CARDIOGENESIS CORP /CA
Form 10-K
March 31, 2009

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

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [NO FEE REQUIRED]**
For the transition period from to

Commission file number: 0-28288

Cardiogenesis Corporation
(Exact name of Registrant and specified in its charter)

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

11 Musick, Irvine, California 92618
(Address of principal executive offices)

(949) 420-1800
(Registrant s telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes o No þ

Indicate by check mark if 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 Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act. Yes o No þ

As of June 30, 2008, the aggregate market value of the Registrant s voting stock held by non-affiliates was approximately $12,610,566.

As of February 27, 2009, there were 45,486,818 shares of common stock, no par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of Part III of this Form 10-K are incorporated by reference to the Registrant s Proxy Statement for the 2009 Annual Meeting of Shareholders.

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PART I

Item 1. *Business.*

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on the beliefs of our management as well as assumptions made by and information currently available to us. When we use the words believe, plan, will likely result, expect, intend, will continue, is anticipated, estim may, could, would, should, and similar expressions in this Form 10-K as they relate to us or our management, we a intending to identify forward-looking information statements. These statements reflect our current views with respect to expected future plans, initiatives, operating conditions and other potential events and are subject to certain risks, assumptions, and uncertainties. The statements contained herein that are not purely historical are forward-looking statements including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. Such statements include information contained in this Form 10-K regarding pending legal proceedings and the results thereof as well as any statements regarding our future product development, governmental or other regulatory approval prospects and related matters. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth in Risk Factors below.

Business Overview

We design, develop and distribute laser-based surgical products and disposable fiber-optic accessories for the treatment of cardiac ischemia associated with advanced cardiovascular disease through laser myocardial revascularization. This therapeutic procedure can be performed surgically as transmyocardial revascularization, or TMR. TMR is a laser-based heart treatment in which transmural channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis. Typically, TMR is performed by a cardiac surgeon while the patient is under general anesthesia as an adjunctive procedure to coronary bypass grafting (CABG), or may be performed on a stand-alone basis through a small left anterior thoracotomy incision in the chest.

Long term follow up of prospective, randomized, multi-center controlled clinical trials has demonstrated improved survival and a significant reduction in angina and increase in exercise duration in patients treated with our TMR System, along with medications, when compared with patients who received medications alone.

In May 1997, we received CE Mark approval for our TMR 2000 System. We have also received CE Mark approval for our minimally invasive Port Enabled Angina Relief with Laser, or PEARL, 5.0 and 8.0 handpieces and our PHOENIX handpieces, in November 2005 and October 2006, respectively. The CE Mark allows us to commercially distribute these products within the European Union. In February 1999, we received approval from the U.S. Food and Drug Administration, or FDA, for the marketing of our TMR products for treatment of patients suffering from chronic, severe angina.

In December 2004, we received FDA approval for the Solargen 2100s laser system, the advanced laser console for our TMR System. In addition, in November 2007 we received FDA approval for the PEARL 5.0 handpiece designed for delivering our TMR therapy with surgical robotic systems. We are in the process of completing the Investigational Device Exemption, or IDE, trial for our PEARL 8.0 handpiece, and are supporting the initial clinical application of the PHOENIX handpiece at prominent cardiac centers in the European Union and other international locations.

Background

According to the American Heart Association, or the AHA, cardiovascular disease is the leading cause of death and disability in the United States. Coronary artery disease is the principal form of heart disease and is characterized by a progressive narrowing of the coronary arteries, which are arteries that supply blood to the heart. This narrowing process is usually caused by atherosclerosis, which is the buildup of fatty deposits, or plaque, on the inner lining of

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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 (i) is unable to engage in any physical activity without angina and (i) may experience angina even at rest. Currently, the AHA estimates that approximately 9.8 million Americans experience angina symptoms.

The primary therapeutic options for treatment of coronary artery disease are: (i) drug therapy, (ii) percutaneous coronary intervention, or PCI, and (iii) coronary artery bypass grafting, or CABG. Each of these approaches is designed 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 amount of 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 PCI or CABG.

Introduced in the early 1980s, PCI is a less-invasive alternative to CABG. In a typical PCI procedure, 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 artery. Typically a stent, a small metal frame, is then delivered to the area of blockage, expanded within the coronary artery and permanently implanted in order to keep the coronary artery open. The newest type of stent, the drug eluting stent, or DES, has approved formulations imbedded on the stent for the purpose of inhibiting restenosis of the coronary artery.

CABG is surgical procedure developed in the 1960s in which conduit blood 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, which allows 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 from their symptoms through the use of PCI. Many bypass grafts fail within one to fifteen years following the procedure. Repeating the 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, including the severity of the patient s overall condition, the extent of coronary artery disease and the small size of the blocked arteries.

Medically refractory patients who are not candidates for these procedures are left with no viable surgical or interventional alternative other than, in limited cases, heart transplantation.

The TMR Procedure

TMR is a surgical procedure performed on the beating or non-beating heart, in which a laser device is used to create channels through the myocardium directly into the heart chamber. The channels are intended to supply blood to ischemic, or oxygen-deprived, regions of the myocardium and reduce angina in the patient. TMR can be performed as an adjunct to CABG or as minimally invasive sole therapy through a small incision between the ribs. TMR offers cardiac patients who have regions of ischemia not amenable to PCI or CABG a means to alleviate their symptoms and improve their quality of life.

Our Strategy

Our goal is to become a recognized leader in providing clinically effective therapies for ischemic cardiac disease. Our strategies to achieve this goal are as follows:

Expand the Market for our Products. We are seeking to expand market awareness and acceptance of our products among opinion leaders in the field of cardiovascular medicine, including cardiologists, and the entire referring physician community. Our strategy includes a thoughtful expansion of our direct sales force

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combined with development of key opinion leaders in the cardiothoracic and cardiology specialties. We continue to deliver advanced physician training programs, including training for our PEARL 5.0 handpiece compatible with the da Vinci surgical robotic system.

Add Innovative New Technology to our Product Offering. Our focus is to add innovative new tools to help address ischemia associated with advanced cardiovascular disease. We are committed to expanding our TMR product offering with new product initiatives including our minimally invasive handpieces for our PEARL 5.0 handpiece and PEARL 8.0 handpiece, as well as our PHOENIX handpiece. The premarket approval, or PMA, supplement for the PEARL 5.0 handpiece was approved by the FDA in November 2007. The investigational device exemption, or IDE, study for the PEARL 8.0 handpiece is ongoing. Our PHOENIX handpiece combines the delivery of TMR with biologic or pharmacologic therapeutic agents. Each of our PEARL 5.0 handpiece, PEARL 8.0 handpiece and PHOENIX handpiece received a CE Mark.

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

Products and Technology

Our TMR System

Our TMR System consists of a laser console and a line of fiber-optic handpieces referred collectively throughout this Annual Report on Form 10-K as the TMR System. Each handpiece utilizes an optical fiber assembly to deliver laser energy from the source laser base unit to its distal tip. Our holmium: YAG lasers utilize a solid state crystal to generate a 2.1 micron wavelength laser light by photoelectric excitation of a solid state holmium crystal. The flexible fiberoptic assembly used to deliver the laser energy to the patient enables direct access to all potential target regions of the heart.

We have received FDA approval for U.S. commercial distribution of our TMR System for treatment of stable patients with: (i) angina refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and (ii) a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization. Such patient group is referred to in this Annual Report on Form 10-K as the Canadian Cardiovascular Society Class 4 group.

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

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

SoloGrip III. The single use SoloGrip III handpiece 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 handpiece s fiber-optic delivery system has an easy to install connector that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation.

PEARL 5.0. The PEARL 5.0 handpiece has been designed and is compatible for use with Intuitive Surgical s da Vinci surgical robot. The PEARL 5.0 handpiece received FDA approval in November 2007.

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New Product Pipeline

PEARL 8.0. The PEARL 8.0 handpiece has received CE Mark and Health Canada approval, and is part of an FDA approved investigational device exemption, or IDE, study that is underway to validate the safety and feasibility of utilizing a thoracoscopic technique for TMR. The trial is a single arm consecutive series, or open label, validation study of the advanced port access delivery system.

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

Sales and Marketing

We sell our products in the United States through our direct sales force. As of December 31, 2008, we had 14 sales representatives. We promote market awareness of our approved surgical products among opinion leaders in the cardiovascular field and are recruiting physicians and hospitals to use our TMR products. Our ability to generate sales depends on the level of sales force interaction with customers and on the geographic coverage of our sales force. We are a smaller company and therefore, are faced with challenges in recruiting and retaining qualified sales personnel.

