dividends or redeeming shares while the obligations to Laurus remain outstanding.

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, 2006, including the 1996 Stock Option Plan, as amended, and the 1996 Director Stock Option Plan, as amended.

(a)	**(b)**	**(c)**	**(d)**
Number of Securities		**Number of Securities**	

Plan Category	to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	Total of Securities Reflected in Columns (a) and (c)
Stock Option Plans Approved by Shareholders(1)	3,491,000	$ 0.89	4,822,000	8,313,000
Employee Stock Purchase Plan Approved by Shareholders(2)	(2)	(2)	267,743	267,743
Equity Compensation Plans Not Approved by Shareholders(3)	6,015,000	$ 0.97	N/A	6,015,000
Total	9,506,000	$ 0.94	5,089,743	14,595,743

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(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 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.

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 financial statements and notes thereto included in this Annual Report on Form 10-KSB.

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 advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous myocardial channeling (PMC). 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.

In February 1999, we received final approval from the FDA for our TMR products for certain indications, and we are permitted to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark (CE Mark) allowing the commercial sale of our TMR laser systems and our PMC catheter system to customers in the European Community. Effective July 1999, the Centers for Medicare and Medicaid Services (CMS) began providing Medicare coverage for TMR. As a result, hospitals and physicians are eligible to receive Medicare

reimbursement for TMR equipment and procedures performed on Medicare recipients.

As noted in Part I, Item 1 above, considering the costs involved in carrying out the trials required by the FDA in order to confirm the safety and efficacy of PMC, 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.

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As of December 31, 2006, we had an accumulated deficit of $170,113,000. We may continue to incur operating losses. 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, 2006 Compared to Year Ended December 31, 2005

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 $17,117,000 for the year ended December 31, 2006 increased $776,000, or 5%, when compared to net revenues of $16,341,000 for the year ended December 31, 2005. The increase in net revenues was primarily due to an increase in domestic laser revenues of $1,029,000 and other service revenues of $117,000, offset by a decrease in domestic and international handpiece revenues of $87,000 and $308,000, respectively.

For the year ended December 31, 2006, domestic laser sales increased by $1,029,000 compared to the year ended December 31, 2005 primarily due to an increase in lasers sold to new customers and conversions of loaner lasers into laser sales

The decrease in domestic handpiece revenue of $87,000 was attributed primarily to a decrease in unit sales. Domestic handpiece revenue for the year ended December 31, 2006 consisted of $2,026,000 in sales to customers operating under our loaned laser program as compared to $1,717,000 in sales of product to customers operating under our loaned laser program in 2005. In the years ended December 31, 2006 and 2005, sales of product to customers not operating under our loaned laser program were $9,308,000 and $9,703,000, respectively.

International sales, accounting for approximately 2% of total sales for the year ended December 31, 2006, decreased $283,000 from the prior year when international sales accounted for 4% of total sales. The decrease in international sales occurred primarily as a result of a $308,000 decrease in handpiece revenues offset with a $25,000 increase in laser revenue. The decrease in international handpiece revenues was a result of a decrease in unit sales and average handpiece unit sales price.

Gross Profit

Gross profit decreased to 79% of net revenues for the year ended December 31, 2006 as compared to 82% of net revenues for the year ended December 31, 2005. Gross profit in absolute dollars increased by $130,000 or 1% to $13,473,000 for the year ended December 31, 2006, as compared to $13,343,000 for the year ended December 31, 2005. The overall decrease in gross margin for the year ended December 31, 2006 resulted primarily from a capital product mix shift towards the SolarGen lasers, which are typically sold new or as partially depreciated evaluation units. In 2005, one third of the lasers sold were largely depreciated first generation TMR2000 lasers. In addition, the Company recorded obsolescence charges during 2006 for excess parts used to maintain and service TMR2000 lasers in response to the product mix shift. Lastly, margins in the fourth quarter and full year 2006 were negatively impacted

by an increase in depreciation charged to cost of sales resulting from the placement of a greater number of SolarGens as evaluation units.

Research and Development

Research and development expenditures of $1,474,000 decreased $251,000, or 14.6%, for the year ended December 31, 2006 as compared to $1,725,000 for the year ended December 31, 2005. The decrease was primarily due to costs incurred in 2005 that did not recur in 2006, such as a decrease of $209,000 related to overhead expenses and a decrease of $150,000 associated with a reduction in expenses associated with the start up of the PEARL trials.

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The decrease was partially offset by an increase of approximately $144,000 in outside services related to a mechanism of action study.

Sales, General and Administrative/Salaries and Employee Benefits

Sales, general and administrative expenditures, including salaries and employee benefits, of $13,477,000 decreased $633,000, or 4.5%, for the year ended December 31, 2006 when compared to $14,110,000 for the year ended December 31, 2005. The decrease resulted primarily from a decrease in marketing expenses of approximately $1,422,000, of which approximately $537,000 was the result of a reduction in headcount and related employee expenses, $479,000 was the result of a reduction in advertising and marketing expenses, and approximately $293,000 was the result of reduced training and clinical research expenses. The decrease in marketing expenses was partially offset by an increase in sales, general and administrative expenses of $125,000 related to compensation paid to the late Joseph Kletzel II while he served as interim Chief Operating Officer from May to July 2006 and also as interim Chief Executive Officer from July to November 2006, and approximately $682,000 associated with the legal settlement reached with our former Chairman, Chief Executive Officer and President.

