CARDIOGENESIS CORP /CA
Form 10-K
March 31, 2005

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004
Commission file number: 0-28288

Cardiogenesis Corporation
(formerly known as Eclipse Surgical Technologies, Inc.) (Exact name of Registrant as specified in its charter)

California	**77-0223740**
(State of incorporation)	*(I.R.S. Employer Identification Number)*

26632 Towne Center Drive, Suite 320
Foothill Ranch, California 92610
(Address of principal executive offices)
(714) 649-5000
(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, no par value
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated herein by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Yes o No þ

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2.)

Yes o No þ

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant was approximately $19,920,658 as of June 30, 2004, based upon the closing sale price reported for that date of $0.56 on the OTC Bulletin Board. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

Indicate the number of shares outstanding of each of the issuer s classes of common stock outstanding as of the latest practicable date.

42,186,988 shares
As of March 11, 2005

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PART I

Item 1. *Business.*

This Annual Report on Form 10-K 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 Item 7 and elsewhere.

General

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. TMR and PMC are recent 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 incision in the chest under general anesthesia. PMC is performed by a cardiologist in a catheter-based procedure which utilizes local anesthesia. Clinical studies have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with TMR or PMC 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. 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 final approval from the Food and Drug Administration (FDA) for our TMR products for treatment of stable patients with certain types of angina. Effective July 1999, the Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financial Administration (HCFA) began to provide Medicare coverage for any TMR procedures. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on Medicare patients.

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 are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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In March 1999, we merged with the former Cardiogenesis Corporation. Under the terms of the combination, each share of the former Cardiogenesis common stock was converted into 0.8 of a share of our common stock, and the former Cardiogenesis has become a wholly owned subsidiary of ours. As a result of the transaction, our outstanding shares increased by approximately 9.9 million shares. The transaction was structured to qualify as a tax-free reorganization and has been accounted for as a pooling of interests.

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. The American Heart Association estimates that more than six million Americans experience angina symptoms.

The primary therapeutic options for treatment of coronary artery disease are drug therapy, balloon angioplasty also known as percutaneous transluminal coronary angioplasty or (PTCA), other interventional techniques which augment or replace PTCA such as stent placement and atherectomy, 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. 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. Most 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.

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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 continuing to pursue FDA approval for use in the U.S., offer potential relief to a large population of patients with severe 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, for the status of our PMA application with the FDA seeking approval of PMC for public sale and use in the United States.

Business Strategy

Our objective is to become a recognized leader in the field of myocardial revascularization, with TMR and PMC established as well-known and acceptable therapies. Our strategies to achieve this goal are as follows:

Add Innovative New Technology to our Market Basket. Our focus is to add innovative new tools to help address 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.

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 and expansion of direct international sales and support organizations and third party distributors and agents. In addition, we have developed a comprehensive training program to assist physicians in acquiring the expertise necessary to utilize our TMR and PMC products and procedures.

Demonstrate Clinical Utility of PMC. We are seeking to demonstrate the clinical safety and effectiveness of PMC. We have completed a pivotal clinical trial regarding PMC, and the study results were submitted to the FDA in a PMA application in December 1999, along with subsequent supplements. As discussed below 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

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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 are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. We cannot assure you, however, that we will receive a favorable determination from the FDA.

Leverage Proprietary Technology. We believe that our significant expertise in laser and catheter-based systems for cardiovascular disease and the proprietary technologies we have developed are important factors in our efforts to demonstrate the safety and effectiveness of our TMR and PMC procedures. We are seeking to develop additional proprietary technologies for TMR, PMC and related procedures. 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 TMR, PMC and other 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 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 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.

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).

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).

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.

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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 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.

celleratOR System

In December 2004, we signed a distribution agreement to begin selling platelet rich plasma (PRP) products. Our new autologous platelet and growth factor concentrating system, celleratOR, consists of a general use centrifuge and cell separator tubes. The cell separator tubes, due to their proprietary design, allow for the greatest amount of flexibility in the end user determining the concentration and volume of the platelet and growth factor concentrate, called PRP. The benefits of this technology are known and embraced in several surgical specialties because of its potential for contributing to improved patient outcomes. celleratOR is our first new product beyond laser myocardial revascularization devices, and we expect it to be a useful addition to patient-centered cardiovascular medicine.

Regulatory Status

United States. In February 1999, we received approval from the FDA for use of our TMR 2000 laser console and SoloGrip handpiece for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

We 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 are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

In addition, the new Pearl 5.0 mm and 8.0 mm minimally invasive handpieces have been included in applications to the FDA and to international health authorities, and we are currently working with these respective agencies toward approvals.

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 Community.

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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.

In the United States, we currently offer a TMR 2000 laser base unit at a current end user list price of $355,000 per unit, a SolarGen 2100s laser system at a current end user list price of $395,000, and the disposable TMR handpiece (at least one of which must be used with each TMR procedure) at an end user unit list price of $3,630. In addition to sales of lasers to hospitals outright, in an effort to accelerate market adoption of the TMR procedure, we developed a program in which we loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price.

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 TMR or PMC 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 TMR or PMC in vivo. To date over 1,260 cardiothoracic surgeons 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 PMC applications. In 2004, we developed the new and improved SolarGen laser system as well as handpieces for our minimally invasive and robotic assisted TMR platforms.

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 TMR and PMC handpiece systems to a single contract manufacturer. We also outsource the manufacturing of our SolarGen 2100s laser system to a different single contract manufacturer. The PMC laser system is provided to us under a manufacturing agreement with a laser manufacturing company.

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.

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Competition

We expect that the market for TMR and PMC, which is currently in the early stages of development, will be competitive. At this point in time, we believe that our only 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 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 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 than we currently can.

We believe that the factors which will be critical to market 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.

TMR and PMC also compete with other methods for the treatment of cardiovascular disease, including drug therapy, PTCA 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 TMR or PMC products will be accepted 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,

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and proposed clinical protocols. If the FDA clears the IDE application, human clinical trials may begin. The results obtained from these trials are accumulated and, if satisfactory, are submitted to the FDA in support of a PMA application. Prior to U.S. commercial distribution, premarket approval is required from the FDA. In addition to the results of clinical trials, the PMA application must include other information relevant to the safety and effectiveness of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. By law, the FDA has 180 days to review a PMA application. While the FDA has responded to PMA applications within the allotted time frame, reviews more often occur over a significantly longer period and may include requests for additional information or extensive additional 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. In January 2005, we again met with the agency and agreed on major trial parameters. We are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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, postmarket surveillance and adverse event reporting requirements. 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 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 require-

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ment. Our facilities are subject to ongoing, periodic inspections by the FDA and California regulatory authorities.

Sales, manufacturing and further development of our TMR and PMC 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 9001 standards 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 TMR and PMC 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 TMR, PMC and other 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 that occur, 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 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

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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 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 or PMC. 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.

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

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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, 2004 we had 38 employees, of which 20 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.

Our executive officers as of March 1, 2005 were as follows:

Name	Age	Position
Michael J. Quinn	61	President, Chief Executive Officer, and Chairman of the Board and Director
Christine G. Ocampo	32	Vice President, Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary
Joseph R. Kletzel, II	55	Senior Vice President, General Manager of Pacific Division
Richard P. Lanigan	46	Senior Vice President of Marketing
Henry R. Rossell, Jr.	49	Senior Vice President, General Manager of Atlantic Business Unit
Gerard A. Arthur	46	Vice President, General Manager of Worldwide Services Division
Janet M. Fauls	42	Vice President, Regulatory, Quality and Clinical Affairs Division
Lee S. Langford	31	Vice President, General Manager of Central Division

Michael J. Quinn has served as our Chief Executive Officer, Chairman of the Board and Director since October 2000 and also President from October 2000 to May 2002 and from November 2003 to the present. From November 1999 to September 2000, Mr. Quinn served as Chief Executive Officer, President and a member of the Board of Directors for Premier Laser Systems, a manufacturer of surgical and dental products. From January 1998 to November 1999, Mr. Quinn served as President and Chief Operating Officer of Imagyn Medical Technologies, Inc., a manufacturer of minimally invasive surgical specialty products. From 1995 through December 1997, Mr. Quinn served as President and Chief Operating Officer of Fisher Scientific

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Company. Prior to 1995, Mr. Quinn held senior operating management positions at major healthcare organizations including American Hospital Supply Corporation, Picker International, Cardinal Health Group and Bergen Brunswig.

Christine G. Ocampo has served as our Vice President, Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary since November 2003. From 2001 to November 2003, Ms. Ocampo served in the role of Vice President and Corporate Controller. She first joined the Company in April 1997 and spent four years as our Accounting Manager. Prior to joining us, Ms. Ocampo held a management position in Finance at Mills-Peninsula Health Systems in Burlingame, CA, and spent three years as an Audit Senior for Ernst & Young LLP. She graduated with a Bachelors of Science in Accounting from Seattle University and became a licensed Certified Public Accountant in 1996.

Joseph R. Kletzel, II has served as the Senior Vice President, General Manager of Pacific Division, which includes all of the United States west of the Mississippi, since July 2004. Mr. Kletzel is a veteran executive with more than 25 years of operations and strategic management experience with leading biotech and medical device companies. Mr. Kletzel has been a member of the Cardiogenesis Board of Directors for nearly three years and will continue to serve on the Board. From 2000 to 2004 Mr. Kletzel served as Chief Operating Officer of La Jolla, CA-based Advanced Tissue Sciences, one of the nation s leaders in human tissue engineering. From 1996 to 1998, Mr. Kletzel was President of Pittsburgh-based Fisher Scientific International, an international manufacturer and distributor of laboratory supplies and equipment, and, from 1992 to 1996, was President and Chief Operating Officer of Chatsworth, CA-based Devon Industries, a privately-held international manufacturer of surgical products. Mr. Kletzel has a bachelor s degree in biology from Villanova University and is a former Captain in the U.S. Marine Corps.