We work closely with our clinical practitioners and scientific experts in advancing the clinical and scientific understanding and awareness through ongoing clinical and basic research initiatives. Due to our investment in this critical area, new and interesting clinical and scientific information about our products and therapies have been presented at scientific symposia and medical meetings, and published in related peer reviewed and industry journals. We have made oral and poster presentations at major medical society conferences, including: the Society of Thoracic Surgeons, the American Association of Thoracic Surgeons, the Transcatheter Cardiovascular Therapeutics, the Western Thoracic Society and the International Conference for Cardiovascular Stem Cell Therapy. We also sponsor educational symposia in conjunction with major society events to educate and inform attendees on the latest developments with our technology and applications.

In the United States, we currently offer the SolarGen 2100s laser system at a current end user list price of $439,500, and the single use SoloGrip III handpiece at an end user unit list price of $4,395. The PEARL 5.0 handpiece is priced at $5,950. In addition to sales of lasers to hospitals, we offer a range of leasing and financial options to our prospective customers.

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

We continue to advance our physician training programs to assist physicians in acquiring the expertise necessary to utilize our products and procedures, including the PEARL 5.0 handpiece. Over 1,900 cardiothoracic surgeons and fellows have been trained on our TMR System.

Research and Development

We believe that focusing our research efforts and product offerings is essential to our ability to stimulate growth and maintain our market leadership position. Our ongoing research and product development efforts are focused on the development of new and enhanced lasers and fiber-optic handpieces for TMR and additional applications in the treatment of ischemic disease. In 2006, we received FDA approval for our PEARL 5.0 handpiece.

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The IDE study for the PEARL 8.0 handpiece is ongoing. We also developed and validated our initial PHOENIX handpiece and are supporting the initial clinical sites outside the United States that are implementing this advanced technology. For the years ended December 31, 2008 and 2007, we incurred research and development expenses of $904,000 and $681,000, respectively.

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

Clinical Trials

Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) premarket notification. In the United States, these trials require submission of an application for an IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy and financial disclosure by clinical investigators. A clinical trial may be suspended by the FDA or the investigational review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain clearance or approval of one of our products. Similarly, in the European Union, the clinical study must be approved by the local ethics committee and in some cases, including studies of high-risk devices, by the competent authority in the applicable country.

We currently have two ongoing clinical trials. The post approval study, or the Post Approval Study, is an FDA required study of TMR to provide further information on the 30-day postoperative mortality predictors, effectiveness as a function of operator experience, and the disease characteristics of the population being treated. We are required to enroll 500 patients in our Post Approval Study. Our second ongoing clinical trial is the PEARL 8.0 handpiece study, or the PEARL 8.0 Study, which is a prospective, multicenter, single arm study of the feasibility and safety of thoracoscopic TMR using our PEARL 8.0 handpiece in patients with stable, medically refractory, severe angina who are not candidates for CABG or PCI. We are required to enroll 30 patients in order to complete the PEARL 8.0 Study.

Manufacturing

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

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

Competition

Currently, we believe our only direct competitive technology is manufactured by PLC Medical Systems, Inc., or PLC, which directly markets FDA-approved TMR products outside the United States. Other competitors may also enter the market, including large companies in the laser and cardiac surgery markets. Many of these companies

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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 PMA for TMR in 1998. PLC has received a CE Mark which permits commercial sales of its products in the European Union community. PLC has been issued patents for its apparatus and methods for TMR. Novadaq, a Canadian company publicly traded on the Toronto Stock Exchange, has assumed full sales and distribution responsibility in the United States for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in March 2007.

We believe that the factors which will be critical to maximizing our market development success include:

the timing of receipt of requisite regulatory approvals,

favorable reimbursement for the procedure,

efficacy and ease of use of our TMR products and applications,

breadth of product line, system reliability,

brand name recognition, and

effectiveness of distribution channels and cost of capital equipment and disposable devices.

Our products also compete with other methods for the treatment of cardiovascular disease, including drug therapy, PCI, CABG, and Enhanced External Counterpulsation (EECP). Even with the FDA approval of our TMR System, our products may not be accepted and adopted by cardiovascular professionals. Moreover, technological advances in other therapies for cardiovascular disease such as pharmaceuticals or future innovations in cardiac surgery, or PCI could make such other therapies more effective or less costly than our TMR procedure and could eventually render our technology obsolete. Such competition could harm our business.

Our TMR 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. We may not be able to compete successfully in the event a competitor is able to obtain a PMA for its products prior to our doing so. Further, 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

United States

Laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease with TMR are considered medical devices, and as such are subject to regulation in the United States by the FDA and outside the United States by comparable international regulatory agencies. Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior PMA from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose a lower risk are placed in either class I or II, which in many cases requires the manufacturer to submit to the FDA a

premarket notification or 510(k) submission requesting permission for commercial distribution. This process is known as requesting 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as many life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a legally marketable device, are placed in class III, and require a PMA. Both premarket clearance and PMA applications are subject to the payment of user fees, paid at the time of submission for FDA review. All of our current devices require the rigorous PMA process for approval to market the product in the United States.

To obtain a PMA for a medical device, we must file a PMA application that includes clinical data and the results of preclinical and other testing sufficient to show that there is a reasonable assurance of safety and efficacy of

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the product for its intended use. To begin a clinical study, an IDE must be obtained and the study must be conducted in accordance with FDA regulations. An IDE application must contain preclinical test data demonstrating the safety of the product for human investigational use, information on manufacturing processes and procedures, and proposed clinical protocols. If the FDA clears the IDE application, human clinical trials may begin. The results obtained from these trials are accumulated and, if satisfactory, are submitted to the FDA in support of a PMA application. In addition to the results of clinical trials, the PMA application must include other information relevant to the safety and efficacy of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. By law, the FDA has 180 days to review a PMA application. While the FDA has responded to PMA applications within the allotted time frame, reviews more often occur over a significantly longer period and may include requests for additional information or extensive additional clinical trials. There can be no assurance that we will not be required to conduct additional trials which may result in substantial costs and delays, nor can there be any assurance that a PMA will be obtained for each product in a timely manner, if at all. In addition, changes in existing regulations or the adoption of new regulations or policies could prevent or delay regulatory approval of our products. Furthermore, even if a PMA is granted, subsequent modifications of the approved device or the manufacturing process may require a supplemental PMA or the submission of a new PMA which could require substantial additional clinical efficacy data and FDA review. After the FDA accepts a PMA application for filing, and after FDA review of the application, a public meeting is frequently held before an FDA advisory panel in which the PMA is reviewed and discussed. The panel then issues a favorable or unfavorable recommendation to the FDA or recommends approval with conditions which, subsequently, is issued as a conditional approval or an approvable letter by the FDA. Although the FDA is not bound by the panel s recommendations, it tends to give such recommendations significant weight. In February 1999, we received a PMA for our TMR System for use in certain indications. However, in the case of our PMC products, the FDA Advisory Panel recommended against approval of our PMC products 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 was not adequate to support approval by the FDA of our PMC products. 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 our PMC products. We came to agreement with the FDA on a final trial design and received formal FDA approval in January 2006. In light of the costs involved in carrying out the trials, we decided that at this time it is more important to devote resources to our core business and other shorter-term product development opportunities rather than to pursue FDA approval for our PMC products. We realize that without obtaining FDA approval, the potential sales for our PMC products will be significantly limited. We currently do not intend to continue to manufacture our PMC products. Therefore, we do not expect significant revenues from our PMC product line in the foreseeable future.

Products manufactured or distributed by us pursuant to a PMA will be subject to pervasive and continuing regulation by the FDA, including, among other things, post-market surveillance and adverse event reporting requirements. Upon our receipt of PMA for our TMR System in 1999, the FDA required us to complete a post-market approval study relating to the device. We continue to provide updates on our progress in completing the post-market approval study in our annual reports to the FDA. Our 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 production facilities and in accordance with Good Manufacturing Practices, or GMP, regulations, and to list our devices with the FDA. Furthermore, as a condition to receipt of 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, which are also known as off-label indications. Changes in existing regulatory requirements or adoption of new requirements could harm our business. We may be required to incur significant costs to comply with laws and regulations in the future, and current or future laws and regulations may harm our business.

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

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requires laser manufacturers to file new product and annual reports, maintain manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product. In addition, we are subject to California regulations governing the manufacture of medical devices, including an annual licensing requirement. Our facilities are subject to ongoing, periodic inspections by the FDA and California regulatory authorities.

