CARDIOGENESIS CORP /CA
Form 10-K
April 16, 2002

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2001

Commission file number: 0-28288

CardioGenesis Corporation

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

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

26632 Towne Center Drive
Suite 320
Foothill Ranch, California 92610
(Address of principal executive officers)

(714) 649-5000

(Registrant s telephone number, including area code)

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, no par value	Nasdaq National Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $32,343,786 as of March 29, 2002, based upon the closing sale price reported for that date on the Nasdaq National Market. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

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

36,506,723 shares
As of March 29, 2002

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PART I

Item 1. *Business.*

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this document or incorporated by reference herein are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth in Item 7 and elsewhere.

General

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc., incorporated in California in 1989, designs, develops, manufactures and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous transluminal myocardial revascularization (PMR). TMR and PMR are recent laser-based heart treatments in which channels are made in the heart muscle. It is believed these procedures encourage new vessel formation, or angiogenesis. TMR is performed by a cardiac surgeon through a small incision in the chest under general anesthesia. PMR is performed by a cardiologist in a catheter based procedure which utilizes local anesthesia. Clinical studies have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with TMR or PMR plus medications, when compared with patients who received medications alone.

We received CE Mark approval for our TMR system in May 1997 and our PMR systems in April 1998. On February 11, 1999, we received final approval from the FDA for our TMR products for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization. Effective July 1, 1999, the Health Care Financial Administration began to provide Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

On March 17, 1999, we merged with the former CardioGenesis Corporation. Under the terms of the combination, each share of the former CardioGenesis common stock was converted into 0.8 of a share of our common stock, and the former CardioGenesis has become a wholly owned subsidiary of ours. As a result of the transaction, our outstanding shares increased by approximately 9.9 million shares. The transaction was structured to qualify as a tax-free reorganization and has been accounted for as a pooling of interests. Accordingly, the accompanying financial statements have been restated as if the combined entity existed for the 1999 period prior to the merger.

Background

Cardiovascular disease is the leading cause of death and disability in the U.S. according to the American Heart Association. Coronary artery disease is the principal form of cardiovascular disease and is characterized by a progressive narrowing of the coronary arteries which supply blood to the heart. This narrowing process is usually due to atherosclerosis, which is the buildup of fatty deposits, or plaque, on the inner lining of the arteries. Coronary artery disease reduces the available supply of oxygenated blood to the heart muscle,

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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, Class 4, in which the patient is unable to conduct any physical activity without angina and angina may be present even at rest. The American Heart Association estimates that more than six million Americans experience angina symptoms.

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

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

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

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

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

The TMR and PMR Procedures

TMR, or transmyocardial revascularization, is a surgical procedure performed on the beating or non-beating heart, in which a laser device is used to create pathways through the myocardium directly into the heart chamber. The pathways are intended to supply blood to ischemic, or oxygen-deprived regions of the myocardium and reduce angina in the patient. TMR can be performed using open chest surgery or minimally

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invasive surgery through a small incision between the ribs. TMR offers end-stage cardiac patients who have regions of ischemia not amenable to PTCA or CABG a means to alleviate their symptoms and improve their quality of life. We have received FDA approval for U.S. commercial distribution of our TMR laser system for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

PMR, or percutaneous transluminal myocardial revascularization, is an interventional procedure performed by a cardiologist. PMR is based upon the same principles as TMR, but the procedure is much less invasive. The patient is under local anesthesia and is treated through a catheter inserted in the femoral artery at the top of the leg. A laser transmitting catheter is threaded up into the heart chamber, where channels are created in the inner portion of the myocardium (i.e. heart muscle). We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

Business Strategy

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

Expand Market for our Products. We are seeking to expand market awareness of our products among opinion leaders in the cardiovascular field, the referring physician community and the targeted patient population. In connection with the FDA approved TMR product, we have prioritized our efforts in the U.S. on the top 600 hospitals that perform the greatest number of cardiovascular procedures. We also sell our products in Europe and to the rest of the world through our direct international sales organization along with several distributors and agents. In addition, we have developed a comprehensive training program to assist physicians in acquiring the expertise necessary to utilize our TMR or PMR products and procedures.

Demonstrate Clinical Utility of PMR. We are seeking to demonstrate the clinical safety and effectiveness of PMR. We have completed a pivotal clinical trial regarding PMR, and the study results were submitted to the FDA in a Pre Market Approval Supplemental application in December of 1999. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

Leverage Proprietary Technology. We believe that our significant expertise in laser and catheter-based systems for cardiovascular disease and the proprietary technologies we have developed are important factors in our efforts to demonstrate the safety and effectiveness of our TMR and PMR procedures. We are seeking to develop additional proprietary technologies for TMR, PMR and related procedures. We have over 80 foreign and U.S. patents or allowed patent applications and more than 150 U.S. and foreign patent applications pending relating to various aspects of TMR, PMR and other cardiovascular therapies.

Products and Technology

The Company s TMR System

The Company s TMR system consists of our TMR 2000 laser console and a line of fiber-optic, laser-based surgical tools. Each surgical tool utilizes an optical fiber assembly to deliver laser energy from the source laser base unit to the distal tip of the surgical handpiece or PMR catheter. The compact base unit occupies a

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small amount of operating room floor space, operates on a standard 208 or 220-volt power supply, and is light enough to move within the operating room or among operating rooms in order to use operating room space efficiently. Moreover, the flexible fiberoptic assembly used to deliver the laser energy to the patient enables ready access to the patient and to various sites within the heart.

Our TMR system and related surgical procedures are designed to be used without the requirement of the external systems utilized with certain competitive TMR systems. For example, our TMR 2000 system does not require electrocardiogram synchronization, which monitors the electrical output of the heart and times the use of the laser to minimize electrical disruption of the heart, or transesophageal echocardiography, which tests each application of the laser to the myocardium during the TMR procedure to determine if the pathway has penetrated through the myocardium into the heart chamber.

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

SoloGrip. The single use SoloGrip handpiece system contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle.

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

The Company s PMR System

The Company s PMR System is currently sold only outside the United States. The PMR System consists of the PMR Laser and ECG Monitor.

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

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

Regulatory Status

On February 11, 1999, we received final approval from the FDA for use of our TMR 2000 laser console and SoloGrip handpiece for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

In February 1996, we obtained FDA clearance to undertake Phase I of a clinical study of TMR intended to assess the safety and effectiveness of TMR Used in Conjunction with CABG as compared with CABG alone. In September 1996, the FDA provided us with clearance to begin Phase II of this study, which was subsequently completed. In July 1999, we submitted a PMA supplement to the FDA for an expanded indication to our approved TMR labeling to include TMR in conjunction with CABG. In January 2000, we received a response from the FDA requesting that we either provide more information or modify our labeling request. Since TMR and CABG are each presently utilized to treat separate regions of the heart, we concluded that our present FDA approved labeling is adequate, and that the physician can best decide how to use the laser system within the approved labeling. As a result, in March 2000, we decided that we will not pursue any wording changes to our already approved TMR labeling, and have withdrawn our submission to the FDA for TMR in conjunction with CABG.

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We submitted a PMA supplement for our PMR system to the FDA in December 1999. The PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. As discussed below, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

We have decided not to pursue any additional claims for adjunctive procedures. Therefore, all studies involving adjunctive procedures have been halted and terminated.

In addition, we have obtained approval to affix the CE Marking to substantially all of our products, which enables us to commercially distribute our TMR and PMR products throughout the European Community.

On July 9, 2001, the Food and Drug Administration Advisory Panel recommended against approval by the Food and Drug Administration of our PMR device for public sale and use in the United States. The practical effect of the Advisory Panel s recommendation is to delay indefinitely, until such time as the Food and Drug Administration decides differently, the introduction of our PMR device for sale and use in the United States. Consequently, the Advisory Panel s recommendation has effectively delayed potential revenue, if any, that may have been derived in the future from the sale of our PMR device. Moreover, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. However, we do not expect to conduct further clinical trials.