Richard P. Lanigan has been our Senior Vice President of Marketing since November 2003. Prior to November 2003, Mr. Lanigan served in a variety of different capacities. From March 2001 to October 2003, Mr. Lanigan was Vice President of Government Affairs and Business Development. From March 2000 to March 2001, Mr. Lanigan served as Vice President of Sales and Marketing and from 1997 to 2000, he was the Director of Marketing. From 1992 to 1997, Mr. Lanigan served in various positions, most recently Marketing Manager, at Stryker Endoscopy. From 1987 to 1992, Mr. Lanigan served in Manufacturing and Operations management at Raychem Corporation. From 1981 to 1987, he served in the U.S. Navy where he completed six years of service as Lieutenant in the Supply Corps. Mr. Lanigan has a Bachelors of Arts in Finance from Notre Dame and a Masters degree in Systems Management from the University of Southern California.

Henry R. Rossell, Jr. has been our Senior Vice President, General Manager of the Atlantic Business Unit since January 2004. Prior to that, Mr. Rossell served as our Senior Vice President of Worldwide Sales and Marketing since January 2003. From 1999 to 2002, Mr. Rossell served as Senior Vice-President, Sales and Marketing, Surgical Products Division at Imagyn Medical Technologies, Inc. From 1998 to 1999, he served as Vice President of the Education Services Group at Medascend, Inc. From 1994 to 1998, Mr. Rossell served as Vice President of Sales at Deknatel Snowden-Pencer and at Genzyme Surgical Products following the acquisition of Deknatel by Genzyme. Prior to Genzyme, Mr. Rossell spent 17 years in several sales management positions at Baxter Healthcare International where his most recently held position was Area Vice President, Corporate Sales and Marketing. Mr. Rossell has a Bachelors of Arts in History from Duke University.

Gerard A. Arthur has 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.

Janet M. Fauls has served as Vice President, Regulatory, Quality and Clinical Affairs since November 2001. Prior to joining Cardiogenesis, Ms. Fauls held various management positions, most recently Director of Worldwide Regulatory Affairs, Biologics at Allergan. In the preceding 15 years, she held increasingly

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responsible management positions in Regulatory Affairs at Edwards Lifesciences, Alliance Pharmaceutical Corporation, and Allergan. From 1984 to 1987, she served as a chemist in the aerospace industry. Ms. Fauls holds a Bachelor of Science degree in Chemistry from the University of California, Santa Barbara.

Lee S. Langford joined Cardiogenesis in January 2005 as Vice President, General Manager of the Central Division. Prior to that, from 2002 to 2004 Mr. Langford worked for Given Imaging, first as a Capital Sales Representative, then as a Regional Manager. From 2000 to 2002 Mr. Langford excelled as a sales representative with Imagyn Medical Technologies in their surgical and oncology divisions. Mr. Langford is a graduate of the U.S. Military Academy (West Point) and served as a commissioned officer in the U.S. Army (Ranger Infantry Officer), attaining the rank of Captain.

Risk Factors

In addition to the other information included in this Form 10-K, the following risk factors should be considered carefully in evaluating us and our business.

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

We have incurred significant losses since inception. For example, for the fiscal years 2004, 2003 and 2002 we incurred net losses of $1,319,000, $348,000 and $530,000 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 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.

We have recently obtained $6.0 million of convertible debt financing which we believe will be sufficient to satisfy our capital needs for at least the next 12 months. However, 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;

until such time, if ever, as we obtain FDA and other regulatory approvals for our PMC laser systems; 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 systems for any manufacturer s TMR procedures. Hospitals and physicians are eligible to receive Medicare

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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 would 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. CMS does not have a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS does not intend to commence any action on TMR coverage at this time.

As PMC has not been approved by the FDA, the CMS has not approved reimbursement for PMC. If we 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 to receive international reimbursement approvals could hurt market acceptance of our TMR and PMC products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

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 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 an alternative process in which additional data in support of our PMA supplement for PMC could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved.

In March 2004, the FDA informed us that the data submitted in August 2003 was 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. In January 2005, we again met with the agency and agreed on major trial parameters. We are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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In August 2004, we decided to rename the PMC platform to Percutaneous Myocardial Channeling (PMC). The new name more literally depicts the immediate physiologic tissue effect of the percutaneous procedure.

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 incur impairment charges on long-lived assets if future events indicate asset values my not be recoverable.

In January 1999, we entered into an agreement with PLC Systems, Inc., which granted us non-exclusive worldwide use of certain PLC patents. In return, we paid PLC a license fee totaling $2,500,000 over a forty-month period. The present value of the payments of $2,300,000 was recorded as an asset and is included in other assets. The PLC patents are valuable to our PMC product line. The PMC product line is not approved for sale in the United States but is sold internationally. If PMC product sales decline in the future, we may suffer an impairment of the asset s value on our balance sheet.

We may fail to obtain required regulatory approvals in the United States to market our new minimally invasive and robotically assisted handpieces.

The Pearl 5.0 mm and 8.0 mm minimally invasive handpieces have been included in applications to the FDA and to international health authorities, and we are currently working with these respective agencies toward approvals. 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.

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;

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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 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 TMR and PMC 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

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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.

In 2001 we began a restructuring of our business to bring our cost structure more in line with our revenues. As part of this restructuring we significantly reduced our workforce. Growth in our business may place a significant strain on our limited personnel, 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 TMR and PMC systems;

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

the costs associated with such growth, which are difficult to quantify, but could be significant;

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.

To accommodate any such growth and compete effectively, we may need to obtain additional funding to improve information systems, procedures and controls and expand, train, motivate and manage our employees, and such funding may not be available in sufficient quantities, if at all. If we are not able to manage these activities and implement these strategies successfully to expand to meet any increased demand, our operating results could suffer.

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.

Our common stock is listed on the OTC Bulletin Board which 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. The OTC Bulletin Board is a significantly more limited market in comparison to the Nasdaq system. The listing of our shares on the OTC Bulletin Board may result in a 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.

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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 11, 2005, the closing prices of our common stock as reported on the OTC Bulletin Board ranged from a high of $1.16 per share to a low of $0.35 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; 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 will suffer.

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

are more effective than our products;

are more effectively marketed than our products; or

may render our products or technology obsolete.

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If we obtain the FDA s approval for our PMC laser system, 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 TMR and PMC procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMC technology. 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;

require us to seek licenses from third parties;

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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. 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 were historically 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 TMR or PMC 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. Though we are in the process of responding to the FDA s Circulatory Devices Panel s recent recommendation against approval of our PMC product 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 require increased product liability coverage as sales of approved products increase and as 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. For example, in November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

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. 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;

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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;

our common stock is suspended for 5 consecutive days or 5 days during any 10 consecutive days from a principal market;

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 effect 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 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 2.6 million 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 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.

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.

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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 unrestricted and restricted portions 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 unrestricted portion of the debt. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be forced to make such repayments in cash, which we currently forecast will be required to sustain our operations. Our operations could be materially adversely impacted if we are forced to make repeated cash payments on the unrestricted portion of the Laurus debt. Further, prior to the full repayment of the unrestricted portion of the Laurus debt, we will only be able to require conversions of the $3,000,000 restricted cash amount to the extent the market price of our common stock exceeds certain levels. To the extent that the market price of our common stock does not reach such specified levels, we will be not be entitled to take possession of any of the restricted cash during the term of the Laurus note. Our inability to access such cash could limit our ability to achieve our operational objectives. The restricted portion of the debt will continue to accrue interest during the entire period that we are unable to require conversion. In addition, to the extent that conversions of the restricted portion of the debt are not effected during the term of the note, we have only a limited ability to convert a specified amount of the restricted debt (subject to meeting certain minimum market price thresholds and volume requirements), and we will be required to repay the remaining restricted principal and interest in cash. The cash required to pay such amounts would most likely come out of working capital and restricted cash, which may not be sufficient to repay the amounts due.

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

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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 $.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 will require 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. The Financial Accounting Standards Board has adopted changes that will require companies to record a charge to earnings for employee stock option grants and other equity incentives beginning July 1, 2005. This accounting change will reduce 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. ***Properties.***

Our headquarters, located in Foothill Ranch, California, are comprised of 12,533 square feet of leased space. The lease expires in October 2006. We believe our facilities are adequate to meet our foreseeable requirements. There can be no assurance that additional facilities will be available to us, if and when needed, thereafter.

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

In November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. In connection with his departure, Mr. Eckstein has made certain breach of contract claims arising out of his employment agreement with us, as well as certain tort claims and is seeking unspecified monetary damages. Pursuant to the terms of Mr. Eckstein s employment agreement, the matter has been submitted to binding arbitration. We believe Mr. Eckstein s claims are without merit and we are vigorously defending against these claims. However, if Mr. Eckstein were to prevail on some or all of his claims, we cannot assure you that such claims would not have a material adverse effect on our financial condition, results of operations or cash flows. Because of the preliminary stage of this case, an estimate of potential damages, if any, would be premature and speculative. As a result, we have not made any such estimate.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

None.

PART II

Item 5. ***Market for Registrants Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.***

Our common stock is traded on the OTC Bulletin Board under the symbol CGCP.OB. In 2002, our common stock was listed on the Nasdaq SmallCap Market and Nasdaq National Market. 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, Nasdaq National Market and Nasdaq SmallCap Market for the respective market on which our common stock was listed during the quarter being reported.

2003	**High**	**Low**
First Quarter	$ 0.66	$ 0.22
Second Quarter	$ 0.85	$ 0.24
Third Quarter	$ 1.49	$ 0.72
Fourth Quarter	$ 1.92	$ 0.70

2004	**High**	**Low**
First Quarter	$ 1.40	$ 0.59
Second Quarter	$ 0.87	$ 0.44
Third Quarter	$ 0.75	$ 0.47
Fourth Quarter	$ 0.70	$ 0.35

As of March 11, 2005, shares of our common stock were held by 242 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, to generate increased growth and for general corporate purposes. Moreover, certain restrictions contained in the terms of our financing transaction with Laurus (described below) prohibit us from paying dividends or redeeming shares while the obligations to Laurus remain outstanding.