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

Foreign Regulation

Sales of medical devices outside of the United States 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 the European Union, a manufacturer must obtain the certifications necessary to affix the CE Mark to its products. A CE Mark 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 Mark, a manufacturer must be in compliance with appropriate International Standards Organization, or ISO, quality standards and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within the European Union require further approval by their national regulatory agencies. We have achieved ISO and European Union certification for our external manufacturing facilities. In addition, we have completed CE Mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union community. Failure to maintain the right to affix the CE Mark or other requisite approvals could prohibit us from selling our products in the European Union or elsewhere.

Patents and Proprietary Rights

Our success depends, in part, on our ability to obtain patent protection for our products, preserve our trade secrets, and operate without infringing the proprietary rights of others. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business, as well as collaborate with, and license technology from, academic institutions. We currently own or license four U.S. pending patent applications and 63 U.S. and foreign issued patents. Our patents or patent applications may be challenged, invalidated or circumvented in the future or the rights granted may not provide a competitive advantage. We intend to vigorously protect and defend our intellectual property while also maintaining a defensive, strategic patent position. We do not know if patent protection will continue to be available for surgical methods in the future. Costly and time-consuming litigation brought by us may be necessary to enforce our patents and to protect our trade secrets and know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Our patent rights will also eventually expire, as will those of our competitors, which will thus allow others to exploit certain intellectual property that is currently proprietary.

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

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

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competitors or other third parties in the future. In particular, the introduction in the U.S. market of our PMC products, should we pursue that option in the future, 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 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.

Our current and potential competitors and other third parties may have filed, or in the future may file, patent applications for, or have received or in the future may 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 United States or internationally. In this regard, we note that we have recently been named as a defendant in a patent infringement lawsuit that is more fully described in Part I, Item 3 Legal Proceedings below. In the event we were to require licenses to patents issued to third parties, such licenses may not be available or, if available, may not be available on terms acceptable to us. In addition, we may not be successful in any attempt to redesign our products or processes to avoid infringement or any such redesign may not 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, or CMS, began coverage of FDA approved TMR Systems for any manufacturer s TMR procedures.

In contrast to Medicare which covers a significant portion of the patients who are candidates for TMR, private insurers and health plans each make an individual decision whether or not to provide reimbursement for TMR and, if so, at what reimbursement level. While our experience with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans has generally been positive, private insurance and private health plans may choose to not approve reimbursement for TMR in the future. The lack of private insurance and health plan 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, or TEC, assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/Blue Shield plans and other third-party payers use the center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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In foreign markets, reimbursement is obtained from a variety of sources, including governmental authorities, private health insurance plans and labor unions. In most foreign countries, there are also private insurance systems that may offer payments for alternative therapies. Although not as prevalent as in the United States, health maintenance organizations are emerging in certain European countries. We may need to seek international reimbursement approvals, and we may not be able to obtain 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 United States 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 United States 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 United States 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, 2008 we had 34 full-time employees, of which 21 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. We consider our relations with our employees to be good.

Executive Officers

The following gives certain information regarding our executive officers and significant employees as of March 1, 2009:

Name	Age	Position
Richard P. Lanigan	49	President
William R. Abbott	52	Senior Vice President, Chief Financial Officer, Secretary and Treasurer

Richard P. Lanigan has been our President since November 2006. Prior to November 2006, Mr. Lanigan served in a variety of different capacities. From November 2005 to October 2006, Mr. Lanigan served as our Senior Vice President of Operations. From November 2003 to October 2005, Mr. Lanigan was our Senior Vice President of Marketing. From March 2001 to October 2003, Mr. Lanigan was our Vice President of Government Affairs and

Business Development. From March 2000 to February 2001, Mr. Lanigan served as our Vice President of Sales and Marketing and from 1997 to 2000 he was the Director of Marketing. From 1992 to 1997, Mr. Lanigan served in various positions, most recently Marketing Manager, at Stryker Endoscopy. From 1987 to 1992, Mr. Lanigan served in Manufacturing and Operations Management at Raychem Corporation. From 1981 to 1987, he served in the U.S. Navy where he completed six years of service as Lieutenant in the Supply Corps. Mr. Lanigan has a Bachelor of Business Administration from the University of Notre Dame and a Masters of Science in Systems Management from the University of Southern California.

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

General Information

We are a California corporation, incorporated in California in 1989. Our corporate headquarters are located at 11 Musick, Irvine, California, 92618, and our telephone number is (949) 420-1800.

We make the following reports available on our website, at www.cardiogenesis.com, free of charge as soon as practicable after filing with the U.S. Securities and Exchange Commission, or the Commission:

- our annual reports on Form 10-K;
- our policies related to corporate governance, including our Code of Conduct and Ethics, which apply to our directors, officers and employees (including our principal executive officer and principal financial officer), that we have adopted to meet the requirements set forth in the rules and regulations of the Commission and its corporate governance principles; and
- the charters of the Audit, Compensation and Nominating and Corporate Governance Committees of our Board of Directors.

All such reports are also available free of charge via EDGAR through the Commission s website at www.sec.gov. In addition, the public may read and copy materials filed by us with the Commission at the Commission s public reference room located at 100 F St., NE, Washington, D.C., 20549. Information regarding operation of the Commission s public reference room can be obtained by calling the Commission at 1-800-SEC-0330.

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

In addition to other information included in this Annual Report on Form 10-K, the following factors, among others, could cause the actual results to differ materially from those contained in forward-looking statements contained in this Annual Report on Form 10-K, and thus should be considered carefully in evaluating our business and future prospects. The following risk factors are not an exhaustive list of the risks associated with our business. New factors may emerge or changes to these risks could occur that could materially affect our business.

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

Historically, we have incurred significant net operating losses. We had a net loss of $315,000 in the year ended December 31, 2008. As of December 31, 2008 we had an accumulated deficit of $169.9 million. We will have a continuing need for new infusions of cash if we incur losses or fail to generate sufficient cash from operations in the future. We plan to attempt to increase our revenues through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful, or we are unable to achieve regulatory approval for our products, we will be unable to significantly

increase our revenues and it may be necessary to significantly reduce our operations or obtain additional debt or equity financing. If we are required to significantly reduce our operations, our business will be harmed.

Changes in our business, financial performance or the market for our products may require us to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, the recent global economic crisis has made it very difficult for

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companies to obtain financing on commercially reasonable terms, or at all. If we are unable to obtain such financing, we may have to scale back our operations. Even if we obtain such financing, it may restrict our business operations, in the case of debt financing, or cause substantial dilution to our stockholders, in the case of equity financing.

Our ability to maintain revenues and operating income and achieve growth in sales and operating income in the future is dependent upon physician awareness of our products as a safe, efficacious and appropriate treatment for their patients.

Our ability to maintain current sales levels and/or increase our revenues and operating income is dependent upon acceptance of our products and services by cardiac surgeons, cardiologists, hospitals and other healthcare providers in the United States. Our sales and marketing efforts are focused on educating these groups on TMR and its benefits relative to other existing procedures. If cardiac surgeons and cardiologists do not choose to adopt our products in lieu of alternative therapeutic options, we may not be able maintain or increase our revenues, which will negatively impact our business.

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. Hospitals and physicians are eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. If the Centers for Medicare and Medicaid Services, or CMS, were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation could be harmed.

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

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

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product modifications, our ability to commercially distribute and market these products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of most new medical devices only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved

premarket approval, or PMA. The FDA will clear marketing of a non-exempt lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other legally marketed products not requiring PMA approval. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a legally marketed device, require a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance

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process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use. Our currently commercialized products have been cleared through the PMA process. However, our Pearl 8.0 handpiece is currently under an IDE study and will require a PMA supplement, and our PHOENIX handpiece will also require an IDE study and PMA application.

Our failure to comply with U.S. federal and state governmental regulations could lead to the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties, among other things. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

If we, our suppliers, or our manufacturers fail to comply with ongoing FDA or other foreign regulatory authority requirements, our business may be negatively impacted.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and labeling and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with the Quality System Regulations, or QSR, and Medical Devices Directive, or MDD, regulations, which may include International Organization for Standardization, or ISO, standards, for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies enforce the QSR and ISO regulations through inspections. The failure by us or one of our suppliers or manufacturers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

warning letters or untitled letters;

fines and civil penalties;

unanticipated expenditures to address or defend such actions;

delays in clearing or approving, or refusal to clear or approve, our products;

withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

product recall or seizure;

orders for physician notification or device repair, replacement or refund;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales to suffer and may prevent us from generating revenue.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training educational, labeling or promotional materials or subject us to regulatory enforcement actions.