In addition, we recorded an impairment charge of $730,000 that is included in sales, general and administrative expense related to the write-off of the PLC license in December 2006. 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, the Company 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 is included in sales, general and administrative expenses in the consolidated statements of operations included elsewhere in this annual report.

Non-Operating Income (Expense)

For the year ended December 31, 2006, the total non-operating expense of $501,000 represents additional expense of $1,136,000, or 178.9%, as compared to non-operating income of $635,000 for the year ended December 31, 2005. The expense is primarily due to the non-operating charges in relation to the Secured Convertible Term Note (Note) issued in October 2004. The increase in non-operating expense was primarily the result of a prepayment penalty associated to the payoff of the restricted cash balance and mark to market charges on derivatives and warrants, which was partially offset be decreased interest and debt issuance costs associated with the Note. Since the fair value of the warrants and derivatives is tied in large part to our stock price, in the future, if our stock price increases between reporting periods, the warrants and derivatives become more valuable. As such,

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there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements. The following table reflects the components of non-operating income (expense):

		Years Ended December 31,			
		2006	2005	Change	
		($ In thousands)			
Interest expense	Secured Convertible Term Note	$ (241)	$ (444)	$ 203	(46)%
Interest expense	Secured Convertible Term Note prepayment penalty	(483)		(483)	100%
Interest expense	other	(57)	(125)	68	(54)%
Interest income		132	162	(30)	(19)%
Gain on insurance settlement		70		70	100%
Non-cash interest expense	Accretion of discount on Note	(667)	(827)	160	(19)%
Non-cash interest expense	Amortization of debt issuance costs relating to the Note	(164)	(200)	36	(18)%
Non-cash interest expense	Loss on conversion of debt		(387)	387	(100)%
Change in fair value of derivatives		613	2,100	(1,487)	(71)%
Other non-cash income	Change in fair value of warrants	407	356	51	14%
Loss on disposal of assets		(111)		(111)	100%
Total interest (expense) income, net		$ (501)	$ 635	$ (1,136)	179%

Liquidity and Capital Resources

Cash and cash equivalents were $2,118,000 at December 31, 2006 compared to $1,843,000 at December 31, 2005, an increase of $275,000. Net cash provided by operating activities was $2,193,000 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, 2006 was $390,000 primarily related to the acquisition of property and equipment. Cash used in investing activities during the twelve months ended December 31, 2005 was $687,000 related to the acquisition of property and equipment.

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. Cash provided by financing activities during the twelve months ended December 31, 2005 was $158,000 due primarily to the release of restricted cash to unrestricted cash and the proceeds from the issuance of common stock from stock option exercises and the Employee Stock Purchase Plan.

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.

The Note matures in October 2007, absent earlier redemption by us or earlier conversion by Laurus. Annual interest on the Note is 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 may not be less than six and one-half percent (6.5%), subject to certain downward adjustments resulting from certain increases in the market price of our common stock. Interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note, and as of May 2005, we were required to begin making monthly principal payments of approximately $104,000 per month.

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The Note is convertible into shares of our common stock at the option of Laurus and, in certain circumstances, at our option.

The $6,000,000 Note includes embedded derivative financial instruments. In conjunction with the Note, we issued a warrant to purchase 2,640,000 shares of common stock. The accounting treatment of the derivatives and warrant requires that we record the derivatives and 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. Any change in fair value will be recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives and warrant is higher at the subsequent balance sheet date, we will record a non-operating, non-cash charge. If the fair value of the derivatives and warrant is lower at the subsequent balance sheet date, we will record non-operating, non-cash income.

As of December 31, 2006 and 2005, the derivatives were valued as an asset of approximately $376,000 and a liability of $237,000, respectively. These derivatives were valued using the Binomial Option Pricing Model with the following assumptions as of December 31, 2006 and December 31, 2005, respectively: dividend yield of 0% and 0%; annual volatility of 108.2% and 89.8%; and risk free interest rate of 5.1% and 4.4% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The derivatives are classified as current liabilities at December 31, 2006 and 2005. The warrant was valued at $362,000 and $562,000 at December 31, 2006 and 2005, respectively, using the Binomial Option Pricing model with the following assumptions: dividend yield of 0% and 0%; annual volatility of 106% and 88%; risk-free interest rate of 4.9% and 3.9%; and exercise factor of two times and two times.

We have incurred significant losses for the last several years and at December 31, 2006 we had an accumulated deficit of $170,113,000. 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 achieve 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, 2006 plus 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 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 generally accepted accounting principles 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 relate to the

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determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax asset, warranty reserve, the assessment of future cash flows in evaluating intangible assets for impairment and assumptions used in fair value determination of warrants and derivatives.

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.*

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.

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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.

Recently Issued Accounting Standards

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation requires that we recognize in the financial statements the impact of tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006 with the cumulative effect of the change in accounting principle recorded as an adjustment to beginning retained earnings. We have assessed the impact of adopting FIN 48 and have determined that no material impact to the consolidated financial statements exists.

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.

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 year ended December 31, 2006 reflect the impact of adopting SFAS No. 123(R). In

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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 year ended December 31, 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 year ended December 31, 2006 of 20% 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.

Employee stock-based compensation expense recognized under SFAS No. 123(R)for the year ended December 31, 2006 was $364,000, determined by the Black-Scholes valuation model. As of December 31, 2006, total unrecognized compensation cost, adjusted for estimated forfeitures, related to unvested stock options was $154,000, which is expected to be recognized as an expense over a weighted-average period of approximately 6.3 years. See Note 2 to our consolidated financial statements for additional information.