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 (the 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 to Laurus in a private offering.

From January 1, 2005 through March 11, 2005, Laurus elected to convert an aggregate of $355,140 of principal and interest under the Note into an aggregate of 710,281 shares of our common stock at a conversion

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price of $.50 per share. Each of such issuance was made pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Securities Authorized for Issuance Under Equity Compensation Plans

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 equity compensation plans as of December 31, 2004. The table includes the following plans: The Cardiogenesis Corporation Stock Option Plan, the Cardiogenesis Corporation Director Stock Option Plan, and the Cardiogenesis Corporation 1996 Stock Purchase Plan.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Related in Column (a)) (c)
Equity compensations plans approved by security holders(1)	4,177,000	$ 1.28	2,996,000
Employee stock purchase plan approved by security holders(2)			
Equity compensations plans not approved by security holders			
Total	4,177,000	$ 1.28	2,996,000

(1) Consists of the Cardiogenesis Corporation Stock Option Plan and the Cardiogenesis Director Stock Option Plan.

(2) The Cardiogenesis Corporation 1996 Stock Purchase Plan enables employees to purchase our common stock at an 85% percent discount to market value at the beginning or end of each offering period. As such, the number of shares that may be issued during a given period and the purchase price of such shares cannot be determined in advance. However, as of December 31, 2004, an aggregate of 138,001 shares remain available for issuance under the 1996 Stock Purchase Plan. See Note 9 to our Consolidated Financial Statements.

Item 6. ***Selected Consolidated Financial Data.***

The following selected consolidated statement of operations data for fiscal years ended 2004, 2003 and 2002 and the consolidated balance sheet data for 2004 and 2003 set forth below are derived from our consolidated financial statements and are qualified by reference to our consolidated financial statements included herein.

The selected consolidated statement of operations data for fiscal year ended 2001 and 2000 and the consolidated balance sheet data for 2002, 2001 and 2000 have been derived from our audited consolidated financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected for any future period.

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Selected Consolidated Financial Data

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net revenues	$ 15,454	$ 13,518	$ 13,048	$ 14,153	$ 22,210
Cost of revenues	2,193	2,295	2,935	5,777	10,055
Gross profit	13,261	11,223	10,113	8,376	12,155
Operating expenses:					
Research and development	1,442	1,944	657	1,863	5,065
Sales, general and administrative	11,322	9,590	12,297	15,119	22,009
Restructuring and merger-related costs					1,033
Total operating expenses	12,764	11,534	12,954	18,015	27,074
Operating income (loss)	497	(311)	(2,841)	(9,639)	(14,919)
Interest and other (expense) income, net	(1,816)	(37)	2,311	(608)	310
Net loss	$ (1,319)	$ (348)	$ (530)	$ (10,247)	$ (14,609)
Net loss per share basic and diluted	$ (0.03)	$ (0.01)	$ (0.01)	$ (0.31)	$ (0.48)
Shares used in per share calculation	41,152	37,303	36,911	33,311	30,166
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 4,740	$ 1,013	$ 1,490	$ 2,629	$ 3,357
Working capital	6,994	2,001	1,614	1,048	4,662
Total assets	15,683	6,460	7,755	11,309	16,965
Long-term debt, less current portion	7,329	6	1	32	405
Accumulated deficit	(166,277)	(164,958)	(164,610)	(164,080)	(153,833)
Total shareholders equity	4,735	3,820	3,711	3,582	7,974

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor

provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and similar expressions. In addition, any statement to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. 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-K.

Overview

Cardiogenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc., incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic

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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 now eligible to receive Medicare reimbursement for TMR equipment and procedures performed on Medicare recipients.

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 are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

As of December 31, 2004, we had an accumulated deficit of $166,277,000. 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, 2004 Compared to Year Ended December 31, 2003

Net Revenues

We generate our revenues primarily through the sale of our TMR laser base units and related handpieces, and related services. Net revenues of $15,454,000 for the year ended December 31, 2004 increased $1,936,000, or 14%, when compared to net revenues of $13,518,000 for the year ended December 31, 2003. The increase in net revenues was primarily due to an increase in domestic handpiece and laser revenues of $1,113,000 and $692,000, respectively, as well as an increase in international handpiece and laser sales of $3,000 and $65,000, respectively. In addition, service and other revenue of $1,034,000 increased by $63,000 for the year ended December 31, 2004 when compared to $971,000 for the year ended December 31, 2003.

The increase in handpiece revenue is primarily related to a higher average per unit selling price and a higher quantity sold in 2004 as compared to 2003. In the year ended December 31, 2004, domestic handpiece revenue consisted of $2,214,000 in sales to customers operating under our loaned laser program, of which $699,000 was attributed to premiums associated with such sales. In the year ended December 31, 2003, domestic handpiece revenue consisted of $2,649,000 in sales of product to customers operating under our loaned laser program, of which $781,000 was attributed to premiums associated with such sales. In the years

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ended December 31, 2004 and 2003, sales of product to customers not operating under our loaned laser program were $7,936,000 and $6,387,000, respectively.

For the year ended December 31, 2004, domestic laser sales increased by $692,000 compared to the year ended December 31, 2003 primarily from a moderate increase in the conversion of loaned lasers to outright sales. International sales, accounting for approximately 3% of total sales for the year ended December 31, 2004, increased $67,000 from the prior year when international sales also accounted for 3% of total sales. The increase in international sales occurred primarily as a result of a higher average selling price of lasers sold abroad.

Gross Profit

Gross profit increased to 86% of net revenues for the year ended December 31, 2004 as compared to 83% of net revenues for the year ended December 31, 2003. Gross profit in absolute dollars increased by $2,038,000 to $13,261,000 for the year ended December 31, 2004, as compared to $11,223,000 for the year ended December 31, 2003. The increase in gross profit as a percent of sales, and in absolute terms, resulted from an increase in margins due to a more favorable product mix as higher-margin laser sales accounted for a greater portion of revenues than in prior periods. In addition, margins on disposable handpieces increased due to improvements in manufacturing which resulted in higher yields.

Research and Development

Research and development expenditures of $1,442,000 decreased $502,000 or 26% for the year ended December 31, 2004 when compared to $1,944,000 for the year ended December 31, 2003. The decrease resulted from decreases in the costs associated with our efforts to obtain FDA clearance for PMC. Such costs were $1.4 million in 2003 compared to $288,000 in 2004 , with the decrease being partially offset by increased spending on research and development activity for our minimally invasive TMR platform in 2004.

For the years ended December 31, 2004 and 2003, research and development expense included a credit of $152,000 and $601,000, respectively, due to the reversal each year of amounts recorded in accrued liabilities in prior years for estimated clinical trial obligations subsequently determined no to be needed.

Sales, General and Administrative

Sales, general and administrative expenditures of $11,322,000 increased $1,732,000 or 18% for the year ended December 31, 2004 when compared to $9,590,000 for the year ended December 31, 2003. The increase in expenses resulted primarily from an increase in employee expenses of $1,504,000 primarily related to an increase in our sales force, as well as higher sales commissions paid out associated with an increase in sales revenue. Additionally, advertising and marketing, and training and clinical research expense increased $202,000 and $214,000 respectively, due to the promotion of new products. This was offset by a decrease in facilities and office expense of $137,000 related to operational cost reduction efforts.

Non-Operating Expense (Income)

Total non-operating expense of $1,816,000 increased $1,779,000 or 4808% for the year ended December 31, 2004 when compared to $37,000 for the year ended December 31, 2003. This increase is primarily due to non-operating, non-cash charges recorded in 2004 in relation to the Secured Convertible Term Note (Note) issued in October 2004. These non-operating, non-cash charges resulted from mark to market charges on derivatives and warrants and 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, there is no

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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.

		2004	2003	Years Ended December 31, Change	
				) In thousands ($	
Interest expense	Secured Convertible Term Note	$ 77	$	$ 77	100%
Interest expense	other	58	44	14	32%
Non-cash interest expense	Change in derivative value	1,263		1,263	100%
Non-cash interest expense	Accretion of discount on Note	141		141	100%
Non-cash interest expense	Amortization of debt issuance costs relating to the Note	35		35	100%
Other non-cash expense- Change in fair value of warrants		290		290	100%
Interest income		(48)	(7)	(41)	586%
Total interest expense, net		$ 1,816	$ 37	$ 1,779	

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Net Revenues

We generate our revenues primarily through the sale of our TMR laser base units and related handpieces, and related services . Net revenues of $13,518,000 for the year ended December 31, 2003 increased $470,000, or 4%, when compared to net revenues of $13,048,000 for the year ended December 31, 2002. The increase in net revenues was due to an increase in domestic handpiece and laser revenues of $268,000 and $286,000, respectively, offset by a decrease in international handpiece and laser sales of $9,000 and $69,000, respectively.

The increase in handpiece revenue is primarily related to a higher average per unit selling price in 2003 as compared to 2002. In an effort to accelerate market adoption of the TMR procedure, we developed a program pursuant to which we loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. In the year ended December 31, 2003, domestic handpiece revenue consisted of $2,649,000 in sales to customers operating under our loaned laser program, of which $781,000 was attributed to premiums associated with such sales. In the year ended December 31, 2002, domestic handpiece revenue consisted of $2,832,000 in sales of product to customers operating under our loaned laser program, of which $756,000 was attributed to premiums associated with such sales. In the years ended December 31, 2003 and 2002, sales of product to customers not operating under our loaned laser program were $6,387,000 and $5,937,000, respectively.