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We may also be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and certain malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR or Good Manufacturing Practices, or GMP, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In addition, we are subject to extensive regulation relating to the marketing and sale of our products, including our interactions with physicians. If we are found to have violated any of these rules or regulations, we may face fines or other penalties and our sales efforts may be negatively impacted.

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

We currently derive approximately 99% of our revenues from our TMR System. 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 System. 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 System 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 System, if concerns over the safety of our TMR System were to arise, the FDA could restrict the currently-approved uses of our TMR System. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR System 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 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 Mark. The CE Mark 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 Mark, a manufacturer must be in compliance with the applicable 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 the European Union 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 Mark or other requisite approvals could prohibit us from selling our products in 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

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enforcement action such as prohibitions against us marketing our products in the European Union, which would significantly reduce international revenue.

We purchase some of the key components of our products from single suppliers. The loss of these suppliers could prevent or delay shipments of our products or delay our clinical trials or otherwise adversely affect our business.

Some of the key components of our products are currently purchased from only single suppliers. We do not have long-term contracts with the third-party suppliers of our product components. If necessary or desirable, we could source our product components and related services from other suppliers. However, establishing additional or replacement suppliers for these components, and obtaining any additional regulatory clearances or approvals, if necessary, that may result from adding or replacing suppliers, will take a substantial amount of time and could result in increased costs and impair our ability to produce our products, which would adversely impact our business, operating results and prospects. In addition, some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third-party vendors could adversely and materially affect our reputation, our attempts to complete our clinical trials or commercialization of our products. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including, warning letters, product recalls, termination of distribution, product seizures or civil penalties, among others.

If we experience any delay or deficiency in the quality of products supplied to us by third-party suppliers, or if we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of our products would be interrupted for an extended period of time, which would adversely affect our business, operating results and prospects. In addition, we may be required to obtain prior regulatory clearance or approval from the FDA or foreign regulatory authorities to use different suppliers or components. As a result, regulatory clearance or approval of our products may not be received on a timely basis, or at all, and our business, operating results and prospects would be harmed.

If our independent contract manufacturers fail to timely deliver to us sufficient quantities of some of our products and components in a timely manner, our operations may be harmed.

Our reliance on independent contract manufacturers to manufacture most of our products and components involves several risks, including:

inadequate capacity of the manufacturer s facilities;

interruptions in access to certain process technologies; and

reduced control over product availability, quality, delivery schedules, manufacturing yields and costs.

Shortages of raw materials, production capacity constraints or delays by our contract manufacturers could negatively affect our ability to meet our production obligations and result in increased prices for affected parts. Any such reduction, constraint or delay may result in delays in shipments of our products or increases in the prices of components, either of which could have a material adverse effect on our business.

We do not have long term supply agreements with our current contract manufacturers and we often utilize purchase orders, which are subject to acceptance by the supplier. Failure to accept purchase orders could result in an inability to obtain adequate supply of our product or components in a timely manner or on commercially reasonable terms.

An unanticipated loss of any of our contract manufacturers could cause delays in our ability to deliver our products while we identify and qualify a replacement manufacturer, which delays could negatively impact our revenues.

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If clinical trials of our current or future product candidates do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere, we will be unable to commercialize these products.

We are currently conducting clinical trials and will likely need to conduct additional clinical trials in the future in support of new product approvals. Clinical testing is expensive, typically takes many years and has an uncertain outcome. The initiation and completion of any of these studies may be prevented, delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at the expected rate, or complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;
- sites participating in an ongoing clinical study may withdraw, requiring us to engage new sites;
- difficulties or delays associated with bringing additional clinical sites on-line;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule or consistent with the investigator agreement, clinical study protocol, good clinical practices, and other FDA and Institutional Review Board requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in U.S. federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy; or
- the study design is inadequate to demonstrate safety and efficacy.

Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing in addition to those we have planned. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that device.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully perform their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

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Our third-party distributors may not effectively distribute our products.

We depend on medical device distributors and strategic relationships for the marketing and selling of our products internationally. We depend on these distributors efforts to market our product, yet we are unable to control their efforts completely. In addition, we are unable to ensure that our distributors are complying all applicable laws regarding the sales of our products. If our distributors fail to market and sell our products effectively and in compliance with applicable laws, our operating results and business may suffer substantially, or we may have to make significant additional expenditures or concessions to market our products.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in such promotion.

Our currently marketed products have been cleared by the FDA for specific treatments. We cannot, however, prevent a physician from using our products outside of those indications cleared for use, known as off-label use. There may be increased risk of injury if physicians attempt to use our products off-label. We train our sales force not to promote our products for off-label uses. Furthermore, the use of our products for indications other than those indications for which our products have been cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management s attention from our core business, be expensive to defend and result in sizable damage awards against us that may not be covered by insurance. If we are deemed by FDA to have engaged in the promotion of any our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry. Any of these events could harm our business and results of operations and cause our stock to decline.

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

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

- the dependence on the growth of the market for our currently approved and reimbursed products;
- our ability to successfully expand sales to potential customers and increasing clinical adoption of the TMR procedure;
- domestic and international regulatory developments;
- rapid technological change;
- the highly competitive nature of the medical devices industry; and
- the risk of entering emerging markets in which we have limited or no direct experience.

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

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

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

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

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

Our international operations subject us to certain operating risks, which could adversely impact our net sales, results of operations and financial condition.

We sell our products in parts of Asia and the European Union. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export, and custom regulations and laws. Compliance with these regulations is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic or social instability. Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic instability;

a shortage of high-quality sales people and distributors;

changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

the imposition of new trade restrictions;

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the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

difficulties in maintaining consistency with our internal guidelines;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; and

difficulties in enforcing or defending intellectual property rights.

Any of these factors may adversely impact our operations. In Europe, healthcare regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries, which could negatively affect our results of operations.

Our operations are currently conducted at a single location that may be at risk from earthquakes or other natural disasters.

We currently conduct all of our activities at a single location in Irvine, California, near known earthquake fault zones. We have taken precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, any future natural disaster, such as an earthquake, could cause substantial delays in our operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses. A disaster could seriously harm our business and results of operations. The insurance coverage we maintain may not be adequate to cover our losses in any particular case.

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

The Pink Sheets is a significantly more limited market in comparison to other larger trading markets such as the NASDAQ Stock Market. The listing of our shares on the Pink Sheets results in a relatively illiquid market available for existing and potential stockholders to trade shares of our common stock, which could ultimately depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

Applicability of penny stock rules to broker-dealer sales of our common stock could have a negative effect on the liquidity and market price of our common stock.

A penny stock is generally a stock that (i) is not listed on a national securities exchange, (ii) is listed on the Pink Sheets or on the OTC Bulletin Board, (iii) has a price per share of less than $5.00 and (iv) is issued by a company with net tangible assets less than $5 million. The penny stock trading rules impose additional duties and responsibilities upon broker-dealers and salespersons effecting purchase and sale transactions in common stock and other equity securities, including determination of the purchaser s investment suitability, delivery of certain information and

disclosures to the purchaser, and receipt of a specific purchase agreement before effecting the purchase transaction. Many broker-dealers will not effect transactions in penny stocks, except on an unsolicited basis, in order to avoid compliance with the penny stock trading rules. When our common stock is subject to the penny stock trading rules, such rules may materially limit or restrict the ability to resell our common stock, and the liquidity typically associated with other publicly traded equity securities may not exist.

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

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended February 27, 2009, the closing prices of our common stock as reported on the Pink Sheets ranged

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from a high of $0.42 per share to a low of $0.11 per share. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

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

We participate in a highly dynamic industry, which often results in significant volatility in the market price of our common stock irrespective of our performance. Fluctuations in the price of our common stock may be exacerbated by conditions in the healthcare and technology industry segments or conditions in the financial markets generally.

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. Novadaq, a Canadian company publicly traded on the Toronto Stock Exchange, has assumed full sales and distribution responsibility in the United States for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in March 2007. If PLC Systems, or any new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business may suffer.

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

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

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

competitors, at which we are able to:

develop products;

complete clinical testing and regulatory approval processes;

obtain third party reimbursement acceptance; and

supply adequate quantities of the product to the market.

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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 U.S. patents covering technology that could be used for certain of our procedures and potential new applications. We do not know if such competitors, potential competitors or others have filed and hold international patents covering our procedures and potential new applications. In addition, international patents may not be interpreted the same as any counterpart U.S. patents.

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

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

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

Defending and prosecuting intellectual property suits, including the pending lawsuit described elsewhere in this Annual Report on Form 10-K, U.S. 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;

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.