Sales and Marketing

We have received FDA approval for our surgical TMR laser system. The Health Care Finance Administration has also announced its coverage policy for the TMR with FDA approved systems. We are promoting market awareness of our approved surgical products among opinion leaders in the cardiovascular field and are recruiting physicians and hospitals.

In the United States, we currently offer a laser base unit at a current end user list price of $320,000 per unit, and the disposable TMR handpiece (at least one of which must be used with each TMR procedure) at an end user unit list price of $2,745. In order to accelerate market adoption of the TMR procedure, we intend to continue to either sell lasers to hospitals outright or loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price.

Internationally, we sell our products through a direct sales and support organization and distributors and agents.

We have developed, in conjunction with several major hospitals using our TMR or PMR products, a training program to assist physicians in acquiring the expertise necessary to utilize our products and procedures. This program includes a comprehensive one-day course including didactic training and hands-on performance of TMR or PMR in vivo. To date over 1,000 cardiothoracic surgeons have been trained on the CardioGenesis TMR system.

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

Research and Development

We believe that streamlining our research and product effort 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 PMR applications.

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

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Manufacturing

We outsource the manufacturing and assembly of our TMR and PMR handpiece systems to a contract manufacturer. We are currently exploring manufacturing outsourcing options for the TMR 2000 laser. The PMR laser system is provided to us under a manufacturing agreement with a laser manufacturing company.

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

Competition

We expect that the market for TMR and PMR, which is currently in the early stages of development, will be competitive. At this point in time, we believe that our only competitor is PLC Systems, Inc. (PLC) which is selling FDA-approved TMR products in the U.S. and abroad. Other competitors may also enter the market, including large companies in the laser and cardiac surgery markets. Many of these companies have or may have significantly greater financial, research and development, marketing and other resources than we do.

PLC is a publicly traded corporation which uses a CO2 laser and an articulated mechanical arm in its TMR products. PLC obtained a Pre Market Approval for TMR in 1998. PLC has received the CE Marking, which allows sales of its products commercially in all European Union countries. PLC has been issued patents for its apparatus and methods for TMR. PLC recently announced that Edwards Life Sciences has exercised its option to assume full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies that was signed in January 2001.

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

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

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

Government Regulation

Laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through TMR are considered medical devices, and as such are subject to regulation in

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the U.S. by the FDA and comparable international regulatory agencies. Our devices require the rigorous PMA process for approval to market the product in the U.S. and must bear the CE Marketing for commercial distribution in the European Community.

To obtain a Pre Market Approval (PMA) for a medical device, we must file a PMA application that includes clinical data and the results of pre-clinical and other testing sufficient to show that there is a reasonable assurance of safety and effectiveness of the product for its intended use. To begin a clinical study, an Investigational Device Exemption (IDE) must be obtained and the study must be conducted in accordance with FDA regulations. An IDE application must contain preclinical test data demonstrating the safety of the product for human investigational use, information on manufacturing processes and procedures, and proposed clinical protocols. If the FDA clears the IDE application, human clinical trials may begin. The results obtained from these trials are accumulated and, if satisfactory, are submitted to the FDA in support of a PMA application. Prior to U.S. commercial distribution, premarket approval is required from the FDA. In addition to the results of clinical trials, the PMA application must include other information relevant to the safety and effectiveness of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. By law, the FDA has 180 days to review a PMA application. While the FDA has responded to PMA applications within the allotted time frame, reviews more often occur over a significantly longer period and may include requests for additional information or extensive additional trials. There can be no assurance that we will not be required to conduct additional trials which may result in substantial costs and delays, nor can there be any assurance that a PMA will be obtained for each product in a timely manner, if at all. In addition, changes in existing regulations or the adoption of new regulations or policies could prevent or delay regulatory approval of our products. Furthermore, even if a PMA is granted, subsequent modifications of the approved device or the manufacturing process may require a supplemental PMA or the submission of a new PMA which could require substantial additional clinical efficacy data and FDA review. After the FDA accepts a PMA application for filing, and after FDA review of the application, a public meeting is frequently held before an FDA advisory panel in which the PMA is reviewed and discussed. The panel then issues a favorable or unfavorable recommendation to the FDA or recommends approval with conditions. Although the FDA is not bound by the panel s recommendations, it tends to give such recommendations significant weight. In February 1999, we received a PMA for our TMR laser system for use in certain indications. As discussed above under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

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

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

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

Sales of medical devices outside of the U.S. are subject to foreign regulatory requirements that vary widely by country. In addition, the FDA must approve the export of devices to certain countries. To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with appropriate ISO 9001 standards and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies. We have achieved International Standards Organization and European Union certification for our manufacturing facility. In addition, we have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our TMR and PMR products in member countries of the European Union or elsewhere.

Intellectual Property Matters

Our success will depend, in part, on our ability to obtain patent protection for our products, preserve our trade secrets, and operate without infringing the proprietary rights of others. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business. We have over 80 U.S. and foreign patents or allowed patent applications and more than 150 U.S. and foreign patent applications pending relating to various aspects of TMR, PMR and other cardiovascular therapies. Our patents or patent applications may be challenged, invalidated or circumvented in the future or the rights granted may not provide a competitive advantage. We intend to vigorously protect and defend our intellectual property. We do not know if patent protection will continue to be available for surgical methods in the future. Costly and time-consuming litigation brought by us may be necessary to enforce our patents and to protect our trade secrets and know-how, or to determine the enforceability, scope and validity of the proprietary rights of others.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We typically require our employees, consultants and advisors to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting, or advisory relationships with us. These agreements may be breached and we may not have adequate remedies for any breach. 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 PMR. There can be no assurance, however, that claims or proceedings will not be initiated by a competitor, or that claims by other parties will not arise in the future. In particular, the introduction in the United States market of the Company s PMR technology, should that occur, may create new exposures to claims of infringement of third party patents. Any such claims in the future, with or without merit, could be time-consuming and expensive to respond to and could divert the attention of our

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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.

Until recently, patent applications in the U.S. were maintained in secrecy until patents issue, and patent applications in foreign countries are maintained in secrecy for a period after filing. Most of our U.S. applications are maintained in secrecy unless they have issued. Publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries and the filing of related patent applications. Accordingly, we can not assure that our current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights that will prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or internationally. In the event we were to require licenses to patents issued to third parties, such licenses may not be available or, if available, may not be available on terms acceptable to us. In addition, we may not be successful in any attempt to redesign our products or processes to avoid infringement or that any such redesign could be accomplished in a cost-effective manner. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would harm our business.

Third Party Reimbursement

We expect that sales volumes and prices of our products will 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 (CMS), formerly known as HCFA, began coverage of FDA approved TMR systems for any manufacturer s TMR procedures. In October of 1999, CMS further clarified its coverage policy to include coverage of TMR when performed as an adjunctive to Coronary Artery Bypass Graft.

We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. Private insurance and private health plans may not approve reimbursement for TMR or PMR. The lack of private insurance and health plans reimbursement may harm our business. Based on physician feedback, we know that private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/ Blue Shield s Technology Evaluation Center (TEC) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/ Blue Shield plans and other third-party payers use the center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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

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

Product Liability and Insurance

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

Employees

As of December 31, 2001 we had 59 employees, of which 30 employees were in sales and marketing. In January 2002, we reduced our staff by approximately 28%. In November 2001, we entered into an employment agreement with Michael J. Quinn, our Chief Executive Officer. Darrell F. Eckstein, our Interim Chief Financial Officer, was provided with a letter employment agreement when he was hired in December 2000. None of our employees are covered by a collective bargaining agreement and we have not experienced any work stoppages to date.