For the year ended December 31, 2003, domestic laser sales increased by $286,000 compared to the year ended December 31, 2002 primarily from a moderate increase in the conversion of loaned lasers to outright sales. International sales, accounting for approximately 3% of total sales for the year ended December 31, 2003, decreased $78,000 from the prior year when international sales accounted for 4% of total sales. The decrease in international sales occurred primarily as a result of fewer handpiece sales resulting from decreased sales and marketing efforts in the international market compared to 2002. Service and other revenue of $971,000 slightly decreased by $6,000 for the year ended December 31, 2003 when compared to $977,000 for the year ended December 31, 2002.

Gross Profit

Gross profit increased to 83% of net revenues for the year ended December 31, 2003 as compared to 78% of net revenues for the year ended December 31, 2002. Gross profit in absolute dollars increased by $1,110,000 to

$11,223,000 for the year ended December 31, 2003, as compared to $10,113,000 for the year ended December 31, 2002. The increase in gross profit as a percent of sales, and in absolute terms, resulted from improved margins on lasers sold. These margins improved primarily due to sales of lasers originally placed

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under our laser loan program that were converted to outright sales. In addition, margins on disposable handpieces increased due to improvements in manufacturing which resulted in higher yields.

Research and Development

Research and development expenditures of $1,944,000 increased $1,287,000 or 196% for the year ended December 31, 2003 when compared to $657,000 for the year ended December 31, 2002. The increase in overall research and development expense resulted primarily from an increase in costs for outside services of $463,000 related to the PMC approval process. For the year ended December 31, 2003, a reduction of $601,000 was recorded on accrued liabilities recorded in prior years for estimated clinical trial obligations. This reduction of accrued liabilities decreased $828,000 for the year ended December 31, 2002 and contributed to the overall increase in research and development expenditures.

Sales, General and Administrative

Sales, general and administrative expenditures of $9,590,000 decreased $2,707,000 or 22% for the year ended December 31, 2003 when compared to $12,297,000 for the year ended December 31, 2002. The decrease in expenses resulted primarily from a decrease in employee expenses of $1,077,000 primarily related to reductions in our workforce. Additionally, outside services, advertising and marketing, training and clinical research, and facilities and office expense decreased $564,000, $396,000, $152,000, $118,000, respectively, due to overall cost cutting efforts.

Interest and Other Income (Expense), Net

Interest and other income (expense), net is comprised of interest income, interest expense and our former ownership interest in Microheart, Inc., a privately-held company (Microheart).

Interest income of $7,000 decreased $32,000 or 82% for the year ended December 31, 2003 when compared to $39,000 for the year ended December 31, 2002. This decrease was due to lower interest rates and lower investments in cash equivalents.

Interest expense of $44,000 increased $31,000 or 238% for the year ended December 31, 2003 when compared to $13,000 for the year ended December 31, 2002. This increase is primarily due to a higher level of financing for equipment under capital lease and amortization of debt issue costs.

A gain on the sale of an investee of $2,285,000 for the year ended December 31, 2002 resulted from the sale of our ownership interest in Microheart in April 2002.

Liquidity and Capital Resources

Cash and cash equivalents were $4,740,000 at December 31, 2004 compared to $1,013,000 at December 31, 2003, an increase of $3,727,000. Net cash used in operating activities was $967,000 for the twelve months ended December 31, 2004 primarily due to increased accounts receivable balances from increased sales. Cash and cash equivalents were $1,013,000 at December 31, 2003 compared to $1,490,000 at December 31, 2002, a decrease of $477,000. We used $680,000 of cash for operating activities in the twelve months ended December 31, 2003 primarily to pay down accounts payable and accrued liabilities. During the year ended December 31, 2002, we incurred operating losses of $2,841,000, which, when coupled with the payment of current liabilities partially offset by non-cash operating expenses, resulted in the use of $3,196,000 to support operating activities.

Cash used in investing activities during the twelve months ended December 31, 2004 was $401,000 related to the acquisition of property and equipment. Cash used in investing activities during the twelve months ended December 31, 2003 was $80,000 and was attributed to the acquisition of property and equipment. Cash provided by investing activities during the twelve months ended December 31, 2002 was $2,223,000 primarily consisting of the net proceeds obtained from the sale of our ownership interest in Microheart.

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Cash provided by financing activities during the twelve months ended December 31, 2004 was $5,095,000 due primarily to proceeds from the sale of common stock to private entities and the proceeds from the Secured Convertible Term Note agreement with Laurus Funds. In January 2004, we sold 3,100,000 shares of common stock to private investors for a total price of $2,700,000. We 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.

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 shown in net cash provided by financing activities and $2,877,250 which was deposited in a restricted cash account and is shown in the Supplemental schedule of non-cash investing and financing activities. Funds deposited in the restricted cash account will only be released to us, if at all, upon satisfaction of certain conditions, such as: 1) voluntary conversion of the restricted funds by Laurus, and 2) conversion rights of the restricted funds by us subject to certain stock price levels and trading volume limitations.

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, commencing November 2004. In addition, commencing May 2005, we are required to make monthly principal payments of $100,000 per month. To the extent that funds are released from the restricted cash account prior to repayment in full of the unrestricted portion of the Note proceeds, the monthly payment amount may be increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date. 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, 2004, the derivatives were valued at $2,337,777. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions: dividend yield of 0%; annual volatility of 70.5%; and risk free interest rate of 3.25% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The warrant was valued at $766,020 at December 31, 2004 using the Binomial Option Pricing model with the following assumptions: dividend yield of 0%; annual volatility of 70.5%; risk-free interest rate of 3.94%; and exercise factor of 2. Both the derivatives and warrant were classified as long-term liabilities.

Cash provided by financing activities during the twelve months ended December 31, 2003 was $283,000 primarily due to proceeds from employee stock option exercises and common stock purchased under the Employee Stock Purchase Plan. Cash used in financing activities during the twelve months ended December 31, 2002 was $254,000 resulting from payments on short term borrowings of $825,000. This was offset by net proceeds of $486,000 obtained from the sale of our common stock to the State of Wisconsin Investment Board in April 2002 and proceeds of $85,000 received from the sale of stock under the Employee Stock Purchase Plan.

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We have incurred significant losses for the last several years and at December 31, 2004 we had an accumulated deficit of $166,277,000. Our ability to maintain current operations is dependent upon maintaining our sales at least at the same levels achieved this year.

We also plan to continue our cost containment efforts by focusing on sales, general and administrative expenses. We have significantly reduced our cost of revenues, primarily due to the outsourcing of a significant portion of our manufacturing which allows us to purchase products at lower costs. To reduce operating expenses, we have focused our efforts on reducing headcount and overall expenses in functions that are not essential to core and critical activities.

Currently, our primary goal is to maintain 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, 2004 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 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.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(In thousands)		
Secured Convertible Term Note, net of restricted cash	$ 3,000	$ 800	$ 2,200		
Secured Convertible Term Note Interest(1)	$ 203	$ 54	$ 149		
Capital Lease Obligations	$ 23	$ 5	$ 12	$ 6	
Operating Leases	$ 686	$ 366	$ 320	$	$
Total	$ 3,912	$ 1,225	$ 2,681	$ 6	$

(1) Assumes 6.75% effective interest rate.

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 determination of the allowance for bad debt, inventory reserves, valuation allowance

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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 receipt of a purchase order 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 that an arrangement exists, delivery has occurred under the Company s standard FOB shipping point terms, the sales price is fixed or determinable and the ability to collect 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 return for the hospital purchasing a minimum number of handpieces at a premium over the list price. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months. The revenue on the handpieces is recognized upon shipment at an amount equal to the list price. The premium over the list price represents revenue related to the use of the laser unit and is recognized ratably, generally over the 24-month useful life of the placed lasers.

Revenues from service contracts, rentals, and per procedure fees are recognized upon performance or over the terms of the contract as appropriate.

Accounts Receivable:

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

Inventories:

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

Valuation of Long-lived Assets:

We assess potential impairment of our 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 assets 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.

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Income Taxes:

We account for income taxes using the 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.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

Quantitative Disclosures

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities. However, we do have multiple embedded derivatives included in the Secured Convertible Term Note (the Note) entered into with Laurus Master Fund in October 2004. Pursuant to the Note agreement, a warrant totaling 2.6 million 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 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 a 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.

We are subject to interest rate risks on cash and cash equivalents and any future financing requirements. Our primary interest rate risk exposures relate to the impact of interest rate movements on our ability to obtain adequate financing to fund future operations. We are also exposed to interest rate risk on our note payable obligation resulting from the Secured Convertible Term Note. This Note bears an interest rate of prime plus 2%, and as such, is exposed to variability. In the future, the interest rate could be increased to levels that would have a material affect on our financial statements.

The following table presents the future principal cash flows or amounts and related weighted average effective interest rates expected by year for our existing cash and cash equivalents and long-term debt instruments:

	2005	2006	2007	2008	2009	Total Fair Value
			In Thousands			
Assets						
Cash, cash equivalents	$ 4,740	$	$	$	$	$ 4,740
Weighted average interest rate	1.1%					1.1%
Liabilities						
Fixed rate debt lease obligation	$ 5	$ 6	$ 6	$ 6	$	$ 23
Weighted average interest rate	6.8%	6.8%	6.8%	6.8%		6.8%
Variable rate note payable, net of restricted cash	$ 800	$ 1,200	$ 1,000	$	$	$ 3,000
Weighted average effective interest rate(1)	25%	25%	25%			25%

(1) Includes interest expense at 6.75%, accretion of the debt discount, and amortization of debt issuance costs relating to the Secured Convertible Term Note.

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Qualitative Disclosures

Interest Rate Risk. We do not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. Given the relatively small number of foreign currency transactions, we do not believe that our potential exposure related to currency rate movements would have a material impact on future net income or cash flows.

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

Quarterly Results of Operations

The following table sets forth certain quarterly financial information for the periods indicated. This information has been derived from unaudited financial statements that, in the opinion of management, have been prepared on the same basis as the audited information, and includes all normal recurring adjustments necessary for a fair presentation of such information. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future periods.