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

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

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

Furthermore, our competitors:

may have developed or will develop similar products;

may duplicate our products; or

may design around any patents issued to or licensed by us.

Because patent applications in the United States are maintained in secrecy until the patents are issued, it is possible that:

others may have filed applications for inventions covered by our pending patent applications before us; or

we may infringe upon patents that may eventually be issued to others on such applications.

If we are unable to adequately protect our intellectual property, our business may be adversely impacted.

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

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

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.

We maintain insurance against product liability claims in the amount of $10 million per occurrence and $10 million in the aggregate. 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 depend heavily on key personnel and turnover of key employees and senior management could harm our business.

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

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

As of December 31, 2008, we had 9,035,000 shares reserved for exercise of outstanding options and warrants. If our shareholders sell substantial amounts of our common stock, including shares issuable upon exercise of options or warrants or shares issued in previous financings, in the public market, the market price of our common stock could decline. If these sales were to occur, we may also find it more difficult to sell equity or equity-related securities in the future at a time and price that we deem appropriate and desirable.

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

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

We have a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals, thereby entrenching current management and possibly depressing the market price of our common stock. The rights issued under the stockholder rights plan would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our board of directors. In addition, 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. 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 our ownership or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock.

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

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

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

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

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

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We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. If we do not pay dividends, our stock may be less valuable to you because a return on your investment will only occur if our stock price appreciates.

Unstable market conditions may have severe adverse consequences on our business.

Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse, or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a radical economic downturn or increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans or plans to acquire additional technology.

These economic conditions not only limit our access to capital but also make it extremely difficult for our customers, or vendors and us to accurately forecast and plan business activities, and they could cause U.S. and foreign businesses to slow spending on our products, which would delay and lengthen sales cycles. Furthermore, during challenging economic times our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. In addition, the recent economic crisis could also adversely impact our suppliers ability to provide us with materials and components, either of which may negatively impact our business, financial condition and results of operations. There is a risk that one or more of our current suppliers may encounter difficulties during challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

Item 2. ***Properties.***

We do not own real property. Our headquarters, located in Irvine, California, are comprised of approximately 7,800 square feet of leased space. The lease expires in November 2011. We believe our facilities are adequate, suitable, and of sufficient capacity to meet our immediate and foreseeable requirements. There can be no assurance that additional facilities will be available to us on favorable terms, if and when needed, thereafter.

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

As previously reported, Cardiofocus, Inc., or Cardiofocus, filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1.08-cv-10285) against us and a number of other companies. In the complaint, Cardiofocus alleges that we and the other defendants have violated patent rights allegedly held by Cardiofocus.

On June 13, 2008, we filed requests for reexamination of the patents being asserted against us with the United States Patent and Trademark Office and asserted that prior art had been identified that raised substantial new issues of patentability with respect to the inventions claimed by Cardiofocus patents. In August 2008, the United States Patent and Trademark Office granted our reexamination requests. Reexamination requests filed by other named defendants were also granted.

Because the reexamination requests were granted and substantial new issues of patentability raised, we, along with other named defendants, moved to stay the litigation until the reexamination of Cardiofocus asserted patents is completed. On October 14, 2008, an Order was issued by the Court staying the present litigation for one (1) year or until the reexamination is completed, which ever occurs sooner. After one year, if the reexamination continues, the

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Court will consider further extensions of the stay, for a period not to exceed one additional year, upon good cause shown by the defendants.

We intend to continue to vigorously defend ourselves. However, any litigation involves risks and uncertainties and the likely outcome of the case cannot be determined at this time. In addition, litigation involves significant expenses and distraction of management resources which may have an adverse effect on our results of operations.

Except as described above, we are not a party to any material legal proceeding.

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

No matters were submitted to a vote of our shareholders during the quarter ended December 31, 2008.

PART II

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

Price Range of Common Stock

Our common stock is quoted on the Pink Sheets under the symbol CGCP.PK. The following table shows the high and low bid quotations for our common stock as reported by the Pink Sheets during the quarter being reported. Prices below reflect inter-dealer prices, without retail write-up, write-down or commission and may not represent actual transactions.

2007	**High**	**Low**
First Quarter	$ 0.41	$ 0.25
Second Quarter	$ 0.35	$ 0.21
Third Quarter	$ 0.31	$ 0.17
Fourth Quarter	$ 0.38	$ 0.21

2008	**High**	**Low**
First Quarter	$ 0.43	$ 0.28
Second Quarter	$ 0.36	$ 0.23
Third Quarter	$ 0.38	$ 0.21
Fourth Quarter	$ 0.31	$ 0.11

Holders of Common Stock

As of February 27, 2009, shares of our common stock were held by 214 shareholders of record.

Dividend Policy

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

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Equity Compensation Plan

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans as of December 31, 2008.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	(b) (Weighted Average Exercise Price of Outstanding Options and Rights	(c) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	(d) Total of Securities Reflected in Columns (a) and (c)
Equity compensation plans approved by security holders(1)	3,295,000	$ 0.66	5,113,858	8,408,858
Total	3,295,000	$ 0.66	5,113,858	8,408,858

(1) Consists of the following equity compensation plans: (i) the Stock Option Plan and the Director Stock Option Plan and (ii) the Cardiogenesis Corporation Employee Stock Purchase Plan, or the Employee Stock Purchase Plan. The Employee Stock Purchase Plan enables employees to purchase our common stock at a 15% discount to the lower of market value at the beginning or end of each six month offering period. As such, the number of shares that may be issued pursuant to the Employee Stock Purchase Plan during a given six month period and the purchase price of such shares cannot be determined in advance.

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

Management s Discussion and Analysis of Financial Condition and Results of Operations contains certain statements relating to future results, which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and sim expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based on the beliefs of management, as well as assumptions and estimates based on information available to us as of the dates such assumptions and estimates are made, and are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated, depending on a variety of factors, including those factors discussed in Risk Factors in Part I, Item 1. Should one or more of those risks or uncertainties materialize adversely, or should underlying assumptions or estimates prove incorrect, actual results may vary materially from those described.

Those events and uncertainties are difficult or impossible to predict accurately and many are beyond our control. Except as may be required by applicable law, we assume no obligation to publicly release the result of any revisions that may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements. The following discussion should be read in conjunction with our financial statements and notes thereto included in this Annual Report on Form 10-K.

Overview

We are a California corporation, incorporated in 1989, and we primarily design, develop and distribute laser-based surgical products and disposable fiber-optic accessories for the treatment of cardiac ischemia associated with advanced cardiovascular disease through laser myocardial revascularization. This therapeutic procedure can be performed surgically as transmyocardial revascularization, or TMR. TMR is a procedure used to relieve severe angina or chest pain in very ill patients who aren t candidates for bypass surgery or PCI. TMR is a laser-based heart treatment in which transmural channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis. Typically, TMR is performed by a cardiac surgeon

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while the patient is under general anesthesia as an adjunctive procedure to coronary bypass, or may be performed on a stand-alone basis through a small left anterior thoracotomy incision in the chest.

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

In December 2004, we received FDA approval for the Solargen 2100s laser system, or Solargen 2100s, the advanced laser console for TMR. In addition, in November 2007 we received FDA approval for the PEARL 5.0 robotic handpiece delivery system, or the PEARL 5.0 handpiece, which is designed for delivering TMR therapy with surgical robotic systems. We are in the process of completing the Investigational Device Exemption, or IDE, trial for the PEARL 8.0 Thoracoscopic handpiece delivery system, or the PEARL 8.0 handpiece, and are supporting the initial clinical application of the PHOENIX handpiece at prominent cardiac centers in the European Union and other international locations.

As of December 31, 2008, we had an accumulated deficit of $169.9 million. 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, 2008 Compared to Year Ended December 31, 2007

Net Revenues

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

Net revenues of $12,150,000 for the year ended December 31, 2008 increased $91,000, or 1%, when compared to net revenues of $12,059,000 for the year ended December 31, 2007. The increase in net revenues was due to an increase in laser revenue of $388,000, which is partially offset by decreases in handpiece revenue of $284,000 and service and other revenues of $13,000.

For the year ended December 31, 2008, domestic laser sales increased by $397,000 compared to the year ended December 31, 2007 primarily due to a higher average sales price.

The decrease in domestic handpiece revenue of $167,000 was attributed primarily to a decrease in unit sales. Domestic handpiece revenue for the year ended December 31, 2008 consisted of $700,000 in sales to customers

operating under our loaned laser program as compared to $895,000 in sales of product to customers operating under our loaned laser program in 2007. In the years ended December 31, 2008 and 2007, sales of handpieces to customers not operating under our loaned laser program were $7,239,000 and $7,211,000, respectively.