Item 7. ***Financial Statements***

The information required by Item 7 is included on pages F-1 to F-25 immediately following the signature page.

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

None.

Item 8A. ***Controls and Procedures.***

Evaluation of Disclosure Controls and Procedures

An evaluation was carried out under the supervision and with the participation of the Company s management, including our President and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2006. Based upon that evaluation, the President and the Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures at December 31, 2006 were effective in timely alerting them to the material information relating to the Company (or the Company s consolidated subsidiaries) required to be included in the Company s periodic filings with the SEC, such that the information relating to the Company, required to be disclosed in SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to the Company s management, including our President and CFO, as appropriate to allow timely decisions regarding required disclosure.

Remediation of Material Weakness in Internal Control

As reported in our 2005 Form 10-KSB, and our March 31, 2006 and June 30, 2006 Forms 10-QSB, we determined that the Company did not maintain effective controls over cash disbursements. The Company determined that certain employee expense reports were not reviewed and the expenses were not authorized.

The foregoing led our management to conclude that our disclosure controls and procedures were not effective as of June 30, 2006 because of a material weakness in our internal controls over financial reporting.

In the third quarter of 2006, the Company implemented an appropriate level of review for each employee expense report which included a new expense policy specifically addressing the issues that were identified. Management believes that these procedures, implemented upon the identification of the material weakness, will allow the Company to maintain effective internal control over financial reporting.

As such, we believe that the remediation initiative outlined above was sufficient to eliminate the material weakness in internal control over financial reporting as discussed above.

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Inherent Limitations on Effectiveness of Controls

All internal control systems no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in internal control over financial reporting

Other than as noted above, there were no changes in the Company s internal control over financial reporting that occurred during the quarter ended December 31, 2006 that has materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

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 2007 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 2007 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 2007 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 2007 definitive proxy statement which is incorporated herein by this reference.

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Item 13. ***Exhibits.***

EXHIBIT INDEX

Exhibit No.	Description
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)	Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.10(15)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.11(16)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.12(17)	Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(18)*	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(19)*	Stock Option Plan, as amended and restated July 2005
10.3(20)*	Director Stock Option Plan, as amended and restated July 2005
10.4(21)*	Employee Stock Purchase Plan, as amended and restated July 2005
10.5(22)	Lease for the Company s executive offices in Irvine, California
10.6(23)*	401(k) Plan, as restated January 1, 2005
10.8(24)*	Description of the Stock Option Plan
10.9(25)*	Description of the Director Stock Option Plan
10.10(26)*	Form of Stock Option Agreement for Executive Officers under the Stock Option Plan

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Exhibit No.	Description
10.11(27)*	Form of Grant Notice under the Stock Option Plan
10.12(28)*	Form of Stock Option Agreement for Directors under the Director Stock Option Plan
10.13(29)*	Form of Grant Notice under the Director Stock Option Plan
10.14(30)*	Settlement Agreement and General Release between the Registrant and Michael J. Quinn, dated October 24, 2006
10.15(30)*	Summary of Director Compensation
10.16(30)*	Summary of Executive Compensation
21.1(30)	List of Subsidiaries
23.1(30)	Consent of KMJ/Corbin & Company LLP
31.1(30)	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(30)	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(30)	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 4.3 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(15) Incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(16) Incorporated by reference to Exhibit 4.5 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(17) Incorporated by reference to Exhibit 4.6 to the Registrant s Current Report on Form 8-K filed October 28, 2004

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

(19) Incorporated by reference to Exhibit 10.2 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(20) Incorporated by reference to Exhibit 10.3 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(21) Incorporated by reference to Exhibit 10.4 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(22) Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 10-K filed August 25, 2006

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(23) Incorporated by reference to Exhibit 10.6 to the Registrant s Annual Report on Form 10-K filed March 31, 2005

(24) Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(25) Incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(26) Incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(27) Incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(28) Incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(29) Incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(30) 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.

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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 29, 2007

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.

Signature	Title	Date
/s/ RICHARD P. LANIGAN Richard P. Lanigan	President (*Principal Executive Officer*)	March 29, 2007
/s/ WILLIAM R. ABBOTT William R. Abbott	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (*Principal Financial and Accounting Officer*)	March 29, 2007
/s/ GARY S. ALLEN, M.D. Gary S. Allen, M.D.	Director	March 29, 2007
/s/ ROBERT L. MORTENSEN Robert L. Mortensen	Director	March 29, 2007
/s/ MARVIN J. SLEPIAN, M.D. Marvin J. Slepian, M.D.	Director	March 29, 2007

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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, 2006 and the related consolidated statements of operations, stockholders equity and cash flows for each of the two years in the period ended December 31, 2006. 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, 2006 and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2006 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 26, 2007

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CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEET
December 31, 2006

		(In thousands)
ASSETS		
Current assets:		
Cash and cash equivalents	$	2,118
Accounts receivable, net of allowance for doubtful accounts of $98		2,327
Inventories, net of inventory reserve of $28		2,229
Prepaids and other current assets		421
Total current assets		7,095
Property and equipment, net		617
Other assets		63
Total assets	$	7,775
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$	326
Accrued liabilities		1,606
Deferred revenue		1,332
Current portion of note payable		89
Current portion of capital lease obligation		11
Current portion of secured convertible term note and related obligations, net		955
Total current liabilities		4,319
Capital lease obligation, less current portion		31
Other long-term liability		137
Total liabilities		4,487
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		173,401
Accumulated deficit		(170,113)
Total shareholders equity		3,288