	Three Months Ended							
	2004				2003			
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
	(In thousands, except per share data)							
Net revenues	$ 4,041	$ 3,376	$ 2,837	$ 5,200	$ 3,422	$ 3,090	$ 3,594	$ 3,412
Gross profit	3,488	2,858	2,338	4,577	2,800	2,588	2,973	2,862
Operating income (loss)	269	(244)	(928)	1,400	119	(879)	(121)	570
Net income/ (loss)	267	(264)	(924)	(398)	121	(878)	(129)	538
Net income/ (loss):								
Basic and diluted	0.01	(0.01)	(0.02)	(.01)	0.00	(0.02)	0.00	0.01
Weighted average shares outstanding								
Basic	40,490	41,279	41,338	41,446	37,121	37,136	37,351	37,597
Weighted average shares outstanding								
Diluted	41,204	41,279	41,338	41,446	37,145	37,136	37,351	38,446

See Item 15 below and the Index therein for a listing of the consolidated financial statements and supplementary data filed as part of this report.

Recently Issued Accounting Standards

In September 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings Per Share (EITF 04-8). EITF 04-8 addresses when the dilutive effect of contingently convertible debt with a market price trigger should be included in diluted earnings per share (EPS). Under EITF 04-8, the market price contingency should be ignored and these securities should be treated as non-contingent, convertible securities and always included in the diluted EPS computation unless their inclusion would be anti-dilutive. EITF 04-8 requires these securities be included in diluted EPS using either the if-converted method or the net share settlement method, depending on the conversion terms of the security. EITF 04-8 is effective for all periods ending after December 15, 2004 and is to be applied by retrospectively restating previously reported

EPS. The adoption of EITF 04-8 will have an effect on our diluted EPS computation if, in future periods, the inclusion of contingently convertible debt becomes dilutive.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, excessive spoilage, double freight, and rehandling costs be recognized as current-period charges regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. Additionally,

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SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We are currently evaluating the effect that the adoption of SFAS No. 151 will have on our consolidated results of operations and financial position, but we do not expect the adoption of this Statement to have a material impact.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and restrictive stock grants and units, to be recognized as a compensation cost based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. We are required to adopt SFAS No. 123R no later than July 3, 2005. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are currently assessing the impact that adoption of this Standard will have on our consolidated result of operations, financial position and cash flows. However, we believe that adoption of this standard will result in a charge to reported earnings.

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

None.

Item 9A. ***Controls and Procedures***

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended as of the end of the period covered by this report, which we refer to as the Evaluation Date . Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in our periodic reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

During the fiscal quarter ended December 31, 2004, no change in our internal control over financial reporting occurred that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. ***Other Information***

None.

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PART III

Item 10. ***Directors and Executive Officers of the Registrant.***

Certain information required by Part III, Item 10 is omitted from this Annual Report on Form 10-K because we will file a definitive proxy statement within 120 days after the end of our fiscal year pursuant to Regulation 14A for our 2005 Annual Meeting of Shareholders, and the information included in the proxy statement is incorporated herein by reference.

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

Certain of the information concerning our executive officers required by this Item is contained in the section of Part I of this Annual Report on Form 10-K entitled Item 1. Business Employees.

The information concerning our directors and the remaining information concerning our executive officers required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2005 Annual Meeting of Shareholders.

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

The information required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2005 Annual Meeting of Shareholders.

Item 13. ***Certain Relationships and Related Transactions.***

The information required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2005 Annual Meeting of Shareholders.

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

The information required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2005 Annual Meeting of Shareholders.

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PART IV

Item 15. ***Exhibits and Financial Statement Schedule.***

(a)(1) ***Financial Statements.*** The financial statements required to be filed by Item 8 herewith are as follows:

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Report of Independent Registered Public Accounting Firm	43
Consolidated Balance Sheets as of December 31, 2004 and 2003	44
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2004, 2003 and 2002	45
Consolidated Statements of Shareholders Equity for the years ended December 31, 2004, 2003 and 2002	46
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002	47
Notes to Consolidated Financial Statements	48

(2) ***Financial Statement Schedule***

The following financial statement schedule is filed herewith

Schedule II Valuation and Qualifying Accounts	64

(3) ***Exhibits.***

The exhibits listed under Item 15(b) are filed or incorporated by reference herein

(b) ***Exhibits.***

The exhibits below are filed or incorporated herein by reference.

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)	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Center Drive, Suite 320, Foothill Ranch, California
4.2(7)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A

4.3(8)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.4(9)	First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.5(10)	Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.6(11)	Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
4.7(12)	Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein

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Exhibit No.	Description
4.8(13)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.37 per share
4.9(14)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.00 per share
4.10(15)	Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.11(16)	Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.12(17)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.13(18)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.14(19)	Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(20)	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(21)	Stock Option Plan, as restated June, 2004
10.3(22)	Directors Stock Option Plan, as restated June, 2004
10.4(23)	1996 Employee Stock Purchase Plan, as restated June, 2004
10.5(24)	Facilities Lease for 26632 Towne Center Dr., Suite 320, Foothill Ranch, California
10.6(29)	401(k) Plan, as restated January 1, 2005
10.8(25)	1996 Equity Incentive Plan of the former Cardiogenesis Corporation
10.10(26)	Employment Agreement, dated as of September 27, 2001, between the Company and Michael J. Quinn
10.11(27)	Amendment No. 1 to Employment Agreement, dated July 3, 2002, between the Company and Michael J. Quinn
10.11(29)	Amendment No. 2 to Employment Agreement, dated May 19, 2003, between the Company and Michael J. Quinn
10.11(29)	

	Amendment No. 3 to Employment Agreement, dated March 16, 2005, between the Company and Michael J. Quinn
21.1(28)	List of Subsidiaries
23.1(29)	Consent of PricewaterhouseCoopers LLP
31.1(29)	Certification of the Chief Executive 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
31.2(29)	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(29)	Certifications of the Chief Executive Officer 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 on 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 14, 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 3.1.5 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

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(6) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q/ A filed on August 16, 2001

(7) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(8) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(9) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 18, 2002

(10) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed August 20, 2001

(11) Incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(12) Incorporated by reference to Exhibit 4.5 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(13) Incorporated by reference to Exhibit 4.6 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(14) Incorporated by reference to Exhibit 4.7 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(15) Incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(16) Incorporated by reference to Exhibit 4.3 to the Registrant s Current Report on Form 8-K filed October 28, 2004

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

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

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

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

(21) Incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(22) Incorporated by reference to Exhibit 4.2 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(23) Incorporated by reference to Exhibit 4.3 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(24) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q/ A filed on August 16, 2001

(25) Incorporated by reference to Exhibit 4.1 to the former Cardiogenesis Corporation s Registration Statement on Form S-8 (File No. 333-35095), filed on September 8, 1997

(26) Incorporated by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K filed on April 16, 2002

(27) Incorporated by reference to Exhibit 10.13 to the Registrant s Quarterly Report on Form 10-Q filed on August 14, 2002

(28) Incorporated by reference to Exhibit 21.1 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

(29) Filed herewith

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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/ MICHAEL J. QUINN

Michael J. Quinn
President, Chief Executive Officer
Chairman of the Board and Director
(Principal Executive Officer)

Date: March 31, 2005

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/ MICHAEL J. QUINN Michael J. Quinn	President, Chief Executive Officer, Chairman of the Board and Director (*Principal Executive Officer*)	March 31, 2005
/s/ CHRISTINE G. OCAMPO Christine G. Ocampo	Vice President, Chief Financial Officer, Secretary and Treasurer (*Principal Accounting and Financial Officer*)	March 31, 2005
/s/ JOSEPH R. KLETZEL, II Joseph R. Kletzel, II	Senior Vice President, General Manager of Pacific Division, Director	March 31, 2005
/s/ ROBERT L. MORTENSEN Robert L. Mortensen	Director	March 31, 2005
/s/ MARVIN J. SLEPIAN, M.D. Marvin J. Slepian, M.D.	Director	March 31, 2005
/s/ ROBERT C. STRAUSS Robert C. Strauss	Director	March 31, 2005
/s/ KURT E. WEHBERG, M.D. Kurt E. Wehberg, M.D.	Director	March 31, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Cardiogenesis Corporation

In our opinion, the accompanying consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Cardiogenesis Corporation and its subsidiaries (the Company) at December 31, 2004 and December 31, 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements and the financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the Standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Orange County, California
March 16, 2005

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CARDIOGENESIS CORPORATION
CONSOLIDATED BALANCE SHEETS
December 31, 2004 and 2003

	2004	2003
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,740	$ 1,013
Accounts receivable, net	3,578	1,830
Inventories, net	1,782	1,339
Prepaids and other current assets	513	453
Total current assets	10,613	4,635
Property and equipment, net	601	408
Restricted cash	2,884	
Other assets	1,585	1,417
Total assets	$ 15,683	$ 6,460
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 893	$ 876
Accrued liabilities	1,263	1,159
Customer deposits		25
Deferred revenue	658	573
Current portion of capital lease obligation	5	1
Current portion of Secured Convertible Term Note	800	
Total current liabilities	3,619	2,634
Capital lease obligation, less current portion	18	6
Other long-term liability	496	
Secured Convertible Term Note and related obligations	6,815	
Total liabilities	10,948	2,640
Commitments and contingencies (Note 8)		
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding;		
Common stock:		
no par value; 75,000 shares authorized; 41,500 and 37,859 shares issued and outstanding at December 31, 2004 and 2003, respectively	171,012	168,778
Accumulated deficit	(166,277)	(164,958)
Total shareholders equity	4,735	3,820

Total liabilities and shareholders equity	$ 15,683	$ 6,460

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

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CARDIOGENESIS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the Years Ended December 31, 2004, 2003 and 2002