International sales of $230,000, accounted for approximately 2% of total sales for the year ended December 31, 2008, a decrease of approximately $123,000 from the prior year when international sales were $353,000 and accounted for 3% of total sales. The decrease in international sales occurred primarily as a result of a $117,000 decrease in handpiece revenues as a result of a decrease in unit sales.

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Gross Profit

Gross profit increased to 82% of net revenues for the year ended December 31, 2008 as compared to 76% of net revenues for the year ended December 31, 2007. Gross profit in absolute dollars increased by $801,000, or 9%, to $9,911,000 for the year ended December 31, 2008, as compared to $9,110,000 for the year ended December 31, 2007. The overall increase in gross margin for the year ended December 31, 2008 resulted from a combination of higher laser and handpiece average sales prices, a decrease in inventory obsolescence charges of $346,000, and recognition of $234,000 of deferred revenue for which there is no associated cost of goods sold. Inventory obsolescence charges for the years ended December 31, 2008 and 2007 were $187,000 and $533,000, respectively. Approximately $155,000 of the obsolescence charges in 2008 were related to PMC inventory. The remaining $32,000 was related to the TMR 2000 laser product line. In the fourth quarter of 2007, we announced to our customers that since the amount of our TMR 2000 laser component inventory available was limited and no longer being manufactured, we would not be able to guarantee component availability to service and support the TMR 2000 laser. Therefore, we recorded an impairment charge for the TMR 2000 laser finished goods and excess parts used to maintain and service the TMR 2000 laser system. Also, in 2007, an inventory obsolescence charge of $221,000 related to expired product associated with our PMC product line was incurred.

Research and Development

Research and development expense represents expenses incurred in connection with the development of technologies and products including the costs of third party studies, salaries and stock-based compensation associated with research and development personnel.

Research and development expenditures of $904,000 increased $223,000, or 33%, for the year ended December 31, 2008 as compared to $681,000 for the year ended December 31, 2007. As a percentage of revenues, research and development expenditures were 7% for the year ended December 31, 2008 as compared to 6% for the prior year period. The increase in expenditures as a percentage of revenue and in dollars was primarily due to an increase in employee related expenses of approximately $68,000 due to an increase in headcount, and an increase of $198,000 in consulting services.

Sales and Marketing

Sales and marketing expense represents expenses incurred in connection with the salaries, stock-based compensation, commissions, taxes and benefits for sales, marketing and service employees and other sales, general and administrative expenses directly associated with the sales, marketing and service departments.

For the year ended December 31, 2008, sales and marketing expenditures of $6,487,000 increased $2,046,000, or 46%, when compared to $4,441,000 for the year ended December 31, 2007. As a percentage of revenues, sales and marketing expenditures were 53% for the year ended December 31, 2008 as compared to 37% for the prior year period. The dollar and percentage increase in sales and marketing expenditures resulted primarily from an increase in compensation expense of approximately $1,240,000 related to investments made to strengthen the sales and marketing organization, and an increase in employee benefits expense of $119,000 associated with a higher average headcount in 2008 as compared to 2007. Travel and entertainment expenses also increased in 2008 by $329,000 due to higher headcount and increased sales activity.

General and Administrative

General and administrative expenditures represent all other operating expenses not included in research and development or sales and marketing expenses. For the year ended December 31, 2008, general and administrative

expenditures totaled $2,840,000, or 23% of net revenues, as compared to $3,132,000, or 26% of net revenues for the year ended December 31, 2007. This represents a reduction of $292,000, or 9%. The decrease in general and administrative expenditures both in dollars and as a percentage of net revenues for the 2008 year end as compared to the 2007 period resulted primarily from a $176,000 reduction in incentive compensation, an $87,000 reduction in insurance expense, and a $20,000 reduction in general and administrative related depreciation.

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Other Income (Expense)

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

	Years Ended December 31,	
	2008	2007
	($ In thousands)	
Interest expense Secured Convertible Term Note	$	$ (51)
Interest expense other	(23)	(18)
Interest income	59	120
Loss on disposal of assets		(2)
Non cash interest expense Accretion of discount on Note		(72)
Non cash interest expense Amortization of debt issuance costs relating to the Note		(17)
Change in fair value of derivatives		(376)
Change in fair value of warrants		151
Total other income (expense), net	$ 36	$ (265)

For the year ended December 31, 2008, total other income, net was $36,000 as compared to total other expense, net of $265,000 for the year ended December 31, 2007. During the year ended December 31, 2007, we incurred an expense of $376,000 related to the change in fair value of the derivatives associated with a certain outstanding secured convertible term note, or the Note. In addition, there was other income of $151,000 in 2007 associated with the change in fair value of the warrants issued to the holder of the Note. As a result of the repayment of the Note in October 2007, we did not incur any charges related to the Note during the year ended December 31, 2008.

Liquidity and Capital Resources

Cash and cash equivalents were $2,907,000 at December 31, 2008 compared to $2,824,000 at December 31, 2007, an increase of $83,000. Net cash provided by operating activities was $261,000 for the twelve months ended December 31, 2008 primarily due to a decrease in accounts receivable and inventories. Net cash provided by operating activities was $1,908,000 for the twelve months ended December 31, 2007 primarily due to a decrease in accounts receivable as a result of the decrease in sales.

Cash used in investing activities during the twelve months ended December 31, 2008 was $202,000 related primarily to the acquisition of property and equipment and the purchase of marketable securities. The $75,000 purchase of marketable securities is comprised entirely of auction rate securities and the entire balance was sold in January 2009, at par. Cash used in investing activities during the twelve months ended December 31, 2007 was $61,000 related to the acquisition of property and equipment.

Cash provided by financing activities for the year ended December 31, 2008 was $24,000 primarily due to proceeds from the Employee Stock Purchase Plan purchases during the year. Cash used in financing activities for the year ended December 31, 2007 was $1,141,000, primarily due to payments on the Note.

We have incurred significant losses and as of December 31, 2008 we had an accumulated deficit of $169.9 million. Our ability to maintain current operations is dependent upon maintaining our sales at least at the same levels achieved

this year. Currently, our primary goal is to achieve and sustain profitability at the operating level and our actions have been guided by this initiative. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been reduced or eliminated.

We believe our cash balance as of December 31, 2008, our projected cash flows from operations and actions we have taken to reduce sales, general and administrative expenses will be sufficient to meet our capital, debt and

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operating requirements through the next twelve months. However, our actual future capital requirements will depend on many factors, including the following:

- the success of the commercialization of our products;
- sales and marketing activities, and expansion of our commercial infrastructure, related to our approved products and product candidates;
- the results of our clinical trials and requirements to conduct additional clinical trials;
- the rate of progress of our research and development programs;
- the time and expense necessary to obtain regulatory approvals;
- activities and payments in connection with potential acquisitions of companies, products or technology; and
- competitive, technological, market and other developments.

We believe that if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

We will have a continuing need for new infusions of cash if we incur losses or are otherwise unable to generate positive cash flow from operations in the future. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues and may have to obtain additional financing to continue our operations or scale back our operations. Due to the recent global economic crisis, it has become very difficult for companies to obtain debt or equity financing on reasonable terms, if at all. As a result, we may not be able to obtain additional financing if required, or even if we were to obtain any financing, it may contain burdensome restrictions on our business, in the case of debt financing, or result in significant dilution, in the case of equity financing.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition:

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

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

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

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

We enter into contracts to sell our products and services and, while the majority of our sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the contract value should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for such multiple element arrangements in accordance with Emerging Issues Task Force Issue, or EITF, No. 00-21, *Revenue Arrangements with Multiple Deliverables*. For arrangements that involve multiple elements, such as sales of lasers and handpieces, revenue is allocated to each respective element based on its relative fair value and recognized when revenue recognition criteria for each element have been met.

Investments in Marketable Securities:

Effective January 1, 2008, we adopted SFAS No. 157, except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS No. 157-2. SFAS No. 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS No. 157, we measure our cash and cash equivalents and marketable securities at fair value. Our investments in marketable securities consist of auction rate securities which are classified within level 3 due to a lack of a liquid market for such securities. We have formed our own opinion on the condition of the securities based on information regarding the quality of the security and the quality of the collateral, among other things.