Total liabilities and shareholders equity	$	7,775

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2006 and 2005

	2006	2005
	(In thousands, except per share amounts)	
Net revenues	$ 17,117	$ 16,341
Cost of revenues	3,644	2,998
Gross profit	13,473	13,343
Operating expenses:		
Research and development	1,474	1,725
Salaries and employee benefits	7,784	7,442
Sales, general and administrative	5,693	6,668
Total operating expenses	14,951	15,835
Operating loss	(1,478)	(2,492)
Other (expense) income:		
Interest expense	(781)	(569)
Interest income	132	162
Gain on insurance settlement	70	
Loss on disposal of fixed assets	(111)	
Non-cash interest expense	(831)	(1,414)
Change in fair value of derivatives	613	2,100
Other non-cash income	407	356
Total other (expense) income	(501)	635
Net loss	$ (1,979)	$ (1,857)
Net loss per share:		
Basic and diluted	$ (0.04)	$ (0.04)
Weighted average shares outstanding:		
Basic and diluted	45,248	43,414

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
For the Years Ended December 31, 2006 and 2005

	Common Stock		Accumulated	
	Shares	Amount	Deficit	Total
		(In thousands)		
Balances, December 31, 2004	41,500	$ 171,012	$ (166,277)	$ 4,735
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	273	126		126
Issuance of common stock for option exercises	146	47		47
Issuance of common stock related to conversions	3,183	1,815		1,815
Net loss			(1,857)	(1,857)
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

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2006 and 2005

	2006	2005
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (1,979)	$ (1,857)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Derivative and warrant fair value adjustments	(1,020)	(2,456)
Amortization related to discount on notes payable	667	827
Impairment of PLC license	730	
Loss on disposal of fixed assets	111	
Depreciation and amortization	667	512
Loss on conversion of debt		387
Provision for doubtful accounts	183	213
Inventory reserves	147	
Interest income on restricted cash	(39)	
Stock-based compensation expense	364	
Amortization of other assets	195	194
Amortization of debt issuance costs	164	200
Gain on insurance settlement	(70)	
Changes in operating assets and liabilities:		
Accounts receivable	557	298
Inventories	348	(1,070)
Prepaids and other current assets	280	488
Other assets	20	19
Accounts payable	(751)	184
Accrued liabilities	681	(43)
Deferred revenue	938	(264)
Net cash provided by (used in) operating activities	2,193	(2,368)
Cash flows from investing activities:		
Acquisition of property and equipment	(460)	(687)
Insurance proceeds received	70	
Net cash used in investing activities	(390)	(687)
Cash flows from financing activities:		
Decrease in restricted cash, net of interest income		376
Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan	37	173
Payments on short term borrowings	(308)	(278)
Repayments on secured convertible term note	(1,251)	(107)

Repayments of capital lease obligations	(6)	(6)
Net cash (used in) provided by financing activities	(1,528)	158
Net increase (decrease) in cash and cash equivalents	275	(2,897)
Cash and cash equivalents at beginning of year	1,843	4,740
Cash and cash equivalents at end of year	$ 2,118	$ 1,843
Supplemental schedule of cash flow information:		
Interest paid	$ 146	$ 146
Taxes paid	$ 30	$ 30
Supplemental schedule of noncash investing and financing activities:		
Financing of insurance premiums	$ 381	$ 295
Financing of fixed assets	$ 31	$
Issuance of common stock from conversion of debt and accrued interest	$	$ 1,427
Repayment of restricted cash portion of secured convertible term note and accrued interest	$ 2,547	$

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

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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 financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Cardiogenesis has sustained significant operating losses for the last several years and may continue to incur losses through 2007. Management believes its cash and cash equivalents balance as of December 31, 2006 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 subsidiary. 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 realizability of accounts receivable, inventories, recoverability of long-lived assets, warranty obligations, valuation of embedded derivatives, deferred tax assets, stock options and warrants.

Principles of Consolidation

Reclassifications:

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.

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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 standard cost, which approximates actual cost 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.

For the year ended December 31, 2006, the Company recorded an impairment charge of $730,000 related to its PMC licensing fee. See Note 5.

Fair Value of Financial Instruments:

The Company s financial instruments consist primarily of cash and cash equivalents, accounts receivable, trade accounts payable, accrued liabilities, capital leases, note payable and the secured convertible term note and related embedded derivatives. The carrying amounts of certain of Cardiogenesis financial instruments including cash and cash equivalents, accounts receivable, trade accounts payable, accrued liabilities and the secured convertible term note approximate fair value due to their short maturities. The fair value of the embedded derivatives related to the secured convertible term note and related obligations was determined using the Binomial Option Pricing Model.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Derivative financial instruments:

The Company s derivative financial instruments consist of embedded derivatives related to the $6,000,000 secured convertible term note (the Note). These embedded derivatives include certain conversion features and variable interest features. The accounting treatment of derivatives requires 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. Any change in fair value is recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives is higher at the subsequent balance sheet date, the Company will record a non-operating, non-cash charge. If the fair value of the derivatives is lower at the subsequent balance sheet date, the Company will record non-operating, non-cash income. As of December 31, 2006, the fair value of the embedded derivatives was an asset of $376,000. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions as of December 31, 2006, respectively: dividend yield of 0%; annual volatility of 108%; and risk free interest rate of 5.1% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The derivatives are classified as current liabilities at December 31, 2006. 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 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 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.*

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 $37,000 at December 31, 2006.