Our executive officers as of April 15, 2002 are as follows:

Name	Age	Position
Michael J. Quinn	58	Chief Executive Officer, President, Chairman of the Board and Director
Darrell F. Eckstein	44	Interim Chief Financial Officer, Vice President, Chief Accounting Officer, Treasurer and Secretary
Richard P. Lanigan	43	Vice President of Government Affairs and Business Development
Michael A. Tuckerman	35	Vice President of Sales
Christopher M. Owens	33	Vice President of Marketing

Michael J. Quinn has served as our Chief Executive Officer, President, Chairman of the Board and Director since October 2000. From November 1999 to September 2000, Mr. Quinn served as Chief Executive Officer, President and a member of the Board of Directors for Premier Laser Systems, a manufacturer of surgical and dental products. From January 1998 to November 1999, Mr. Quinn served as President and Chief Operating Officer of Imagyn Medical Technologies, Inc., a manufacturer of minimally invasive surgical specialty products. From 1995 through December 1997, Mr. Quinn served as President and Chief Operating Officer of Fisher Scientific Company. Prior to 1995, Mr. Quinn held senior operating management positions at

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major healthcare organizations including American Hospital Supply Corporation, Picker International, Cardinal Health Group and Bergen Brunswig.

Darrell F. Eckstein has served as our Interim Chief Financial Officer, Vice President, Chief Accounting Officer, Treasurer and Secretary since January 2002 and Vice President of Operations since December 2000. From 1996 to 2000 he served as Vice President and General Manager of the Surgical Products Division of Imagyn Medical Technologies, a manufacturer of minimally invasive surgical specialty products. From 1995 to 1996, Mr. Eckstein was Vice President of Finance, Chief Financial Officer and an Executive Committee member of Richard-Allen Medical Industries Inc., a medical devices company. From 1991 to 1995, Mr. Eckstein was Vice President of Finance, Chief Financial Officer and an Executive Committee member of National Emergency Services Inc., a health care services company that provides physician contract management, medical billing and insurance services. Prior to 1991, Mr. Eckstein worked for Deloitte and Touche, most recently as a Senior Audit Manager, for 11 years. He received his Bachelor of Science degree in Accounting from Indiana University.

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

Michael A. Tuckerman has been our Vice President of Sales since January 2002 and General Manager, Central Area since May 2001. From 1997 to 2001, Mr. Tuckerman served in various positions, most recently National Manager of Sales, at Heartport Inc. From 1995 to 1997, he served as Technical Sales Representative at Schneider, Inc., a division of Pfizer, Inc., and from 1991 to 1995, Mr. Tuckerman was the Midwest Area Manager for U.S. Surgical Corporation. Mr. Tuckerman has a Bachelors of Science in Marketing from Indiana University.

Christopher M. Owens has been our Vice President of Marketing since March 2001. Prior to CardioGenesis, Mr. Owens was Director of Marketing for the global Lamellar Surgery business of Bausch & Lomb. The Lamellar Surgery business provides surgical products for vision correction procedures. From 1997 to 2000, Mr. Owens served in a variety of sales related positions (most recently National Sales Manager) at Imagyn Medical Technologies, Inc., a manufacturer of minimally invasive surgical specialty products. From 1996 to 1997, Mr. Owens was Marketing Product Manager for Stackhouse, Inc. From 1990 to 1996 he also served as a Product Development Engineer at Baxter Healthcare Corp. He has both a Bachelors and Masters degree in Plastics Engineering from the University of Massachusetts and a Masters in Business Administration from the University of Phoenix.

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

Our headquarters, located in Foothill Ranch, California, are comprised of 17,845 square feet of leased space. The lease expires in July 2006. We believe our facilities are adequate to meet our foreseeable requirements. There can be no assurance that additional facilities will be available to us, if and when needed, thereafter.

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

There are no pending legal proceedings against us other than ordinary litigation incidental to our business, the outcome of which, individually or in the aggregate, is not expected to have a material adverse effect on our business or financial condition.

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

None.

PART II

Item 5. ***Market for Registrants Shares and Related Shareholder Matters.***

(a) Our common stock is traded on the Nasdaq National Market under the symbol CGCP (and, prior to our name change, under the symbol ESTI), since May 31, 1996. For the periods indicated, the following table presents the range of high and low sale prices for the common stock as reported by the Nasdaq National Market.

2001	High	Low
First Quarter	$2.28	$0.81
Second Quarter	$3.12	$0.91
Third Quarter	$2.98	$0.60
Fourth Quarter	$1.65	$0.65

2000	High	Low
First Quarter	$11.50	$6.75
Second Quarter	$ 7.69	$2.88
Third Quarter	$ 4.69	$3.31
Fourth Quarter	$ 4.06	$0.50

As of December 31, 2001 shares of our common stock were held by 203 shareholders of record.

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

Pursuant to a Share Purchase Agreement, dated April 11, 2001, we sold 2,000,000 shares of common stock to the State of Wisconsin Investment Board for a total price of $2,000,000, in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended (the Securities Act), and Rule 506 under the Securities Act.

In connection with entering into our facilities lease at 26632 Towne Centre Dr., Suite 320, Foothill Ranch, California, we issued a Common Stock Purchase Warrant covering 75,000 shares of common stock for an exercise price of $1.63 a share. The warrants are immediately exercisable at any time prior to May 7, 2006 at 5:00 pm (Eastern Time). This Common Stock Purchase Warrant was issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 under the Securities Act.

Pursuant to a Share Purchase Agreement, dated December 21, 2001, we sold 2,222,225 shares of common stock to the State of Wisconsin Investment Board for a total price of $2,000,000 in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 under the Securities Act.

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

The following selected consolidated statement of operations data for fiscal years ended 2001, 2000 and 1999 and the consolidated balance sheet data for 2001 and 2000 set forth below are derived from our

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consolidated financial statements and are qualified by reference to our consolidated financial statements included herein.

The selected consolidated statement of operations data for fiscal years ended 1998 and 1997 and the consolidated balance sheet data for 1999, 1998 and 1997 have been derived from our audited consolidated financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected for any future period. As a result of our 1999 pooling of interest with the former CardioGenesis, all prior period data has been restated as if the combined entity existed for all periods presented.

Selected Consolidated Financial Data

(in thousands, except per share amounts)

	Years Ended December 31,				
	2001	**2000**	**1999(1)**	**1998**	**1997**
Consolidated Statement of Operations Data:					
Net revenues	$ 14,153	$ 22,210	$ 25,324	$ 15,080	$ 13,058
Cost of revenues	5,777	10,055	13,246	7,868	7,295
Gross profit	8,376	12,155	12,078	7,212	5,763
Operating expenses:					
Research and development	1,863	5,065	11,353	29,861	26,217
Sales, general and administrative	15,119	22,009	24,581	28,484	21,004
Restructuring and merger-related costs	1,033		5,214		
Total operating expenses	18,015	27,074	41,148	58,345	47,221
Operating loss	(9,639)	(14,919)	(29,070)	(51,133)	(41,458)
Interest and other income (expense), net	(608)	310	737	3,366	5,240
Net loss	$ (10,247)	$ (14,609)	$ (28,333)	$ (47,767)	$ (36,218)
Net loss per share basic and diluted	$ (0.31)	$ (0.48)	$ (0.99)	$ (1.77)	$ (1.39)
Shares used in per share calculation	33,311	30,166	28,629	27,000	26,027
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 2,629	$ 3,357	$ 13,313	$ 27,941	$ 75,729
Working capital	1,048	4,662	10,031	22,243	68,999
Total assets	11,309	16,965	34,019	52,978	91,714
Long-term debt, less current portion	32	405	815	114	10
Accumulated deficit	(164,080)	(153,833)	(139,224)	(110,891)	(63,124)
Total shareholders equity	3,582	7,974	18,573	37,276	82,374

(1) Cost of revenues includes $2.5 million of inventory write-offs and upgrades associated with the March 1999 merger.

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

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

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the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and 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. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements.

The following discussion should be read in conjunction with financial statements and notes thereto included in this Annual Report on Form 10-K.

Overview

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc. (CardioGenesis , Company), incorporated in California in 1989, designs, develops, manufactures and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous transluminal myocardial revascularization (PMR).