In accordance with the fair value hierarchy described above, the following table shows the fair value of our financial assets that are required to be measured at fair value on a recurring basis at December 31, 2008 (in thousands):

Significant

Description	Fair Value at December 31, 2008	Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable Securities:				
Auction Rate Securities	$ 75	$	$	$ 75

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The following table provides a reconciliation of the beginning and ending balances for our assets measured at fair value using significant unobservable inputs (Level 3) as defined in SFAS No. 157 at December 31, 2008 (in thousands):

Description	
Balance at December 31, 2007	$
Transfers into Level 3	750
Transfers out of Level 3	(675)
Total unrealized losses	
Total realized gains/(losses)	
Balance at December 31, 2008	$ 75

Marketable securities measured at fair value using Level 3 inputs are comprised entirely of auction rate securities. Although auction rate securities would typically be measured using Level 2 inputs, the recent failure of auctions, beginning in February 2008, and the lack of market activity and liquidity required that these securities be measured using Level 3 inputs. The underlying assets of our auction rate securities are collateralized primarily by the underlying assets of certain AAA-rated funds. The entire balance of auction rate securities, totaling $75,000, was sold in January 2009, at par.

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.

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

We assesses potential impairment of long-lived assets when there is evidence that recent events or changes in circumstances indicate that their carrying value may not be recoverable. Reviews are performed to determine whether the carrying value of assets is impaired based on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the asset s carrying value over its fair value. Events or changes in circumstances which may cause impairment

include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

Income Taxes:

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

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Stock-Based Compensation:

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

On January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors related to our Amended and Restated 2000 Equity Incentive Plan based on estimated fair values. We adopted SFAS No. 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our consolidated financial statements as of and for the years ended December 31, 2008 and 2007 reflect the impact of adopting SFAS No. 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R). The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our consolidated statement of operations. As stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rate for the years ended December 31, 2008 and 2007 was based on historical forfeiture experience and estimated future employee forfeitures. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

Recently Issued Accounting Standards

In September 2006 the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FSP 157-2, *Effective Date of FASB Statement No. 157*, which delays the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. The adoption of SFAS No. 157 related to financial assets and liabilities did not have a material impact on our consolidated financial statements. We are currently evaluating the impact, if any, that SFAS No. 157 may have on our future consolidated financial statements related to non-financial assets and liabilities.

In October 2008, the FASB issued FASB Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*, or FSP 157-3. FSP 157-3 clarifies the application of SFAS 157 in a market that is not active, and provides an illustrative example intended to address certain key application issues. FSP 157-3 is effective immediately. We concluded that the application of FSP 157-3 did not have a material impact on our consolidated financial position and results of operations as of and for the periods ended December 31, 2008.

In December 2007 the FASB issued SFAS No. 141R, *Business Combinations,* which establishes principles and requirements for how the acquirer of a business recognizes and measures in our financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS No. 141R also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what

information to disclose to enable users of the financial statement to evaluate the nature and financial effects of the business combination. SFAS No. 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations we engage in will be recorded and disclosed according to SFAS No. 141, *Business Combinations*, until January 1, 2009. We are currently evaluating the impact, if any, that SFAS No. 141R may have on our future consolidated financial statements.

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

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

The information required by Item 8 is included on pages F-1 to F-23 immediately following the signature page.

Item 9. ***Changes In And Disagreements With Accountants On Accounting And Financial Disclosure.***

None.

Item 9A(T). ***Controls And Procedures.***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

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

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008 based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management s report in this Annual Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

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PART III

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

Information required under Item 10 will be presented in our 2009 definitive proxy statement which is incorporated herein by this reference.

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

Information required under Item 11 will be presented in our 2009 definitive proxy statement which is incorporated herein by this reference.

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

Information required under Item 12 will be presented in our 2009 definitive proxy statement which is incorporated herein by this reference with the exception of the information regarding securities authorized for issuance under our equity compensation plans, which is set forth in Item 5 of this Annual Report on Form 10-K under the heading Equity Compensation Plans.

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

Information required under Item 13 will be presented in our 2009 definitive proxy statement which is incorporated herein by this reference.

Item 14: ***Principal Accounting Fees and Services.***

Information required under Item 14 will be presented in our 2009 definitive proxy statement which is incorporated herein by this reference.

Item 15. ***Exhibits.***

EXHIBIT INDEX

Exhibit No.	Description
3.1.1(1)	Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996
3.1.2(2)	Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001
3.1.3(3)	Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
3.1.4(4)	Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004
3.2(5)	Amended and Restated Bylaws
4.1(6)	Rights Agreement, dated as of August 17, 2001, between the Company and EquiServe Trust Company, N.A., as Rights Agent
4.2(7)	

	First Amendment to Rights Agreement, dated as of January 17, 2002, between the Company and EquiServe Trust Company, N.A., as Rights Agent
4.3(8)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between the Company and EquiServe Trust Company, N.A., as Rights Agent
4.1(9)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A., as Rights Agent
4.5(10)	Securities Purchase Agreement, dated as of January 21, 2004, by and among the Company and the investors identified therein

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Exhibit No.	Description
4.6(11)	Registration Rights Agreement, dated as of January 21, 2004, by and among the Company and the investors identified therein
4.7(12)	Form of Common Stock Purchase Warrant, dated January 21, 2004
10.1(13)*	Form of Indemnification Agreement among the Company and each of its officers and directors
10.2(14)*	Stock Option Plan, as amended and restated July 2005
10.3(15)*	Form of Stock Option Agreement for Executive Officers under the Stock Option Plan
10.4(16)*	Director Stock Option Plan, as amended and restated July 2005
10.5(17)*	Form of Stock Option Agreement for Directors under the Director Stock Option Plan
10.6(18)*	Employee Stock Purchase Plan, as amended and restated July 2005
10.7(19)	Standard Industrial/Commercial Multi-Tenant Lease, dated as of August 8, 2006, between the Company and John Robert Meehan
10.8(20)*	Employment Agreement, dated as of July 30, 2007, between the Company and Richard P. Lanigan
10.9(21))*	Employment Agreement, dated as of July 30, 2007, between the Company and William R. Abbott
21.1(22)	List of Subsidiaries
23.1(22)	Consent of KMJ Corbin & Company LLP
24.1(22)	Power of Attorney (included in the signature page)
31.1(22)	Certification of the President pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934
31.2(22)	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934
32.1(22)	Certifications of the President and Chief Financial Officer pursuant to 18 U.S.C. Section 1350

* Management contract, compensatory plan or arrangement

(1) Incorporated by reference to Exhibit 3.1 to the Company s Registration Statement on Form S-1/A (File No. 33-03770), filed with the Commission on May 21, 1996

(2) Incorporated by reference to Exhibit 3.2 to the Company s Quarterly Report on Form 10-Q for the period ended June 30, 2001, filed with the Commission on August 14, 2001

(3) Incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K, filed with the Commission on August 20, 2001

(4) Incorporated by reference to Exhibit 3.1.4 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed with the Commission on March 10, 2004

(5) Incorporated by reference to Exhibit 3.2 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, filed with the Commission on March 10, 2004

(6) Incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, filed with the Commission on August 20, 2001

(7) Incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, filed with the Commission on January 18, 2002

(8)

Incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, filed with the Commission on January 26, 2004

(9) Incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K, filed with the Commission on October 28, 2004

(10) Incorporated by reference to Exhibit 4.4 to the Company s Current Report on Form 8-K, filed with the Commission on January 26, 2004

(11) Incorporated by reference to Exhibit 4.5 to the Company s Current Report on Form 8-K, filed with the Commission on January 26, 2004

(12) Incorporated by reference to Exhibit 4.6 to the Company s Current Report on Form 8-K, filed with the Commission on January 26, 2004

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

(14) Incorporated by reference to Exhibit 10.2 of the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed with the Commission on August 21, 2006

(15) Incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K, filed with the Commission on August 4, 2005

(16) Incorporated by reference to Exhibit 10.3 of the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed with the Commission on August 21, 2006

(17) Incorporated by reference to Exhibit 10.5 to the Company s Current Report on Form 8-K, filed with the Commission on August 4, 2005

(18) Incorporated by reference to Exhibit 10.4 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed with the Commission on August 21, 2006

(19) Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed with the Commission on August 25, 2006

(20) Incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on August 1, 2007

(21) Incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K, filed with the Commission on August 1, 2007

(22) 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/ RICHARD P. LANIGAN
Richard P. Lanigan
President

Date: March 31, 2009

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Richard Lanigan and William Abbott as his or her attorney-in-fact, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each attorney-in-fact, or his substitute, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ RICHARD P. LANIGAN Richard P. Lanigan	President (*Principal Executive Officer*)	March 31, 2009
/s/ WILLIAM R. ABBOTT William R. Abbott	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (*Principal Financial and Accounting Officer*)	March 31, 2009
/s/ RAYMOND W. COHEN Raymond W. Cohen	Director	March 31, 2009
/s/ PAUL J. MCCORMICK Paul J. McCormick	Director	March 31, 2009
/s/ ROBERT L. MORTENSEN	Director	March 31, 2009