Advertising:

Cardiogenesis expenses all advertising as incurred. Cardiogenesis advertising expenses were $193,000 and $739,000 for 2006 and 2005, 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 Statement of Financial Accounting Standards No. 123 (revised 2004), *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 Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (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 as of December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company s consolidated financial statements for prior periods have not been restated to reflect, and do not include, 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 statement 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 Statement of Financial Accounting Standards

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 statement of operations for the year ended December 31, 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, 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 statement of operations for year ended December 31, 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 year ended December 31, 2006 was 20% for all options and was based on historical forfeiture experience and expected future employee forfeitures. The estimated term of option grants for the years ended December 31, 2006 and 2005 was approximately 4 and 4.5 years, respectively. In the Company s pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

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. Due to the Company s loss position, there were no such tax benefits during the year ended December 31, 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 three 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, 2006, 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 1,678,400 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 $87,000 during the year ended December 31, 2006 in accordance with SFAS No. 123(R).

During the year ended December 31, 2006, there were no purchases of shares under the ESPP. However, the Company issued approximately 56,000 shares of its common stock during 2006, related to proceeds received in 2005. In addition, in November 2006, the Company suspended the ESPP until further notice.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 year ended December 31, 2006 and 2005 were based on the following assumptions:

	Year Ended December 31, 2006	Year Ended December 31, 2005
Expected term	4 years	4.43 years
Expected volatility	106%	88%
Risk-free interest rate	4.9%	3.9%
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:

	Year Ended December 31, 2006	Year Ended December 31, 2005
Expected term	0.50 years	0.50 years
Expected volatility	106%	88%
Risk-free interest rate	4.9%	3.9%
Expected dividends		

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of option activity as of December 31, 2006 and changes during the year then ended, is presented below:

	Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2006	4,537	$ 1.10		
Options granted	1,268	$ 0.49		
Options exercised	(116)	$ 0.32		
Options forfeited/canceled	(2,198)	$ 1.13		
Options outstanding at December 31, 2006	3,491	$ 0.89	6.3	$
Vested or expected to vest	3,396	$ 0.95	6.2	$
Options exercisable at December 31, 2006	3,013	$ 0.95	5.8	$

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 1,500 outstanding and zero exercisable stock options that were in-the-money at December 31, 2006. At December 31, 2006, the aggregate intrinsic value on the outstanding shares was insignificant.

The weighted average grant date fair value of options granted during the year ended December 31, 2006 was $0.35 per option. The aggregate intrinsic value of options exercised during the year ended December 31, 2006 was approximately $20,000.

As of December 31, 2006, there was approximately $154,000 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 2.1 years. For the year ended December 31, 2006, the amount of stock-based compensation expense related to stock options was approximately $277,000. This amount includes $29,000 of stock-based expense related to the October 2006 settlement with the former Chief Executive Officer in which he was entitled to retain 689,008 previously issued stock options. For the year ended December 31, 2006, the amount of stock-based compensation expense related to ESPP purchases was approximately $87,000.

As a result of adopting SFAS 123(R) on January 1, 2006, both the Company s loss before income taxes and net loss for the year ended December 31, 2006, was approximately $364,000 higher than if it had continued to account for share-based compensation under APB 25. There was no effect to the Company s net loss per common share, basic and

diluted, for the year ended December 31, 2006, as a result of adopting SFAS 123(R). The net cash provided by operating activities did not change as a result of the adoption of SFAS 123(R).

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

	Year Ended December 31, 2006
Stock-based compensation expense included in:	
Research and development	$ 33
Sales, general and administrative	331
	$ 364

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table illustrates the effect on net loss and net loss per share for the year ended December 31, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to options granted under the Company s stock option plans. For purposes of this pro forma disclosure, the fair value of the options is estimated using the Black-Scholes option-pricing model and amortized on a straight-line basis to expense over the options vesting period (dollars in thousands, except per share data):

	Year Ended December 31, 2005
Net loss as reported	$ (1,857)
Deduct: Share-based employee compensation expense determined under fair value method, net of tax effects	(303)
Net loss pro forma	$ (2,160)
Net loss per common share as reported	
Basic	$ (0.04)
Diluted	$ (0.04)
Net loss per common share pro forma	
Basic	$ (0.05)
Diluted	$ (0.05)

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 convertible notes payable using the as-if converted method.

All potentially dilutive shares, approximately 2,192,047 and 9,844,495 as of December 31, 2006 and 2005, respectively, have been excluded from diluted loss per share as their effect would be antidilutive for the years then ended.

Recently Issued Accounting Standards:

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation requires that the Company recognize in the financial statements the impact of tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006 with the cumulative effect of the change in accounting principle recorded as an adjustment to beginning retained earnings. The Company has assessed the impact of adopting FIN 48 and has determined that no material impact to the consolidated financial statements exists.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

measurements. Specifically, SFAS No. 157 sets forth a definition of fair value, and establishes a hierarchy prioritizing the inputs to valuation techniques, giving the highest priority to quoted prices in active markets for identical assets and liabilities and the lowest priority to unobservable inputs. The provisions of SFAS No. 157 are generally required to be applied on a prospective basis, except to certain financial instruments accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, for which the provisions of SFAS No. 157 should be applied retrospectively. The Company will adopt SFAS No. 157 in the first quarter of 2008 and is still evaluating the effect, if any, on its consolidated financial position or results of operations.