	2004	2003	2002
	(In thousands, except per share amounts)		
Net revenues	$ 15,454	$ 13,518	$ 13,048
Cost of revenues	2,193	2,295	2,935
Gross profit	13,261	11,223	10,113
Operating expenses:			
Research and development	1,442	1,944	657
Sales, general and administrative	11,322	9,590	12,297
Total operating expenses	12,764	11,534	12,954
Operating income (loss)	497	(311)	(2,841)
Interest expense	(135)	(44)	(13)
Interest income	48	7	39
Non-cash interest expense	(1,439)		
Other non-cash expense	(290)		
Gain on sale of investee			2,285
Net loss	(1,319)	(348)	(530)
Other comprehensive loss, net of tax:			
Foreign currency translation adjustment			88
Other comprehensive income			88
Comprehensive loss	$ (1,319)	$ (348)	$ (442)
Net loss per share:			
Basic and diluted	$ (0.03)	$ (0.01)	$ (0.01)
Weighted average shares outstanding	41,152	37,303	36,911

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, 2004, 2003 and 2002

	Common Stock		Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	(Loss)	Deficit	Total
			(In thousands)		
Balances, December 31, 2001	36,507	$ 167,750	$ (88)	$ (164,080)	$ 3,582
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	114	85			85
Issuance of common stock for cash	500	486			486
Foreign currency translation adjustment			88		88
Net loss				(530)	(530)
Balances, December 31, 2002	37,121	168,321		(164,610)	3,711
Issuance of common stock pursuant to exercise of options	607	294			294
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	131	88			88
Issuance of common stock purchase warrants		75			75
Net loss				(348)	(348)
Balances, December 31, 2003	37,859	168,778		(164,958)	3,820
Issuance of common stock pursuant to exercise of options	317	184			184
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	184	87			87
Issuance of common stock for cash	3,140	2,304			2,304
Reclassification of stock purchase warrants to long-term liabilities		(341)			(341)
Net loss				(1,319)	(1,319)
Balances, December 31, 2004	41,500	$ 171,012	$	$ (166,277)	$ 4,735

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, 2004, 2003 and 2002

	2004	2003	2002
		(In thousands)	
Cash flows from operating activities:			
Net loss	$ (1,319)	$ (348)	$ (530)
Adjustments to reconcile net loss to net cash used in operating activities:			
Derivative and warrant fair value adjustments	1,553		
Accretion related to discount on notes payable	141		
Depreciation and amortization	228	261	308
Gain from sale of equity investee			(2,285)
Provision for doubtful accounts	19	26	335
Inventory reserves	32	198	854
Interest expense accrued on note payable	77		
Amortization of other assets	195	195	194
Amortization of debt issuance costs	66	44	
Loss on disposal of property and equipment			28
Reduction of clinical trial accrual	(152)	(601)	(1,282)
Changes in operating assets and liabilities:			
Accounts receivable	(1,767)	105	34
Inventories	(475)	95	729
Prepaids and other current assets	259	202	619
Other assets	(157)	(103)	
Accounts payable	17	(365)	(307)
Accrued liabilities	256	(316)	(1,084)
Current portion of long term liabilities			(495)
Customer deposits	(25)	(25)	(4)
Deferred revenue	85	(48)	(310)
Net cash used in operating activities	(967)	(680)	(3,196)
Cash flows from investing activities:			
Proceeds from sale of equity in investee			2,285
Acquisition of property and equipment	(401)	(80)	(62)
Net cash (used in) provided by investing activities	(401)	(80)	2,223
Cash flows from financing activities:			
Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan	271	307	85
Net proceeds from sale of common stock to private entities	2,304		486
Payments on short term borrowings	(351)		(794)
Net proceeds from issuance of long-term debt	2,875		
Repayments of capital lease obligations	(4)	(24)	(31)

Net cash provided by (used in) financing activities	5,095	283	(254)
Effect of exchange rates on cash and cash equivalents			88
Net increase (decrease) in cash and cash equivalents	3,727	(477)	(1,139)
Cash and cash equivalents at beginning of year	1,013	1,490	2,629
Cash and cash equivalents at end of year	$ 4,740	$ 1,013	$ 1,490
Supplemental schedule of cash flow information:			
Interest paid	$ 10	$ 19	$ 13
Taxes paid	$ 41	$ 23	$ 60
Supplemental schedule of noncash investing and financing activities:			
Issuance of common stock purchase warrants	$	$ 75	$
Legally restricted proceeds from issuance of long-term debt	$ 2,877	$	$

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), formerly known as Eclipse Surgical Technologies, Inc., was founded in 1989 to develop, manufacture and market surgical lasers and accessories for the treatment of disease. Currently, Cardiogenesis emphasis is on the development and manufacture 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 2005. Management believes its cash and cash equivalents balance as of December 31, 2004 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:

Use of Estimates:

The preparation of financial statements in conformity with generally accepted accounting principles 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.

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.

Accounts Receivables:

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

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

	Balance at Beginning of Period	Additions (1)	Deductions (2)	Balance at End of Period
Allowance for doubtful accounts:				
Year ended December 31, 2002				
Allowance for doubtful accounts	$ 1,354	$ 335	$ 1,240	$ 449
Year ended December 31, 2003				
Allowance for doubtful accounts	$ 449	$ 26	$ 449	$ 26
Year ended December 31, 2004				
Allowance for doubtful accounts	$ 26	$ 19	$ 34	$ 11

(1) Charged to costs and expenses.

(2) Amounts written off against the reserve.

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.

Restricted Cash:

In conjunction with the Secured Convertible Term Note, $2,877,250 of the amounts received by the Company was deposited in a restricted cash account. As of December 31, 2004, the Company has received $7,000 of interest income related to this balance, which is also restricted. Funds deposited in the restricted cash account will only be released to the Company, if at all, upon satisfaction of certain conditions, such as: 1) voluntary conversion of the restricted funds by Laurus, and 2) conversion rights of the restricted funds by Cardiogenesis subject to certain stock price requirements and trading volume limitations. See Note 7.

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

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the asset s carrying value over its fair value. Events or changes in circumstances which may cause impairment include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

Fair Value of Other Financial Instruments:

The Company s financial instruments consist primarily of cash equivalents, accounts receivables, trade accounts payable, accrued liabilities and the Secured Convertible Term Note and related embedded derivatives. The carrying amounts of certain of Cardiogenesis financial instruments including cash equivalents, accounts receivable, accounts payable, and accrued liabilities 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.

Derivative financial instruments

The Company s derivative financial instruments consist of embedded derivatives related to the $6,000,000 Secured Convertible Term Note (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 will be 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, 2004, the derivatives were valued at $2,337,777. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions: dividend yield of 0%; annual volatility of 70.5%; and risk free interest rate of 3.25% as well as probablility analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The derivatives are classified as long-term liabilities. See Note 7.

Revenue Recognition:

Cardiogenesis recognizes revenue on product sales upon receipt of a purchase order, shipment of the products, the price is fixed or determinable and 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 that an arrangement exists, delivery has occurred under the Company s standard FOB shipping point terms, the sales price is fixed or determinable and the ability to collect sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

Cardiogenesis frequently loans lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months. The revenue on the handpieces is recognized upon shipment at an amount equal to the list price. The premium over the list price represents revenue related to the use of the laser unit and is recognized ratably, generally over the 24-month useful life of the placed lasers.

Revenues from service contracts, rentals, and per procedure fees are recognized upon performance or over the terms of the contract as appropriate.

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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.

Advertising:

Cardiogenesis expenses all advertising as incurred. Cardiogenesis advertising expenses were $573,000, $80,000 and $221,000 for 2004, 2003, and 2002, 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 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.

Foreign Currency Translation:

In 2002, there were translation adjustments recorded in Cardiogenesis financial statements attributed to an international subsidiary, a foreign sales corporation (FSC). The FSC used its local currency as its functional currency. Assets and liabilities were translated at exchange rates in effect at the balance sheet date and income and expense accounts at average exchange rates during the year. Resulting translation adjustments were recorded in accumulated other comprehensive income (loss) in shareholders equity. In 2003, the Company decided to discontinue this FSC and at December 31, 2003 and 2004 the only remaining asset is a nominal cash balance.

Stock-Based Compensation:

Cardiogenesis accounts for its stock-based compensation in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Cardiogenesis has elected to adopt the disclosure only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), which requires pro forma disclosures in the financial statements as if the measurement provisions of SFAS 123 had been adopted. In addition, the Company has made the appropriate disclosures as required under the Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure.

Had compensation cost for the Stock Option Plan, the Director s Stock Option Plan and the ESPP been determined based on the fair value of the options at the grant date for awards consistent with the provisions of

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

SFAS 123, Cardiogenesis net loss and net loss per share would have increased to the pro forma amounts indicated below *(in thousands, except per share amounts):*

	Year Ended December 31,		
	2004	2003	2002
Net loss as reported	$ (1,319)	$ (348)	$ (530)
Stock-based employee compensation, net of related tax effects	$ (482)	$ (1,135)	$ (1,404)
Pro forma net loss	$ (1,801)	$ (1,483)	$ (1,934)
Basic and diluted net loss per share as reported	$ (0.03)	$ (0.01)	$ (0.01)
Pro forma basic and diluted net loss per share	$ (0.04)	$ (0.04)	$ (0.05)
Weighted average basic and diluted shares outstanding	41,152	37,303	36,911

The above pro-forma disclosures are not necessarily representative of the effects on reported net income or loss for future years. The aggregate fair value and weighted average fair value per share of options granted in the years ended December 31, 2004, 2003 and 2002 were $593,000, $651,000, and $646,000, and $0.63, $0.33, and $0.58, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for grants in 2004, 2003 and 2002:

	December 31,		
	2004	2003	2002
Expected life of option	7 years	7 years	7 years
Risk-free interest rate	3.7%	3.68%	4.04%
Expected dividends			
Expected volatility	79%	151%	75%

The aggregate fair value and weighted average fair value per share of purchase rights under the ESPP in fiscal years 2004, 2003 and 2002 were $45,000, $55,000 and $56,000, and $0.34, $0.43 and $0.59, respectively. The fair value for the purchase rights under the ESPP is estimated using the Black-Scholes option pricing model, with the following assumptions for the rights granted in 2004, 2003 and 2002:

	December 31,		
	2004	2003	2002
Expected life	0.5 years	0.5 years	0.5 years
Risk-free interest rate	3.7%	3.68%	4.04%
Expected dividends			
Expected volatility	79%	151%	75%

Cardiogenesis accounts for non-employee stock-based awards, in which goods or services are the consideration received for the stock options issued, in accordance with the provisions of SFAS No. 123 and related interpretations.