On February 11, 1999, we received final approval from the FDA for our TMR products for certain indications, and we are now able to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark (CE Mark) allowing the commercial sale of our TMR laser systems and our PMR catheter system to customers in the European Community. Effective July 1, 1999, Health Care Financial Administration began providing Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval (PMA) application in December of 1999 along with subsequent amendments. As discussed above under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

As of December 31, 2001, we had an accumulated deficit of $164,080,000. We expect to 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, 2001 Compared to Year Ended December 31, 2000

Net Revenues

Net revenues of $14,153,000 for the year ended December 31, 2001 decreased $8,057,000, or 36%, when compared to net revenues of $22,210,000 for the year ended December 31, 2000. The decrease in net revenues was due to a reduction in sales of laser systems and disposable handpiece sales.

For the year ended December 31, 2001, domestic laser revenue decreased by $4,800,000 and domestic disposable handpiece revenue decreased by $2,100,000. In 2001, domestic handpiece revenue consisted of $4,700,000 in sales of product to customers operating under the loaned laser program, of which $1,400,000 was attributed to premiums associated with such sales. In 2000, domestic handpiece revenue consisted of $5,100,000 in sales of product to customers operating under the loaned laser program, of which $2,000,000 was attributed to premiums associated with such sales. In 2001 and 2000, sales of product to customers not operating under the loaned laser program was $5,900,000 and $7,600,000, respectively. International sales, accounting for approximately 7% of total sales for the year ended December 31, 2001, decreased $1,200,000 from the prior year when international sales accounted for 10% of total sales. This reduction can be explained

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by a reduction in international sales representation. We define international sales as sales to customers located outside of the United States.

Gross Profit

Gross profit increased to 59% of net revenues for the year ended December 31, 2001 as compared to 55% of net revenues for the year ended December 31, 2000. Gross profit in absolute dollars decreased by $3,779,000 to $8,376,000 for the year ended December 31, 2001, as compared to $12,155,000 for the year ended December 31, 2000. The increase in gross profit as a percent of sales resulted from improved margins on lasers and disposables partially as a result of the outsourcing of the manufacturing process for disposables which occurred in the second half of 2001. The decrease in gross margin in absolute terms resulted from the decrease in sales volumes.

Research and Development

Research and development expenditures of $1,863,000 decreased $3,202,000 or 63% for the year ended December 31, 2001 when compared to $5,065,000 for the year ended December 31, 2000. The decrease in overall research and development expense is comprised of a decrease in employee expenses of $1,400,000 related to reductions in force and a reduction in clinical trials expenses of $785,000 related to the conclusion of several of our major clinical trials. Additionally, the allocation for facilities overhead costs decreased by $620,000 and expenditures for engineering have decreased by $400,000 due to a reduction in development activities.

Sales, General and Administrative

Sales, general and administrative expenditures of $15,119,000 decreased $6,890,000 or 31% for the year ended December 31, 2001 when compared to $22,009,000 for the year ended December 31, 2000. The decrease in expenses resulted primarily from a decrease in employee expenses of $2,700,000 related to reductions in work force and a decrease in travel costs. Additionally, facilities and office expenses decreased by $1,950,000, costs for consulting and outside services decreased by $1,100,000 and marketing expenses decreased by $760,000.

Restructuring and Merger-Related Costs

During the year ended December, 31 2001, we recognized restructuring charges of $1,303,000, which were partially offset by a change in estimate of $270,000 in connection with merger-related costs that were incurred in 1999. The current year restructuring charges related to the company-wide restructuring which began in the second quarter of 2001. The restructuring included a reduction in headcount, the closing of our facilities in Sunnyvale, California and the move to a new facility located in Foothill Ranch, California. As a result of the restructuring, 48 employees were identified to be terminated under the original restructuring plan and have since been terminated, primarily from the finance and manufacturing departments.

The following table summarizes the restructuring activity and the remaining restructuring reserve balance:

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
		(in thousands)		
Provisions	$ 655	$ 344	$ 304	$ 1,303
Payments	(655)	(252)	(176)	(1,083)
Non-cash charges		(52)	(116)	(168)
Balance as of December 31, 2001	$	$ 40	$ 12	$ 52

Personnel and severance costs are comprised of severance, retention and relocation costs. Certain employees were offered a retention incentive to stay employed through a certain date while we were going

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through the restructuring phase. Lease and other contractual commitments are comprised primarily of the termination penalties associated with the early lease termination on our manufacturing and office facilities.

Interest and Other Income (Expense), Net

Interest income of $62,000 decreased $338,000 or 85% for the year ended December 31, 2001 when compared to $400,000 for the year ended December 31, 2000. This decrease was due to lower interest rates and lower investments in cash equivalents.

Interest expense of $18,000 decreased $14,000 or 44% for the year ended December 31, 2001 when compared to $32,000 for the year ended December 31, 2000. This decrease reflects a lower level of debt outstanding.

Equity in net loss of investee of $652,000 for the year ended December 31, 2001, compared to $58,000 for the year ended December 31, 2000, represents our share of the net loss of Microheart, Inc., formerly known as Microheart Holdings, Inc., a privately-held company, of which our ownership was 30.3% as of December 31, 2001.

Year Ended December 31, 2000 Compared to Year Ended December 31, 1999

Net Revenues

Net revenues of $22,210,000 for the year ended December 31, 2000 decreased $3,114,000, or 12%, when compared to net revenues of $25,324,000 for the year ended December 31, 1999. The decrease in net revenues was mainly due to a reduction in sales of laser systems resulting from a change, made at the end of 1999, to a new sales model, which emphasizes laser system placements to develop the disposable handpiece market more rapidly. The reduction in laser sales is partially offset by an increase in disposable handpiece sales generated from the new sales model.

Domestic laser revenue fell by $8,750,000 while domestic disposable handpiece revenue increased by $8,000,000. Domestic handpiece revenue consisted of $5,100,000 in sales of product to customers operating under the loaned laser program, of which $2,000,000 was attributed to premiums associated with those handpieces and $7,600,000 in handpiece sales to customers not operating under the loaned laser program. Compared to the prior year, handpiece sales under the loaned laser program increased $4,500,000 and handpiece sales to customers not operating under the loaned laser program increased $3,500,000. Other domestic changes in revenue from 2000 to 1999 were caused by no revenue recognized in the year 2000 for revenue producing activities such as research revenue of $730,000 recognized in 1999 associated with the sale of intellectual property and revenue of $600,000 recognized in 1999 for product sold in conjunction with active PMR clinical trials. These reductions in revenue were offset by a $300,000 increase in service revenue associated with extended service contracts and service calls. International sales, accounting for approximately 10% of total sales for the year ended December 31, 2000, fell $1,300,000 from the prior year when international sales accounted for 14% of total sales. This reduction is a result of a reduction in international sales representation. We define international sales as sales to customers located outside of the United States.

Gross Profit

Gross profit increased to $12,155,000 or 55% of net revenues for the year ended December 31, 2000 as compared to $12,078,000 or 48% of net revenues for the year ended December 31, 1999. In 1999, we incurred $2,523,000 in cost of revenues for inventory write-offs and a laser upgrade program resulting from our merger with the former CardioGenesis Corporation. Excluding these one-time charges, gross margin in the year ended December 31, 2000 decreased $2,446,000 compared to the prior year. This decrease in gross margin in absolute terms and as a percentage of sales resulted from the fixed component of cost of goods sold becoming a larger portion of sales, due to the decrease in sales volumes.

We began using a new sales model in the quarter ended December 31, 1999. The new sales model was derived to expedite the process of laser system placement and the adoption of TMR. Under the new model, hospitals were given the opportunity to bypass the capital approval process and, as a result, we were able to

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place more lasers than we would have placed if we had continued to sell lasers to hospitals. Given that product margins of lasers and disposable handpieces vary only slightly, the change in composition of our revenue did not significantly affect our gross margin.

Research and Development

Research and development expenditures of $5,065,000 decreased $6,288,000 or 55% for the year ended December 31, 2000 when compared to $11,353,000 for the year ended December 31, 1999. The decrease in overall research and development expense is comprised of a $4,875,000 reduction in expenses related to clinical trials, a $675,000 reduction in engineering project expenses and a $725,000 reduction in employee related expenses as headcount had fallen through general attrition.