In September 2006, the SEC staff issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements.* SAB No. 108 was issued in order to eliminate the diversity in practice surrounding how public companies quantify financial statement misstatements. SAB No. 108 requires that registrants quantify errors using both a balance sheet and income statement approach and evaluate whether either approach results in a misstated amount that, when all relevant quantitative and qualitative factors are considered, is material. The adoption of this statement is not expected to have a material impact on the Company s consolidated financial position or results of operations.

3. Inventories:

Inventories consist of the following *(in thousands)*:

	December 31, 2006
Raw materials	$ 577
Work in process	295
Finished goods	1,357
	$ 2,229

4. Property and Equipment:

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

	December 31, 2006
Computers and equipment	$ 593
Manufacturing and demonstration equipment	287
Leasehold improvements	38
Loaned lasers	3,370

	4,288
Less accumulated depreciation and amortization	(3,671)
	$ 617

Equipment under capital lease of $59,000, net of accumulated amortization of $18,000 at December 31, 2006, is included in property and equipment.

In the fourth quarter of 2006, the Company recognized a loss on disposal of $111,000. The total gross fixed assets of approximately $4,708,000 and related accumulated depreciation of $4,597,000 were written down to zero and the resulting loss was included in other expense.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Other Assets:

Other assets consist of the following *(in thousands):*

	December 31, 2006
Debt issuance costs, net	$ 17
Rental security deposit	46
	$ 63

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, 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, 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.

In connection with the October 2004 financing transaction discussed in Note 7, the Company capitalized debt issuance costs of $417,000. The costs are being amortized over the life of the note using the effective interest method. The total amortization expense related to the debt issuance costs was $164,000 and $200,000 for 2006 and 2005, respectively. These expenses are included in non-cash interest expense in the accompanying consolidated statements of operations.

6. Accrued Liabilities:

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

	December 31, 2006
Accrued accounts payable and related expenses	$ 47
Accrued vacation	155
Accrued salaries and commissions	222
Accrued audit and tax fees	110
Legal settlement with former CEO(1)	500
Accrued other	572
	$ 1,606

(1) See Note 9.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Secured Convertible Term Note and Related Obligations:

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) 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.

The Note matures in October 2007, absent earlier redemption by the Company or earlier conversion by Laurus. The Note is 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 Laurus financing documents restrict the Company from obtaining additional debt financing, subject to certain specified exceptions. In addition, subject to certain exceptions, the Company has granted to Laurus a right of first refusal to provide additional financing in the event that the Company proposes to engage in additional debt financing or to sell any equity securities. The Note is collateralized by all of the Company s assets.

Under certain circumstances, the Note agreement could result in conversion of the Company s common stock at conversion prices that are low enough that the shares required would be in excess of the shares currently 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 be required. Since there is a possibility that a cash payment would be required, certain features of the Note as well as other equity related instruments have been recorded as liabilities on the Company s consolidated balance sheet.

The Note includes certain features that are 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. These features are described below, as follows:

The Note is convertible at the holder s option at any time at the fixed conversion price of $.50 per share. This conversion feature has been identified as an embedded derivative and has 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 must be converted to common stock at the fixed conversion price of $0.50 if the fair value of the Company s common stock is greater than $0.55 per share for the 5 days preceding the payment due date. This conversion feature has 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 be converted at a fixed conversion price of $0.50 per share if the fair value of the Company s common stock is 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 has been

identified as an embedded derivative and has been bifurcated and recorded on the Company s consolidated balance sheet at its fair value. As a result of the repayment of the restricted cash, this derivative is not applicable at December 31, 2006;

Annual interest on the Note is 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 may not be 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 may never be reduced below 0%. Interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note, beginning

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

November 2004. The potential interest rate reduction due to future possible increases in the Company s stock price has been identified as an embedded derivative and has been bifurcated and recorded on the Company s consolidated balance sheet at its fair value;

The Note agreement includes 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. This liquidated damages feature represented an embedded derivative, however since the Company has met the registration requirements, this derivative is no longer valid.

The Note agreement contains certain events of default including delinquency, bankruptcy, change in control and stop trade or trade suspension. In the event of default, Laurus has 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 represents an embedded derivative. However, based on the de minimus value associated with this feature, no value has been assigned at issuance and at December 31, 2006. Pursuant to the terms of the Note, an event of default includes a suspension of trading of the Company s common stock on the OTC Bulletin Board which remains uncured within thirty (30) days of notice of the suspension. To the extent that the delisting is deemed a suspension of trading and the Company is unable to have its common stock listed on the OTC Bulletin Board within such thirty day period, the Company will be in default of its obligations under the Note. If an event of default occurs under the Note, interest on the Note will accrue at the default rate which is the then current prime rate plus 12% per annum until the default is cured. In addition, the holder of the Note will have the right to accelerate the Note and declare it immediately due and payable and exercise its rights as a secured creditor under applicable law and the security agreement with the Company, including the right to foreclose upon the assets of the Company securing the Note, which constitute substantially all of the Company s assets. In addition, to mitigate the financial consequences of any possible default, in May 2006, the Company repaid approximately $2,417,000 of the outstanding principal amount of the Note out of the restricted cash account created for the benefit of Laurus and the Company. In connection with the repayment, the Company was required to pay a prepayment penalty (equal to 20% of the amount to be repaid).