Robert L. Mortensen		
/s/ ANN T. SABAHAT	Director	March 31, 2009
Ann T. Sabahat		
/s/ MARVIN J. SLEPIAN, M.D.	Director	March 31, 2009
Marvin J. Slepian, M.D.		
/s/ GREGORY D. WALLER	Director	March 31, 2009
Gregory D. Waller		

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Cardiogenesis Corporation and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cardiogenesis Corporation and subsidiaries (the Company) as of December 31, 2008 and 2007 and the related consolidated statements of operations, shareholders equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cardiogenesis Corporation and subsidiaries as of December 31, 2008 and 2007 and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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

Costa Mesa, California
March 20, 2009

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CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEETS
December 31, 2008 and 2007

	December 31, 2008	December 31, 2007
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,907	$ 2,824
Accounts receivable, net of allowance for doubtful accounts of $20 and $28, respectively	1,330	1,763
Inventories	1,164	1,602
Short-term investments in marketable securities	75	
Prepaids and other current assets	395	486
Total current assets	5,871	6,675
Property and equipment, net	382	457
Other assets	18	27
Total assets	$ 6,271	$ 7,159
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 200	$ 169
Accrued liabilities	1,103	1,458
Deferred revenue	800	1,210
Current portion of capital lease obligation	6	12
Total current liabilities	2,109	2,849
Capital lease obligation, less current portion	13	19
Total liabilities	2,122	2,868
Commitments and contingencies		
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
no par value; 75,000 shares authorized; 45,487 and 45,274 shares issued and outstanding, respectively	173,999	173,826
Accumulated deficit	(169,850)	(169,535)

Total shareholders equity	4,149	4,291
Total liabilities and shareholders equity	$ 6,271	$ 7,159

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2008 and 2007

	2008	2007
	(In thousands, except per share amounts)	
Net revenues	$ 12,150	$ 12,059
Cost of revenues	2,239	2,949
Gross profit	9,911	9,110
Operating expenses:		
Research and development	904	681
Sales and marketing	6,487	4,441
General and administrative	2,840	3,132
Total operating expenses	10,231	8,254
Operating income (loss)	(320)	856
Other income (expense):		
Interest expense	(23)	(69)
Interest income	59	120
Loss on disposal of fixed assets		(2)
Non-cash interest expense		(89)
Change in fair value of derivatives and warrants		(225)
Total other income (expense), net	36	(265)
Income (loss) before income taxes	(284)	591
Provision for income taxes	31	13
Net income (loss)	$ (315)	$ 578
Net income (loss) per share:		
Basic and diluted	$ (0.01)	$ 0.01
Weighted average shares outstanding:		
Basic and diluted	45,320	45,274

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
For the Years Ended December 31, 2008 and 2007

	Common Stock		Accumulated	
	Shares	Amount	Deficit	Total
		(In thousands)		
Balances, January 1, 2007	45,274	$ 173,401	$ (170,113)	$ 3,288
Vesting of share-based awards		77		77
Reclassification of warrants fair value to equity		348		348
Net income			578	578
Balances, December 31, 2007	45,274	$ 173,826	$ (169,535)	$ 4,291
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	209	35		35
Issuance of common stock for option exercises	4	1		1
Vesting of share-based awards		137		137
Net loss			(315)	(315)
Balances, December 31, 2008	45,487	$ 173,999	$ (169,850)	$ 4,149

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2008 and 2007

	2008	2007
	(In thousands)	
Cash flows from operating activities:		
Net income (loss)	$ (315)	$ 578
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Derivative and warrant fair value adjustments		225
Amortization related to discount on notes payable		72
Loss on disposal of fixed assets		2
Depreciation and amortization	299	464
Provision for doubtful accounts	21	62
Stock-based compensation expense	137	77
Amortization of debt issuance costs		17
Changes in operating assets and liabilities:		
Accounts receivable	412	502
Inventories	341	382
Prepaids and other current assets	91	(65)
Other assets	9	19
Accounts payable	31	(157)
Accrued liabilities	(355)	(148)
Deferred revenue	(410)	(122)
Net cash provided by operating activities	261	1,908
Cash flows from investing activities:		
Acquisition of property and equipment	(127)	(61)
Purchase of investments in marketable securities	(150)	
Proceeds from the sale of marketable securities	75	
Net cash used in investing activities	(202)	(61)
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	36	
Payments on short term borrowings		(89)
Repayments on secured convertible term note		(1,041)
Repayments of capital lease obligations	(12)	(11)
Net cash provided by (used in) financing activities	24	(1,141)
Net increase in cash and cash equivalents	83	706

Cash and cash equivalents at beginning of year	2,824	2,118
Cash and cash equivalents at end of year	$ 2,907	$ 2,824
Supplemental schedule of cash flow information:		
Interest paid	$ 23	$ 54
Taxes paid	$ 14	$ 35
Supplemental schedule of noncash investing and financing activities:		
Reclassification of warrants fair value to equity	$	$ 348
Reclassification of inventories to property and equipment	$ 97	$ 247

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations:

Cardiogenesis Corporation (Cardiogenesis or the Company) was founded in 1989 to design, develop, and distribute surgical lasers and single-use fiber optic laser delivery systems (handpieces) for the treatment of cardiovascular disease. Currently, Cardiogenesis emphasis is on the development of products for transmyocardial revascularization (TMR), a treatment for cardiac ischemia in patients with severe angina.

Cardiogenesis markets its products for sale primarily in the United States and operates in a single segment.

These consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Cardiogenesis has not achieved consistent operating income. Management believes its cash and cash equivalents as of December 31, 2008 and expected results of operations are 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 shareholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the execution of the Company s business plan, operating results or financial condition. Cardiogenesis long term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the execution of the Company s business plan, operating results or financial condition.

2. Summary of Significant Accounting Policies:

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

Use of Estimates:

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

Reclassification:

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

Cash and Cash Equivalents:

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

Investments in Marketable Securities:

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS No. 157), except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS No. 157-2, *Effective Date of FASB Statement No. 157*. SFAS No. 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to

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transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS No. 157, the Company measures its cash and cash equivalents and marketable securities at fair value. The Company s investments in marketable securities consist of auction rate securities which are classified within level 3 due to a lack of a liquid market for such securities. The Company has formed its own opinion on the condition of the securities based on information regarding the quality of the security and the quality of the collateral, among other things.

In accordance with the fair value hierarchy described above, the following table shows the fair value of the Company s financial assets that are required to be measured at fair value on a recurring basis at December 31, 2008 (in thousands):

Description	Fair Value at December 31, 2008	Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable Securities:				
Auction Rate Securities	$ 75	$	$	$ 75

The following table provides a reconciliation of the beginning and ending balances for the Company s assets measured at fair value using significant unobservable inputs (Level 3) as defined in SFAS No. 157 at December 31, 2008 (in thousands):

Description	
Balance at December 31, 2007	$
Transfers into Level 3	750
Transfers out of Level 3	(675)
Total unrealized losses	
Total realized gains/(losses)	
Balance at December 31, 2008	$ 75

Marketable securities measured at fair value using Level 3 inputs are comprised entirely of auction rate securities. Although auction rate securities would typically be measured using Level 2 inputs, the recent failure of auctions (beginning in February 2008) and the lack of market activity and liquidity required that these securities be measured using Level 3 inputs. The underlying assets of the Company s auction rate securities are collateralized primarily by the underlying assets of certain AAA rated funds. The Company s entire balance of auction rate securities, totaling $75,000, was sold in January 2009, at par.

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Accounts Receivable:

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

Inventories:

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

Patent Expenses:

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

Property and Equipment:

Property and equipment are stated at cost and depreciated on a straight-line basis over their estimated useful lives (generally 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 long-lived assets when there is evidence that recent events or changes in circumstances indicate that their carrying value may not be recoverable. Reviews are performed to determine whether the carrying value of assets is impaired based on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the asset s carrying value over its fair value. Events or changes in circumstances which may cause impairment include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

Fair Value of Financial Instruments:

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

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

Derivative Financial Instruments:

In October 2004, the Company completed a financing transaction with Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus), pursuant to which the Company issued a Secured convertible term note (the Note). Prior to the repayment of the Note in October 2007, the Company s derivative financial instruments consisted of embedded derivatives related to the Note. These embedded derivatives included certain conversion features and

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

Revenue Recognition:

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

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

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