Sales, General and Administrative

Sales, general and administrative expenses of $22,009,000 decreased $2,572,000 or 10% for the year ended December 31, 2000 when compared to $24,581,000 for the year ended December 31, 1999. The decrease is due to a $1,500,000 reduction in salary and commissions expense associated with both the elimination of redundant positions that existed between the former CardioGenesis Corporation and us prior to the merger and a decrease in commission payments directly related to the decrease in laser revenue from 2000 compared to 1999. In addition, there was a significant decrease in bad debt expense of $850,000 in the year 2000 compared to 1999.

Restructuring and Merger-Related Costs

There were merger-related costs in 1999 of $5,214,000 associated with the merger between us and the former CardioGenesis Corporation. In March 1999, we recognized merger-related costs of $6,893,000 for financial advisory and legal fees, personnel severance, terminated relationships and other costs including write-offs of fixed assets and inventory. A majority of the 40 employees that were terminated as a result of the merger were located in California and worked in operations, sales, marketing, quality, research and development and administrative functions. In addition, we recognized merger-related costs of $844,000, which were primarily due to an upgrade program to replace customer owned equipment rendered unusable by the merger. The total merger-related costs for the twelve months ended December 31, 1999 were $7,737,000, which included costs attributed to inventory write-offs and a laser upgrade program totaling $2,523,000 that were recorded as a component of cost of revenues.

There were no restructuring related costs recognized in the year 2000 or 1999.

Interest and Other Income (Expense), Net

Interest income of $400,000 decreased $401,000 or 50% for the year ended December 31, 2000 when compared to $801,000 for the year ended December 31, 1999. This decrease was due to lower investments in marketable securities and cash equivalents.

Interest expense of $32,000 decreased $32,000 or 50% for the year ended December 31, 2000 when compared to $64,000 for the year ended December 31, 1999. This decrease reflects a lower level of debt outstanding.

Equity in loss of investee of $58,000 for the year ended December 31, 2000 represents our share of the net loss of Microheart, Inc., a privately-held company, resulting from our November 2000 exercise of warrants which increased our ownership percentage to approximately 32%.

Liquidity and Capital Resources

Cash and cash equivalents were $2,629,000 at December 31, 2001 compared to $3,357,000 at December 31, 2000, a decrease of 22%. We used $6,213,000 of cash for operating activities, including funding our operating loss and changes in accounts receivable, inventories and accrued liabilities. Accounts receivable was $2,330,000 at December 31, 2001 compared to $3,654,000 at December 31, 2000, a decrease of 36%. The

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decrease in accounts receivable is partly attributed to a net increase of $761,000 in the allowance for doubtful accounts. Inventories decreased by $2,185,000 or 40% to $3,215,000 at December 31, 2001 from a level of $5,400,000 at December 31, 2000. This decrease is mainly due to depreciation on lasers loaned to hospitals of $1,100,000 million and a reduction in inventory levels. Accrued liabilities decreased by $1,322,000 or 23% to $4,467,000 at December 31, 2001 compared to $5,789,000 at December 31, 2000, primarily due to payments on obligations and an overall decrease in our operating expenses.

Investing activities, consisting primarily of additions to property and equipment, used cash of $269,000 in the fiscal year 2001. Since our inception, we have satisfied our capital requirements through sales of our equity securities. In addition, our operations have been funded through sales of our products. In the fiscal year 2001, financing activities provided cash of $5,777,000, primarily from the issuance of common stock pursuant to exercise of stock options and various sales of our common stock.

In March 2001, we sold 898,202 shares of common stock to Acqua Wellington North American Equities Fund, Ltd. at a negotiated purchase price of $1.1133 per share. In April 2001, we sold 2,000,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. In August 2001, we established a receivables-based financing arrangement with a finance company. As of December 31, 2001, we have borrowing capacity of approximately $1.2 million based on qualifying accounts receivable and have outstanding borrowings of $100,000. The term of this arrangement is one year from the date of inception, July 25, 2001, and is renewable annually at the mutual consent of both parties. The agreement provides us with the option of borrowing at an annual rate of 12% plus an administrative fee of 0.50% on all outstanding borrowings. In December 2001, we sold 2,222,225 shares of common stock to a governmental entity at a negotiated purchase price of $0.90 per share. In April 2002, we sold our ownership interest in Microheart, Inc. for $2,285,150. In April 2002, we sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share.

We have incurred significant losses for the last several years and at December 31, 2001 have an accumulated deficit of $164,080,000. The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. Our ability to continue as a going concern is dependent upon achieving profitable operations in the future. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

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

Currently, one of our primary goals is to achieve break-even operations followed by profitability. Our actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of December 31, 2001, the borrowing capacity available under our receivable financing arrangement and the infusions to our cash balance in April 2002 will be sufficient to meet our capital and operating requirements through the end of 2002. We believe that if revenue from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

Quarterly Results of Operations

The following table sets forth certain quarterly financial information for the periods indicated. This information has been derived from unaudited financial statements that, in the opinion of management, have been prepared on the same basis as the audited information, and includes all normal recurring adjustments

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necessary for a fair presentation of such information. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future periods.

	Three Months Ended							
	2001				2000			
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Net revenues	$ 3,111	$ 4,030	$ 4,221	$ 2,791	$ 5,677	$ 6,608	$ 5,014	$4,911
Gross profit	1,576	2,447	2,594	1,759	3,346	3,910	2,554	2,345
Operating loss	(2,105)	(2,705)	(2,494)	(2,335)	(4,546)	(3,398)	(3,800)	(3,175)
Net loss	(2,437)	(2,967)	(2,481)	(2,362)	(4,439)	(3,262)	(3,744)	(3,164)
Net loss per share:								
Basic and diluted	(0.08)	(0.09)	(0.07)	(0.07)	(0.15)	(0.11)	(0.13)	(0.10)
Weighted average shares outstanding	30,837	33,631	34,209	34,415	29,664	30,064	30,191	30,729

Critical Accounting Policies and Estimates

We consider certain accounting policies related to use of estimates and revenue recognition to be critical accounting policies.

Use of Estimates

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

Revenue Recognition

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

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

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

Revenues from service contracts are recognized upon performance or over the terms of the contract as appropriate.

Recently Issued Accounting Standards

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 Business Combinations, and SFAS No. 142 Goodwill and Other Intangible Assets, which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is now prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including

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goodwill recorded in past business combinations, will therefore cease upon adoption of this statement, which for us will be January 1, 2002. We do not expect the adoption of these standards will have a material effect on our consolidated financial statements.

In August 2001, the FASB issued SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 develops one accounting model for long-lived assets that are to be disposed of by sale, requires that long-lived assets that are to be disposed by sale be measured at the lower of book value or fair value less cost to sell and expands the scope of discontinued operations to include all components of an entity with operations that (a) can be distinguished from the rest of the entity and (b) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 is effective for all fiscal years beginning after December 15, 2001 and is therefore effective for us beginning with our fiscal quarter ending March 31, 2002. We do not expect the adoption of this standard will have a material effect on our consolidated financial statements.

Factors Affecting Future Results

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

Our ability to continue as a going concern is dependent upon achieving profitable operations in the future.

We will have a continuing need for new infusions of cash until revenues are increased to meet our operating expenses. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If we are unable to increase our sales or achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and will not have sufficient cash to fund our operations.

We may fail to obtain required regulatory approvals to market our products including our PMR laser system in the United States.

Our business could be harmed if any of the following events, circumstances or occurrences related to the regulatory process occurred thereby causing a reduction in our revenues:

the failure to obtain regulatory approvals for our PMR system;

any significant limitations in the indicated uses for which our products may be marketed; and

substantial costs incurred in obtaining regulatory approvals.

The Food and Drug Administration has not approved our PMR laser systems for any application in the United States. The PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. The Food and Drug Administration may not accept the study as safe and effective, and PMR may not be approved for commercial use in the United States. Responding to Food and Drug Administration requests for additional information could require substantial financial and management resources and take several years.