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 requires that the Company record the derivatives and the 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. Any change in fair value will be recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives and warrants is higher at the subsequent balance sheet date, the Company will record a non-operating, non-cash charge. If the fair value of the derivatives and warrants is lower at the subsequent balance sheet date, the Company will record non-operating, non-cash income. 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 are being recorded at fair market value at each balance sheet date.

At December 31, 2006, the derivatives were valued as an asset of approximately $376,000. These derivatives were valued using the Binomial Option Pricing Model with the following assumptions as of December 31, 2006: dividend yield of 0%; annual volatility of 108.2%; and risk free interest rate of 5.1% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The derivatives are classified as current liabilities at December 31, 2006.

The warrant was valued at $362,000 at December 31, 2006, using the Binomial Option Pricing model with the following assumptions: dividend yield of 0%; annual volatility of 106%; risk-free interest rate of 4.9%; and exercise factor of 2 times and 2 times. The fair value of this warrant is included in the Secured Convertible Term Note and related obligations on the consolidated balance sheet and the change in the fair value is included in other non-cash income (expense) on the consolidated statements of operations.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 are being amortized to interest expense over the expected term of the debt, using the effective interest method. At December 31, 2006, the unamortized discount on the Note was $72,000. The weighted average effective interest rate on the Note for the years ended December 31, 2006 and 2005, was 37% and 25%, respectively.

Future principal obligations due under the Note, assuming the Company will not be in default of the provisions in the secured convertible note as discussed above, are as follows:

Year Ending December 31,	
2007	$ 1,041,000

The market price of the Company s common stock significantly impacts the extent to which the Company is permitted to convert the Laurus debt into shares of the Company s common stock. The lower the market price of the Company s common stock as of the respective times of conversion, the more shares the Company will need to issue to Laurus to convert the principal and interest payments then due on the debt. If the market price of the Company s common stock falls below certain thresholds, the Company will be unable to convert any such repayments of principal and interest into equity, and the Company will be forced to make such repayments in cash. The Company s operations could be materially adversely impacted if the Company is forced to make repeated cash payments on the Laurus debt.

The following table presents a reconciliation between the principal amount of the Note and the current carrying amount of the Note on the consolidated balance sheet:

	December 31, 2006 (In thousands)
Principal Note balance	$ 6,000
Principal conversions	(1,184)
Repayment of restricted cash balance	(2,417)
Cash payments	(1,358)
Total secured convertible term note	1,041
Unamortized discount on Note	(72)
Derivative valuation	(376)
Warrant valuation	362
Total secured convertible term note and related obligations	$ 955

During the year ended December 31, 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. During the year ended December 31, 2005, the Company issued an aggregate of 3,182,754 shares of its common stock in connection with the conversion of $1,427,354 in principal and accrued interest on the Note. Each conversion of debt into equity was recorded as an extinguishment of debt and an increase in equity valued at the fair market value on the date of conversion. A gain or loss on extinguishment of debt was recorded at time of conversion and represents the difference in fair market value at the date of conversion less the actual conversion price. In the year ended December 31, 2005, the total loss associated to the Laurus conversions was $387,000.

8. Long-term Liabilities:

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. The warrant is immediately exercisable and has a term of five years. At December 31, 2006, the

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

fair value of this warrant is $137,000 and is classified in the consolidated balance sheet as the other long-term liability and the change in the fair value is included in other non-cash income (expense) on the consolidated statements of operations.

9. 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,	
2007	100
2008	105
2009	120
2010	126
2011	120
	$ 571

Rent expense was approximately $328,000 and $362,000 for the years ended December 31, 2006 and 2005, respectively.

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 will also pay approximately $51,000 to Mr. Quinn s counsel as attorney s fees. The Company accrued the entire amount including $28,000 of related payroll taxes. At December 31, 2006, the balance of the accrual was approximately $500,000. 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

10. Shareholders Equity:

Issuances of Common Stock:

During the year ended December 31, 2006, the Company did not issue any shares of its common stock in connection with conversions of the Note. During the year ended December 31, 2005, the Company issued an aggregate of 3,182,754 shares of its common stock in connection with the conversion of $1,427,354 in principal and accrued interest on the Note. See Note 7.

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. During the year ended December 31, 2005, the Company issued 146,388 shares of common stock for approximately $47,000 in connection with the exercise of options.

During the year ended December 31, 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. During the year ended December 31, 2005, the Company issued 272,697 shares of common stock for $126,000 in connection with purchases under the ESPP.

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, 2006 and 2005, the Company recorded amortization charges to rent expense of $10,000 and $19,000 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. For the year ended December 31, 2004, the Company recorded amortization of $31,000 in connection with these warrants. 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, 2006.

In January 2004, in conjunction with a private equity offering, Cardiogenesis issued a warrant to purchase approximately 3,100,000 shares of common stock at a price of $1.37 per share. The warrants are immediately exercisable and have a term of five years.

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. See Note 7.

During the years ended December 31, 2006 and 2005, 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 currently 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 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2,640,000 shares of common stock. At December 31, 2006, the warrant to purchase approximately 3,100,000 shares was valued at $137,000. At December 31, 2006, the warrant to purchase 2,640,000 shares was valued as an asset of $362,000. For the years ended December 31, 2006 and 2005, the income statement impact to mark to market the value of the warrants resulted in income of $407,000 and $356,000, respectively, and was included in Other non-cash income on the statements of operations.

Options Granted to Employees:

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. During the year ended December 31, 2005, the Company issued approximately 1,081,000 options to purchase shares of the Company s common stock to certain officers, directors, and employees with a weighted average exercise price of $0.55, a 10 year expiration term, and vesting terms ranging from immediate to 3 years.