Compensation expense for non-employee stock-based awards is recognized in accordance with FASB Interpretation 28, Accounting for Stock Appreciation Rights and Other Variable Stock Options or Award Plans, an Interpretation of APB Opinions No. 15, and 25 (FIN 28). Under SFAS No. 123 and FIN 28, the Company records compensation expense based on the then-current fair values of the stock options at each financial date. Compensation recorded during the service period is adjusted in subsequent periods for changes in the stock options fair value.

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net Loss Per Share:

Basic earnings per share (EPS) is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted EPS 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, warrants and convertible notes payable using the treasury stock method.

Options to purchase 4,177,000, 4,070,000, and 3,477,000 shares of common stock were outstanding at December 31, 2004, 2003 and 2002, respectively. The range of per share exercise prices for these options was $0.32-$12.6875 for 2004, 2003 and 2002. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of December 31, 2004 and 2003. Warrants to purchase 275,000 shares of common stock at prices ranging from $.35 to $.44 per share were outstanding as of December 31, 2004 and 2003. Warrants to purchase 3,100,000 and 2,640,000 shares of common stock at $1.37 and $0.50, respectively, per share were also outstanding at December 31, 2004. A $6,000,000 convertible note payable, convertible at $0.50 per share subject to certain downward adjustments due to decreases in the Company s stock price, was outstanding at December 31, 2004. None of the options, warrants or convertible notes were included in the calculation of diluted EPS because their inclusion would have been anti-dilutive.

Recently Issued Accounting Standards:

In September 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings Per Share (EITF 04-8). EITF 04-8 addresses when the dilutive effect of contingently convertible debt with a market price trigger should be included in diluted earnings per share (EPS). Under EITF 04-8, the market price contingency should be ignored and these securities should be treated as non-contingent, convertible securities and always included in the diluted EPS computation unless their inclusion would be anti-dilutive. EITF 04-8 requires these securities be included in diluted EPS using either the if-converted method or the net share settlement method, depending on the conversion terms of the security. EITF 04-8 is effective for all periods ending after December 15, 2004 and is to be applied by retrospectively restating previously reported EPS. The adoption of EITF 04-8 will have an effect on the Company s diluted EPS computation if, in future periods, the inclusion of contingently convertible debt becomes dilutive.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, excessive spoilage, double freight, and rehandling costs be recognized as current-period charges regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company is currently evaluating the effect that the adoption of SFAS No. 151 will have on its consolidated results of operations and financial position, but does not expect the adoption of this Statement to have a material impact.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123 and supercedes APB Opinion No. 25. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and restrictive stock grants and units, to be recognized as a compensation cost based on their fair values. The pro forma disclosures

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CARDIOGENESIS CORPORATION
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previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R no later than July 1, 2005. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is currently assessing the impact that adoption of this Standard will have on its consolidated result of operations, financial position and cash flows. However, the Company believes that adoption of this standard will result in a charge to reported earnings.

3. Inventories:

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

	December 31,	
	2004	**2003**
Raw materials	$ 1,085	$ 1,042
Work in process	210	159
Finished goods	889	511
	2,184	1,712
Less reserves	(402)	(373)
	$ 1,782	$ 1,339

4. Property and Equipment:

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

	December 31,	
	2004	**2003**
Computers and equipment	$ 3,031	$ 2,732
Manufacturing and demonstration equipment	2,240	2,181
Leasehold improvements	193	193
	5,464	5,106
Less accumulated depreciation and amortization	(4,863)	(4,698)
	$ 601	$ 408

Equipment under capital lease of $28,000, net of accumulated amortization of $7,000 at December 31, 2004, is included in computers and equipment.

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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, 2004	December 31, 2003
Debt issuance costs	$ 381	$
Licensing fee for PMC, net	1,119	1,314
Rental security deposit	85	103
	$ 1,585	$ 1,417

On January 5, 1999, Cardiogenesis entered into an Agreement (the PLC agreement) with PLC Medical 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 is being amortized over the life of the underlying patents. The Company has included the related amortization expense in sales, general and administrative expenses in the accompanying Consolidated Statements of Operations. The Company has recorded related accumulated amortization of $1,168,000 and $973,000 as of December 31, 2004 and 2003, respectively. The patent is being amortized straight-line at a rate of approximately $195,000 per year through 2010.

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. If PMC product sales are not substantial and consistent in the future, the Company may suffer an impairment of the asset s value on the balance sheet.

In association with the October 2004 financing transaction discussed in Note 7, the Company capitalized debt issuance costs of $417,000. The costs are classified in other assets. The costs are being amortized over the life of the note using the effective interest method. In 2004, the total amortization expense related to the debt issuance costs was $35,000 and is included in non-cash interest expense on the accompanying 2004 Consolidated Statement of Operations.

6. Accrued Liabilities:

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

	December 31, 2004	December 31, 2003
Accrued research support	$	$ 152
Accrued accounts payable and related expenses	200	327
Accrued vacation	206	203
Accrued commissions	602	234
Accrued other	255	243
	$ 1,263	$ 1,159

7. Long-term Liabilities:

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

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. Additional debt issuance costs of $170,000 were incurred in conjunction with the transaction and are included in accrued liabilities on the accompanying balance sheet. Funds deposited in the restricted cash account will only be released to the Company, if at all, upon satisfaction of certain conditions, such as: 1) voluntary conversion of the restricted funds by Laurus, and 2) conversion rights of the restricted funds by Cardiogenesis subject to certain stock price levels and trading volume limitations.

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 rare 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. Although it is unlikely, 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 balance sheet.

The $6,000,000 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 balance sheet at its fair value;

Beginning May 2005, the Company is required to make monthly principal payments of $100,000 per month. The monthly payment as well as related accrued interest must be converted to common stock at the fixed conversion price of $.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 $.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 $.50 per share. 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;

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 $.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 November 2004. The potential interest rate reduction due to future

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 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, 2004;

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, 2004.

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. As of December 31, 2004, the derivatives were valued at $2,338,000. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions: dividend yield of 0%; annual volatility of 70.5%; and risk free interest rate of 3.25% as well as probablility analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. Warrants were valued at $766,000 at December 31, 2004 using the Binomial Option Pricing model with the following assumptions: dividend yield of 0%; annual volatility of 70.5%; risk-free interest rate of 3.94%; and exercise factor of 2. Both the derivatives and warrants were classified as long-term liabilities.

The initial relative fair value assigned to the embedded derivative was $1,075,000 and the initial relative fair value assigned to the warrant was $631,000, both of which were recorded as discounts to the Note and are being amortized to interest expense over the expected term of the debt, using the effective interest method. At December 31, 2004, the unamortized discount on the Note was $1,565,000. The effective interest rate on the Note for the period ended December 31, 2004 was 152%.

Future principal obligations, net of restricted cash, due under the note are as follows:

2005	$	800,000
2006		1,200,000
2007		1,000,000
Total	$	3,000,000

The market price of the Company s common stock significantly impacts the extent to which the Company is permitted to convert the unrestricted and restricted portions of 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

unrestricted portion of 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

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 unrestricted portion of the Laurus debt.

Further, prior to the full repayment of the unrestricted portion of the Laurus debt, the Company will only be able to require conversions of the $3,000,000 restricted cash amount to the extent the market price of the Company s common stock exceeds certain levels. To the extent that the market price of the Company s common stock does not reach such specified levels, the Company will be not be entitled to take possession of any of the restricted cash during the term of the Laurus note. The restricted portion of the debt will continue to accrue interest during the entire period that the Company is unable to require conversion. In addition, to the extent that conversions of the restricted portion of the debt are not effected during the term of the Note, the Company has only a limited ability to convert a specified amount of the restricted debt (subject to meeting certain minimum market price thresholds and volume requirements), and the Company will be required to repay the remaining restricted principal and interest in cash. The cash required to pay such principal amounts payable would come from the restricted cash and any such interest amounts payable would most likely be paid from available cash, which may not be sufficient to repay the amounts due.

8. Commitments and Contingencies:

Cardiogenesis has entered into an operating lease for an office facility with terms extending through October 2006. The minimum future rental payments are as follows *(in thousands):*

Year Ending December 31,	
2005	$ 350
2006	306
	$ 656

Rent expense was approximately $359,000, $547,000 and $504,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In November 2003, the Company s employment relationship with Darrell Eckstein, Cardiogenesis former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. In connection with his departure, Mr. Eckstein has made certain breach of contract claims arising out of his employment agreement with the Company, as well as certain tort claims and is seeking unspecified monetary damages. Pursuant to the terms of Mr. Eckstein s employment agreement, the matter has been submitted to binding arbitration. The Company believes Mr. Eckstein s claims are without merit and is vigorously defending against these claims. However, if Mr. Eckstein were to prevail on some or all of his claims, the Company cannot give any assurances that such claims would not have a material adverse effect on the Company s financial condition, results of operations or cash flows. Because of the preliminary stage of this case, an estimate of potential damages, if any, would be premature and speculative. As a result, the Company has not made any such estimate. Any legal costs in connection with this case are being expensed as incurred and are included in selling, general and administrative on the accompanying Statement of Operations.