In the future, the Food and Drug Administration could restrict the current uses of our TMR product.

The Food and Drug Administration has approved our TMR product for sale and use by physicians in the United States. At the request of the Food and Drug Administration, we are currently conducting post-market surveillance of our TMR product. We received a letter from the Food and Drug Administration expressing

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concern about the progress of our post-market surveillance study for our TMR product. We have submitted a plan to the Food and Drug Administration to enable the timely completion of our post-market surveillance study. However, if we should fail to meet the requirements mandated by the Food and Drug Administration or fail to complete our post-market surveillance study in an acceptable time period, the Food and Drug Administration could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, though we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the Food and Drug Administration could possibly restrict the currently approved uses of our TMR product. In the future, if the Food and Drug Administration were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians, such as restricting TMR s use with the coronary artery bypass grafting procedure which occurs in more than half the procedures in which TMR is used, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be adversely affected.

The Circulatory Devices Panel of the Food and Drug Administration in July 2001 recommended against approval of our PMR device for public sale and use in the United States, which has effectively delayed potential revenue, if any, that may have been derived in the future from the sale of that device in the United States and which may have other adverse effects.

The Circulatory Devices Panel of the Food and Drug Administration recommended in July 2001 that the Food and Drug Administration not approve our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data regarding adverse events in the clinical trials. Although we do not expect to conduct further clinical trials of our PMR device, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. We will not be able to derive any revenue from the sale of that device in the United States until such time, if any, that the Food and Drug Administration approves the device. Such inability to realize revenue from sales of our PMR device in the United States may have an adverse effect on our results of operations. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the panel s recommendation became public.

The medical community has not broadly adopted our products, and unless our products are broadly adopted, our business will suffer.

Our TMR products and PMR products have not yet achieved broad commercial and clinical adoption. We cannot predict whether or at what rate and how broadly our products will be adopted by the medical community. Our business would be harmed if our TMR and PMR systems fail to achieve significant market acceptance.

The receipt of positive endorsements by physicians is essential for the success of our products in the market place.

Positive endorsements, by physicians, are essential for clinical adoption of our TMR and PMR laser systems. Physicians may elect not to recommend TMR and PMR laser systems for any number of reasons.

Clinical adoption of these products will depend upon:

our ability to facilitate training of cardiothoracic surgeons and interventional cardiologists in TMR and PMR therapy;

willingness of such physicians to adopt and recommend such procedures to their patients; and

raising the awareness of TMR and PMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

physician recommendations;

the degree of invasiveness;

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the effectiveness of the procedure; and

the rate and severity of complications associated with the procedure as compared to other procedures.

To expand our business, we must establish effective sales, marketing and distribution systems.

To expand our business, we must establish effective systems to sell, market and distribute products. To date, we have had limited sales which have consisted primarily of U.S. sales of our TMR lasers and disposable handpieces on a commercial basis since February 1999 and PMR lasers and disposable catheters outside of the U.S. through international distributors.

If our sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer.

With Food and Drug Administration approval of our TMR laser system, we are marketing our products primarily through our direct sales force. If the sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer.

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.

The growth in our business may place a significant strain on our limited personnel, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

the dependence on the growth of the market for our TMR and PMR systems;

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

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

domestic and international regulatory developments;

rapid technological change;

the highly competitive nature of the medical devices industry; and

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

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

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

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to fluctuate significantly from quarter-to-quarter due to a number of events and factors, including:

the level of product demand and the timing of customer orders;

changes in strategy;

delays associated with the Food and Drug Administration and other regulatory approval processes;

personnel changes including our ability to continue to attract, train and motivate additional qualified personnel in all areas;

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the level of international sales;

changes in competitive pricing policies;

the ability to develop, introduce and market new and enhanced versions of products on a timely basis;

deferrals in customer orders in anticipation of new or enhanced products;

product quality problems; and

the enactment of health care reform legislation and any changes in third party reimbursement policies.

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. Over the past year, our revenue has been lower than anticipated, largely attributable to the transition to our new sales strategy. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs again, the price of our common stock may fall again, perhaps substantially.

Growth in our future operating results is highly contingent and subject to significant risks.

Our future operating results will be significantly affected by our ability to:

successfully and rapidly expand sales to potential customers;

implement operating, manufacturing and financial procedures and controls;

improve coordination among different operating functions; and

achieve manufacturing efficiencies as production volume increases.

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

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

Effective July 1, 1999 the Health Care Financing Administration commenced Medicare coverage for TMR systems for any manufacturer s TMR procedures. Hospitals and physicians are now eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. The Health Care Financing Administration has not approved reimbursement for PMR. If it does not in the future provide reimbursement, our ability to successfully market and sell our PMR products will be harmed.

Currently there are over 2,000 private health insurers and managed care organizations in the United States. Even though Medicare beneficiaries appear to account for approximately 52% of all patients treated with the TMR procedure, the remaining 48% are beneficiaries of private insurance and private health plans. We have limited data on the reimbursement of our TMR procedures by private insurance and private health plans. If they do not provide reimbursement, our business will suffer.

Based on physician feedback, we know that private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/ Blue Shield s Technology Evaluation Center (TEC) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/ Blue Shield plans and other third-party payors use the Center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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

The market for TMR laser systems is competitive. If our competitor is more effective in developing new products and procedures and marketing existing and future products, our business will suffer. The market for TMR laser systems is characterized by rapid technical innovation. Accordingly, 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.

We currently compete with PLC Systems. PLC recently announced that Edwards Life Sciences has exercised its option to assume full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies that was signed in January 2001.

If we obtain the Food and Drug Administration s approval for our PMR laser system, we will face competition for market acceptance and market share for that product. Our ability to compete may depend in significant part on the timing of introduction of competitive products into the market, and will be affected by the pace, relative to competitors, at which we are able to:

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

Our products depend on TMR technology that is rapidly changing which may require us to incur substantial product development expenditures to prevent our products from becoming obsolete.

The medical device industry is characterized by rapid and significant technological change. Our future success will depend in large part on our ability to respond to such changes through further product research and development. In addition, we must expand the indications and applications for our products by developing and introducing enhanced and new versions of our TMR and PMR laser systems. Product research and development requires substantial expenditures and is inherently risky. We may not be able to:

- identify products for which demand exists; or
- develop products that have the characteristics necessary to treat particular indications.

Overall increases in medical costs could adversely affect our business.

We believe that the overall escalating cost of medical products and services has led, and will continue to lead, to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by them. We cannot assure you that in either United States or international markets that:

- third party reimbursement and coverage will be available or adequate;
- current reimbursement amounts will not be decreased in the future; or
- future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for our products or our ability to profitably sell our products.

Fundamental reforms in the healthcare industry in the United States and Europe continue to be considered. We cannot predict whether or when any healthcare reform proposals will be adopted and what effect such proposals might have on our business.

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We have a history of losses and may not be profitable in the future.

We have incurred significant losses since inception. Our revenues and operating income will be constrained:

until such time, if ever, as we obtain broad commercial adoption of our TMR laser systems by healthcare facilities in the United States;

until such time, if ever, as we obtain Food and Drug Administration and other regulatory approvals for our PMR laser systems; and

for an uncertain period of time after such approvals are obtained.

We may not achieve or sustain profitability in the future.

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

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

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

operate without infringing upon the patents or proprietary rights of third parties.

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

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

Costly litigation may be necessary to protect intellectual property rights.

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of others. In addition, we may become subject to patent infringement claims or litigation, or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions.

Defending and prosecuting intellectual property suits, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings are both costly and time-consuming. We may be required to litigate further to:

enforce our issued patents;

protect our trade secrets or know-how; or

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

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

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

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

require us to modify our products.

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

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

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

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

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

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

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

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

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

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

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

Certain critical products and components for lasers and disposable handpieces are purchased from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of some of these products to third parties. We may experience harm to our business if these sources have difficulties supplying our needs for these products and components. In addition, we do not have long term supply contracts. As a result, these sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers and manufacturers could cause a delay in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

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

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

Our products could contain defects which could delay regulatory approval or market acceptance of our products.