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, 2006, 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, 2006, 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Employee Stock Purchase Plan:

Cardiogenesis maintains an Employee Stock Purchase Plan (ESPP), under which 1,678,400 shares of common stock have been reserved 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 year 2006, no shares were sold through the ESPP. During fiscal year 2005, approximately 329,000 shares were sold through the ESPP, of which approximately 56,000 shares were issued during 2006. In addition, in November 2006, the Company suspended the ESPP until further notice.

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

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Price per Share
Balance, December 31, 2004	3,246	4,177	$ 1.28
Additional shares reserved	1,150		
Options granted	(1,081)	1,081	$ 0.55
Options forfeited	567	(567)	$ 1.97
Options expired	10	(10)	$ 1.67
Options exercised		(144)	$ 0.32
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

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, 2006:

	Options Outstanding			Options Exercisable	
		Weighted Average	Weighted		Weighted

Exercise Prices	Number Outstanding (In thousands)	Remaining Contractual Life (In Years)	Average Exercise Price	Number Exercisable (In thousands)	Average Exercise Price
$0.25 - $0.46	449	5.71	$ 0.33	420	$ 0.32
$0.47 - $0.51	903	7.41	$ 0.50	524	$ 0.50
$0.54 - $0.58	614	6.24	$ 0.54	590	$ 0.54
$0.59 - $0.83	797	6.22	$ 0.68	751	$ 0.69
$0.84 - $1.16	330	6.27	$ 0.99	330	$ 0.99
$1.19 - $1.40	234	5.32	$ 1.27	234	$ 1.27
$2.57 - $4.00	54	4.25	$ 2.90	54	$ 2.90
$6.06 - $7.44	70	2.52	$ 6.46	70	$ 6.46
$8.00 - $11.50	40	1.60	$ 9.82	40	$ 9.82
	3,491	6.25	$ 0.89	3,013	$ 0.95

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. 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, 2006 and 2005 $0 and $234,000 of employer contributions were made to the plan, respectively.

12. 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 $376,000 and $676,000 for the years ended December 31, 2006 and 2005, respectively. The international sales represent 2% and 4% of total sales for the years ended December 31, 2006 and 2005, 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.

13. Income Taxes:

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

	December 31, 2006
Net operating losses	$ 54,752
Credits	3,490
Research and development	713
Reserves	245
Accrued liabilities	1,008
Depreciation/Amortization	10
Net deferred tax asset	60,218
Less valuation allowance	(60,218)
Net deferred tax assets	$

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, 2006, the Company had federal and state net operating loss carryforwards of approximately $157,458,000 and $22,070,000, respectively, to offset future taxable income. In addition, the Company had federal and state credit carryforwards of approximately $2,508,000 and $1,487,000 available to offset future tax liabilities.

The Company s net operating loss carryforwards, as well as federal credit carryforwards, will expire at various dates beginning in 2007 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.

The deferred tax assets as of December 31, 2006 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 each of the three years ended December 31, 2006 represented current state minimum taxes of $1,600 per year.

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, 2006, two customers individually accounted for 15% and 13% of gross accounts receivable. For the years ended December 31, 2006 and 2005, no customer individually accounted for 10% or more of net revenues.

At December 31, 2006 and 2005, the Company had amounts on deposit with financial institutions in excess of the federally insured limits of $100,000.

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.

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EXHIBIT INDEX

Exhibit No.	Description
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)	Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.10(15)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.11(16)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.12(17)	Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(18)*	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(19)*	Stock Option Plan, as amended and restated July 2005
10.3(20)*	Director Stock Option Plan, as amended and restated July 2005
10.4(21)*	Employee Stock Purchase Plan, as amended and restated July 2005
10.5(22)	Lease for the Company s executive offices in Irvine, California
10.6(23)*	401(k) Plan, as restated January 1, 2005
10.8(24)*	Description of the Stock Option Plan
10.9(25)*	Description of the Director Stock Option Plan
10.10(26)*	Form of Stock Option Agreement for Executive Officers under the Stock Option Plan
10.11(27)*	Form of Grant Notice under the Stock Option Plan
10.12(28)*	Form of Stock Option Agreement for Directors under the Director Stock Option Plan
10.13(29)*	Form of Grant Notice under the Director Stock Option Plan
10.14(30)*	Settlement Agreement and General Release between the Registrant and Michael J. Quinn, dated October 24, 2006

10.15(30)*	Summary of Director Compensation
10.16(30)*	Summary of Executive Compensation
21.1(30)	List of Subsidiaries
23.1(30)	Consent of KMJ/Corbin & Company LLP

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Exhibit No.	Description
31.1(30)	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(30)	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(30)	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 4.3 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(15) Incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(16) Incorporated by reference to Exhibit 4.5 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(17) Incorporated by reference to Exhibit 4.6 to the Registrant s Current Report on Form 8-K filed October 28, 2004

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

(19) Incorporated by reference to Exhibit 10.2 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(20) Incorporated by reference to Exhibit 10.3 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(21) Incorporated by reference to Exhibit 10.4 of the Registrant s Annual Report on Form 10-K filed on August 21, 2006

(22) Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 10-K filed August 25, 2006

(23) Incorporated by reference to Exhibit 10.6 to the Registrant s Annual Report on Form 10-K filed March 31, 2005

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(24) Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(25) Incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(26) Incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(27) Incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(28) Incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(29) Incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K filed on August 4, 2005

(30) Filed herewith