9. Shareholders Equity:

Issuances of Common Stock:

In April 2002, the Company sold 500,000 shares, of common stock at a purchase price of $1.00 per share to a governmental entity. Certain bylaws were amended as a condition of these sales.

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In January 2004, Cardiogenesis sold approximately 3,100,000 shares of common stock to private investors for a total price of $2,700,000.

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 are being amortized over the five-year lease term. For the years ended December 31, 2004, 2003 and 2002, the Company recorded amortization charges to rent expense of $19,000 per year in connection with these warrants. The warrants expire in May 2006 and were outstanding at December 31, 2004.

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 $.35 to $.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 years ended December 31, 2004 and 2003, the Company recorded amortization of $31,000 and $44,000, respectively, 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, 2004.

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, 2004, 2003 and 2002, no warrants were exercised.

Options Granted to Consultants:

At December 31, 2004, 2003, 2002, options for consultants to purchase a total of 70,000, 57,000, and 47,000 shares of common stock, respectively, at exercise prices ranging from $.78 to $1.40 per share were outstanding. The terms under which stock options are exercised are the same as Cardiogenesis Stock Option Plan which is described below. Substantially all of these options were exercisable at the date of grant. These options are included in the Stock Option Plan disclosures below.

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

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $.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, 2004, Cardiogenesis had reserved a total of 10,100,000 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, 2004, Cardiogenesis had reserved 875,000 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 vest over twelve to thirty-six months and expire ten years from date of grant. No shares of common stock issued under the plan are subject to repurchase.

Employee Stock Purchase Plan:

Cardiogenesis maintains an Employee Stock Purchase Plan (ESPP), under which 1,178,400 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 years 2004, 2003 and 2002, approximately 184,000, 131,000 and 114,000 shares, respectively, were sold through the ESPP.

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Price per Share
Balance, December 31, 2001	510	2,787	$ 2.42
Additional shares reserved	1,500		
Options granted	(1,105)	1,105	$ 0.82
Options forfeited	415	(415)	$ 3.86
Balance, December 31, 2002	1,320	3,477	$ 1.74
Additional shares reserved	1,500		
Options granted	(2,034)	2,034	$ 0.52
Options forfeited	834	(834)	$ 1.46
Options exercised		(607)	$ 0.48
Balance, December 31, 2003	1,620	4,070	$ 1.37
Additional shares reserved	1,800		
Options granted	(941)	941	$ .87
Options forfeited	487	(487)	$ 1.72
Options expired	30	(30)	$ 1.44
Options exercised		(317)	$ .58
Balance, December 31, 2004	2,996	4,177	$ 1.28

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, 2004:

	Options Outstanding			Options Exercisable	
Exercise Prices	Number Outstanding (In thousands)	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Exercisable (In thousands)	Weighted Average Exercise Price
$0.32 - $ 0.37	694	8.72	$ 0.35	684	$ 0.35
$0.43 - $ 0.54	55	9.75	$ 0.49	16	$ 0.51

$0.56 - $ 0.83	993	8.48	$ 0.73	583	$ 0.73
$0.84 - $ 0.91	307	7.67	$ 0.87	303	$ 0.87
$1.01 - $ 1.16	771	8.28	$ 1.10	480	$ 1.10
$1.17 - $ 1.40	376	7.98	$ 1.30	360	$ 1.30
$1.67 - $ 1.75	714	4.17	$ 1.70	714	$ 1.70
$2.57 - $ 6.06	147	5.74	$ 3.88	147	$ 3.88
$6.38 - $12.69	120	3.42	$ 8.81	120	$ 8.81
	4,177	7.54	$ 1.28	3,407	$ 1.38

The Company s stock options exercisable under the Stock Option Plan and the Director s Stock Option Plan at December 31, 2004 and 2003 were 3,407,000 and 3,335,000 shares, respectively.

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Employee Retirement Plan:

Cardiogenesis maintains a 401(k) plan for its employees. The plan allows eligible employees to defer up to 15% of their earnings, not to exceed the statutory amount per year on a pretax basis through contributions to the plan. The plan provides for employer contributions at the discretion of the Board of Directors. For the years ended December 31, 2004, 2003 and 2002, $115,000, $85,000 and $93,000 of employer contributions were made to the plan, respectively.

11. Segment Disclosures

The Company operates in one segment. The principal markets for the Company s products are in the United States. International sales occur in Europe, Canada and Asia and amounted to $483,000, $415,000 and $494,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The international sales represent 3%, 3% and 4% of total sales for the years ended December 31, 2004, 2003 and 2002, respectively. The majority of international sales are denominated in Euros.

12. Income Taxes:

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

	December 31	
	2004	**2003**
Net operating losses	$ 53,751	$ 54,420
Credits	3,627	3,750
Research and development	748	525
Reserves	355	321
Accrued liabilities	1,099	511
Depreciation/ Amortization	195	109
Net deferred tax asset	59,775	59,636
Less valuation allowance	(59,775)	(59,636)
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, 2004, the Company had federal and state net operating loss carryforwards of approximately $150,640,000 and $43,424,000, respectively, to offset future taxable income. In addition, the Company had federal and state credit carryforwards of approximately $2,512,000 and $968,000 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 2008 through 2024, if not utilized. Research and experimentation credits carry forward indefinitely for state purposes. The Company also has a manufacturers investment credit for state purposes of approximately $147,000.

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.

Income tax expense for each of the three years ended December 31, 2004 was $800 per year.

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CARDIOGENESIS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. 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, 2004, three customers individually accounted for 11%, 12%, and 15% of gross accounts receivable. For the years ended December 31, 2004, 2003 and 2002, no customer individually accounted for 10% or more of net revenues.

At December 31, 2004 and 2003, 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.

14. Subsequent Event:

From January 1, 2005 through March 11, 2005, Laurus elected to convert an aggregate of $355,140 of principal and interest under the Note into an aggregate of 710,281 shares of Cardiogenesis common stock at a conversion price of $.50 per share. See Note 7. Of this amount, $275,000 in principal was converted into shares of common stock and a corresponding amount was released from restricted cash as available for use by the Company in the first quarter of 2005.

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CARDIOGENESIS CORPORATION
SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions(1)	Deductions(2)	Balance at End of Period
		(In thousands)		
Inventory reserve:				
Year ended December 31, 2002				
Inventory reserve	$ 1,246	$ 854	$ 1,739	$ 361
Year ended December 31, 2003				
Inventory reserve	$ 361	$ 198	$ 186	$ 373
Year ended December 31, 2004				
Inventory reserve	$ 373	$ 32	$ 3	$ 402
Valuation allowance relating to deferred tax asset:				
Year ended December 31, 2002				
Valuation allowance	$ 63,931	$	$ 1,471	$ 62,460
Year ended December 31, 2003				
Valuation allowance	$ 62,460	$	$ 2,824	$ 59,636
Year ended December 31, 2004				
Valuation allowance	$ 59,636	$ 139		$ 59,775

(1) Charged to costs and expenses.

(2) Amounts written off against the reserve.

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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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)	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Center Drive, Suite 320, Foothill Ranch, California
4.2(7)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A
4.3(8)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.4(9)	First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.5(10)	Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.6(11)	Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
4.7(12)	Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
4.8(13)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.37 per share
4.9(14)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.00 per share
4.10(15)	Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.11(16)	Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.

4.12(17)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.13(18)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.14(19)	Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
10.1(20)	Form of Indemnification Agreement by and between the Company and each of its officers and directors
10.2(21)	Stock Option Plan, as restated June, 2004
10.3(22)	Directors Stock Option Plan, as restated June, 2004
10.4(23)	1996 Employee Stock Purchase Plan, as restated June, 2004
10.5(24)	Facilities Lease for 26632 Towne Center Dr., Suite 320, Foothill Ranch, California
10.6(29)	401(k) Plan, as restated January 1, 2005
10.8(25)	1996 Equity Incentive Plan of the former Cardiogenesis Corporation
10.10(26)	Employment Agreement, dated as of September 27, 2001, between the Company and Michael J. Quinn
10.11(27)	Amendment No. 1 to Employment Agreement, dated July 3, 2002, between the Company and Michael J. Quinn

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Exhibit No.	Description
10.11(29)	Amendment No. 2 to Employment Agreement, dated May 19, 2003, between the Company and Michael J. Quinn
10.11(29)	Amendment No. 3 to Employment Agreement, dated March 16, 2005, between the Company and Michael J. Quinn
21.1(28)	List of Subsidiaries
23.1(29)	Consent of PricewaterhouseCoopers LLP
31.1(29)	Certification of the Chief Executive 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
31.2(29)	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(29)	Certifications of the Chief Executive Officer 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 on 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 14, 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 3.1.5 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

(6) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q/ A filed on August 16, 2001

(7) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(8) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(9) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 18, 2002
(10) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed August 20, 2001

(11) Incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(12) Incorporated by reference to Exhibit 4.5 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(13) Incorporated by reference to Exhibit 4.6 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(14) Incorporated by reference to Exhibit 4.7 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(15) Incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed October 28, 2004

(16) Incorporated by reference to Exhibit 4.3 to the Registrant s Current Report on Form 8-K filed October 28, 2004

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

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

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

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

(21) Incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(22) Incorporated by reference to Exhibit 4.2 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(23) Incorporated by reference to Exhibit 4.3 to the Registrant s Registration Statement on Form S-8 (File No. 333-122021) filed January 13, 2005

(24) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q/ A filed on August 16, 2001 (25) Incorporated by reference to Exhibit 4.1 to the former Cardiogenesis Corporation s Registration Statement on Form S-8 (File No. 333-35095), filed on September 8, 1997

(26) Incorporated by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K filed on April 16, 2002

(27) Incorporated by reference to Exhibit 10.13 to the Registrant s Quarterly Report on Form 10-Q filed on August 14, 2002

(28) Incorporated by reference to Exhibit 21.1 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

(29) Filed herewith