We may experience future product defects, malfunctions, manufacturing difficulties or recalls related to the lasers or other components used in our TMR and PMR laser systems. Any such occurrence could cause a delay in regulatory approvals or adversely affect the commercial acceptance of our products. We are unable to quantify the likelihood or costs of any such occurrences, but they could potentially be significant. Our business could be harmed because we may be unable to sufficiently remedy a significant product recall while still maintaining our daily manufacturing quotas.

We must comply with Food and Drug Administration manufacturing standards or face fines or other penalties including suspension of production.

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

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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

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

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our TMR or PMR laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death. We are not aware of any material side effects or adverse events arising from the use of our TMR product. Though we are in the process of responding to the Food and Drug Administration s Circulatory Devices Panel s recent recommendation against approval of our PMR product because of concerns over the safety of the device and the data regarding adverse events in the clinical trials, we believe there are no material side effects or adverse events arising from the use of our PMR product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. In light of this, we believe that the difference in the rates of complications between the treated groups and the control groups in the clinical trials for our PMR product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMR product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the Food and Drug Administration s good manufacturing practices or other regulations could hurt our ability to defend against product liability lawsuits. Although we have not experienced any product liability claims to date, any such claims could cause our business to suffer.

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

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

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

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

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

Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer.

During the last two years, we have had significant change in our senior management team. Our former Chief Executive Officer, Allen Hill, resigned from the company in December 1999. One of our former Directors, Alan Kaganov, acted as interim Chief Executive Officer until we hired our current Chief Executive Officer, Michael Quinn, in October of 2000. Our former Chief Financial Officer, Dick Powers, resigned from the company in July 2000. Ian Johnston, our then Vice President of Finance who resigned in June 2001, acted as interim Chief Financial Officer until our former Chief Financial Officer, J. Stephen Wilkins, was hired in May 2001. In January 2002, our former Chief Financial Officer, J. Stephen Wilkins, resigned and was replaced by Darrell Eckstein who was originally hired in December 2000 as our Vice President of Operations, originally replacing Bill Picht, who resigned earlier in 2000. Additionally, Richard Lanigan moved from Vice President of Sales to Vice President of Government Affairs and Business Development in March 2001 and Michael A. Tuckerman was promoted to Vice President, U.S. Sales, after Thomas Kinder, our former Vice President of Worldwide Sales resigned in January 2002. In addition, Christopher M. Owens was hired as Vice President of Marketing in March 2001. William Von Brendel, who was hired in August 2001 as Vice President and General Manager of the International Business Unit, resigned in January 2002 and is currently providing international sales support under a consulting agreement with us.

Our future business could be harmed by our turnover in senior management if we have difficulty familiarizing and training our new management with respect to our business. Further significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

We 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 Food and Drug Administration 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.

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

We have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer. Noncompliance with international regulatory requirements could result in enforcement action such as not being allowed to market our product in the European Union, which would significantly reduce international revenue.

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

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

foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

various tariffs and trade regulations;

restrictions and foreign medical regulations;

customs duties, export quotas or other trade restrictions; and

difficulty in protecting intellectual property rights.

We may not achieve wide acceptance of our products in foreign markets if we fail to obtain third party reimbursement for the procedures performed with our products.

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

We may engage in future acquisitions that could distract our management, cause us to incur debt, or dilute our shareholders.

We may, from time to time, acquire or invest in other complementary businesses, products or technologies. While there are currently no commitments with respect to any particular acquisition or investment, our management frequently evaluates the strategic opportunities available in complementary

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businesses, products or technologies. The process of integrating an acquired company s business into our operations may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, the anticipated benefits of any acquisition or investment may not be realized. Any future acquisitions or investments by us could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and impairment/amortization expenses related to goodwill and other intangible assets, any of which could materially harm our operating results.

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

The market price of our common stock has been and may continue to be volatile. For example, during 52-week period ended December 31, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $3.12 to a low of $0.60. 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;

announcements of technological innovations or new products or services by us or our competitors;

announcements relating to strategic relationships or acquisitions;

changes in financial estimates by securities analysts;

statements by securities analysts regarding us or our industry;

conditions or trends in the medical device industry; and

changes in the economic performance and/or market valuations of other medical device companies.

Because of this volatility, we may fail to meet the expectations of our shareholders or of securities analysts at some time in the future, and our stock price could decline as a result.

In addition, the stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results. Our common stock could be subject to certain consequences in the future established by the NASDAQ National Market such as being delisted if we do not meet the Nasdaq s continued listing standards. For instance, if our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National Market, or our current net tangible assets fell below $4 million, or if we do not in the future meet the Nasdaq s $10 million in stockholder s equity test starting November 1, 2002, we would be in violation of the Nasdaq s continued listing standards. If our common stock were delisted from the NASDAQ National Market, then we could apply for listing on the Nasdaq SmallCap Market or explore becoming listed on an alternative market. Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

Recently, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought such a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

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

Quantitative Disclosures

The Company is exposed to market risks inherent in its operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of

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business. The Company does not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. The Company has no holdings of derivative or commodity instruments.

Interest Rate Risk. The Company is subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at December 31, 2001 consists of an outstanding balance on a lease obligation.

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

	2002	2003	2004	2005	2006	Total Fair Value
			(In Thousands)			
Assets						
Cash, cash equivalents	$2,629	$	$	$	$	$2,629
Weighted average interest rate	3.0%					3.0%
Liabilities						
Fixed Rate Debt Lease obligation	$ 32	$ 32	$	$	$	$ 64
Weighted average interest rate	6.8%	6.8%				6.8%

Qualitative Disclosures

Interest Rate Risk. The Company s primary interest rate risk exposures relate to the impact of interest rate movements on the Company s ability to obtain adequate financing to fund future operations.

The Company manages interest rate risk on its outstanding long-term debts through the use of fixed rate debt. Management evaluates the Company s financial position on an ongoing basis.

The Company does not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

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

See Item 14(a) below and the Index therein for a listing of the consolidated financial statements and supplementary data filed as part of this report.

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

None.

PART III

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

Certain information required by Part III, Item 10 is omitted from this Annual Report on Form 10-K because we will file a definitive proxy statement within 120 days after the end of our fiscal year pursuant to Regulation 14A for our Annual Meeting of Shareholders, currently scheduled for May 31, 2002, and the information included in the proxy statement is incorporated herein by reference.

Item 11. ***Executive Compensation and Other Matters.***

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

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The information concerning our directors and the remaining information concerning our executive officers required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2002 Annual Meeting of Shareholders.

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

The information required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2002 Annual Meeting of Shareholders.

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

The information required by this item is incorporated by reference to the information set forth under the similarly titled caption contained in the proxy statement to be used by us in connection with our 2002 Annual Meeting of Shareholders.

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PART IV

Item 14. ***Exhibits, Financial Statement Schedule, and Reports on Form 8-K.***

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

(2) *Financial Statement Schedule*

The following financial statement schedule is filed herewith.

(3) *Exhibits.*

The exhibits listed under Item 14(c) are filed or incorporated by reference herein.

(b) *Reports on Form 8-K.*

A report was filed on December 21, 2001, to report the execution of a Share Purchase Agreement dated December 21, 2001, between CardioGenesis and the State of Wisconsin Investment Board, pursuant to which CardioGenesis sold 2,222,225 share of common stock to the State of Wisconsin Investment Board for $2.0 million on December 26, 2001.

(c) *Exhibits.*

The exhibits below are filed or incorporated herein by reference.

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Exhibit Number	Description
2.1(1)	Agreement and Plan of Reorganization among the Company, the former CardioGenesis Corporation and RW Acquisition Corporation dated October 21, 1998.
3.1(2)	Certificate of Amendment and Restated Articles of Incorporation of Registrant.
3.2	Certificate of Amendment to Articles of Incorporation of Registrant (incorporated by reference to the Registrant s Form 10-Q filed August 14, 2001).
3.3	Amended and Restated Bylaws of Registrant.
4.1	Form of Rights Agreement, dated as of August 17, 2001, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent, which includes as Exhibit A the Form of Right Certificate, Form of Assignment and Form of Election to Purchase (incorporated by reference to the Registrant s Form 8-K filed August 20, 2001).
4.2	First Amendment to Rights Agreement, dated as of January 17, 2002, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent (incorporated by reference to the Registrant s Form 8-K filed January 18, 2001).
4.3	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Centre Dr., Suite 320, Foothill Ranch California (incorporated by reference to the Registrant s Form 10-Q/A, Exhibit 10.1, filed August 16, 2001).
4.4	Share Purchase Agreement dated April 11, 2001 between the Company and the State of Wisconsin Investment Board (incorporated by reference to Exhibit 4.1 of the Registrant s Form 8-K filed April 23, 2001).
4.5	Share Purchase Agreement dated December 21, 2001 between the Company and the State of Wisconsin Investment Board (incorporated by reference to Exhibit 4.1 of the Registrant s Form 8-K filed January 18, 2002).
10.1(2)	Form of Director and Officer Indemnification Agreement.
10.2	Stock Option Plan, as amended and restated.
10.3	Director Stock Option Plan, as amended and restated.
10.4(2)	1996 Employee Stock Purchase Plan of CardioGenesis Corporation.
10.5(2)	Facilities Lease for 1049 Kiel Court, Sunnyvale, California.
10.6(2)	Facilities Lease for 1139 Karlstad Drive, Sunnyvale, California.
10.7	Facilities Lease for 26632 Towne Centre Dr., Suite 320, Foothill Ranch, California (incorporated herein by reference to the Registrant s Form 10-Q/A, Exhibit 10.1, filed August 16, 2001).
10.8(2)	401(k) Plan.
10.9(3)	1993 Equity Incentive Plan of the former CardioGenesis Corporation
10.10(4)	1996 Equity Incentive Plan of the former CardioGenesis Corporation
10.11	Employment agreement dated September 27, 2001 between the Company and Michael J. Quinn, Chief Executive Officer.
10.12	Employment Letter Agreement dated December 19, 2000 between the company and Darrell F. Eckstein, Vice President of Operations (incorporated by reference to the Registrant s Form 10-K, filed April 17, 2001).
21.1	List of Subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP
24.1	Power of Attorney (see signature page)

(1) Incorporated herein by reference to Appendix 1 to the Company s Registration Statement on S-4 filed with the Securities and Exchange Commission on February 9, 1999 (File No. 333-72063).

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

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(3) Incorporated herein by reference from the former CardioGenesis Corporation s Form SB-2, (File No. 333-3752-LA), declared effective on May 21, 1996.

(4) Incorporated herein by reference from the former CardioGenesis Corporation s Form S-8, (File No. 333-35095, dated September 8, 1997).

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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
Registrant

By: /s/ MICHAEL J. QUINN

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

Date: April 16, 2002

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.

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints jointly and severally, Michael J. Quinn and/or Darrell F. Eckstein and each one of them, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ MICHAEL J. QUINN Michael J. Quinn	Chief Executive Officer, President, Chairman of the Board and Director (*Principal Executive Officer*)	April 16, 2002
/s/ DARRELL F. ECKSTEIN Darrell F. Eckstein	Interim Chief Financial Officer (*Principal Accounting and Financial Officer, Secretary and Treasurer*)	April 16, 2002
/s/ JACK M. GILL Jack M. Gill	Director	April 16, 2002
/s/ JOSEPH R. KLETZEL Joseph R. Kletzel	Director	April 16, 2002
/s/ ROBERT L. MORTENSEN Robert L. Mortensen	Director	April 16, 2002
/s/ ROBERT C. STRAUSS Robert C. Strauss	Director	April 16, 2002

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REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders of CardioGenesis Corporation

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(a)(1) on page 34 present fairly, in all material respects, the financial position of CardioGenesis Corporation and its subsidiaries (the Company) at December 31, 2001 and December 31, 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(a)(2) on page 34 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PRICEWATERHOUSECOOPERS LLP

San Jose, California

February 1, 2002, except Note 18
as to which the date is April 11, 2002

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CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEETS

December 31, 2001 and 2000
(in thousands)

	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,629	$ 3,357
Accounts receivable, net of allowance for doubtful accounts of $1,114 and $353 at December 31, 2001 and 2000, respectively	2,330	3,654
Inventories, net of reserves of $1,246 and $2,180 at December 31, 2001 and 2000, respectively	3,215	5,400
Prepaids and other current assets	569	837
Total current assets	8,743	13,248
Property and equipment, net	863	1,048
Accounts receivable over one year, net of allowance for doubtful accounts of $240 and $443, at December 31, 2001 and 2000, respectively		119
Other assets	1,703	2,550
Total assets	$ 11,309	$ 16,965
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,548	$ 689
Accrued liabilities	4,467	5,789
Customer deposits	54	186
Deferred revenue	931	1,310
Notes payable	170	86
Current portion of capital lease obligation	30	26
Other current liability	495	500
Total current liabilities	7,695	8,586
Capital lease obligation, less current portion	32	66
Long-term liability, less current portion		339
Total liabilities	7,727	8,991
Commitments and contingencies (Note 11)		
Shareholders equity:		
Preferred stock:		
no par value; 6,600 shares authorized; none issued and outstanding;		
Common stock:		
no par value; 50,000 shares authorized; 36,507 and 30,836 shares issued and outstanding at December 31, 2001 and 2000, respectively	167,750	161,938
Deferred compensation		(66)
Accumulated other comprehensive loss	(88)	(65)
Accumulated deficit	(164,080)	(153,833)
Total shareholders equity	3,582	7,974

Total liabilities and shareholders equity	$ 11,309	$ 16,965

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

For the Years Ended December 31, 2001, 2000 and 1999
(in thousands, except per share amounts)

	2001	2000	1999
Net revenues	$ 14,153	$ 22,210	$ 25,324
Cost of revenues	5,777	10,055	13,246
Gross profit	8,376	12,155	12,078
Operating expenses:			
Research and development	1,863	5,065	11,353
Sales, general and administrative	15,119	22,009	24,581
Restructuring and merger-related costs	1,033		5,214
Total operating expenses	18,015	27,074	41,148
Operating loss	(9,639)	(14,919)	(29,070)
Interest expense	(18)	(32)	(64)
Interest income	62	400	801
Equity in net loss of investee	(652)	(58)	
Net loss	(10,247)	(14,609)	(28,333)
Other comprehensive income (loss), net of tax:			
Unrealized gains (losses) on securities:			
Unrealized holding gains (losses) arising during period		44	(145)
Less: reclassification adjustment for losses included in net income			(5)
Foreign currency translation adjustment	(23)	(34)	26
Other comprehensive income (loss)	(23)	10	(124)
Comprehensive loss	$(10,270)	$(14,599)	$(28,457)
Net loss per share:			
Basic and diluted	$ (0.31)	$ (0.48)	$ (0.99)
Weighted average shares outstanding	33,311	30,166	28,629

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

For the Years Ended December 31, 2001, 2000 and 1999
(in thousands)

	Common Stock		Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 31, 1998.	27,466	$148,947	$ (829)	$ 49	$(110,891)	$ 37,276
Issuance of common stock pursuant to exercise of options	1,448	7,269				7,269
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	74	478				478
Issuance of common stock pursuant to exercise of warrants	449	833				833
Deferred stock compensation		811	(811)			
Amortization of deferred compensation			1,174			1,174
Net change in unrealized gains (losses) on marketable securities				(150)		(150)
Foreign currency translation adjustment				26		26
Net loss					(28,333)	(28,333)
Balances, December 31, 1999.	29,437	158,338	(466)	(75)	(139,224)	18,573
Issuance of common stock pursuant to exercise of options	640	1,064				1,064
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	204	388				388
Issuance of common stock to private entity	526	1,873				1,873
Issuance of common stock to private company in lieu of payment for services	29	44				44
Deferred stock compensation		231	(231)			
Amortization of deferred compensation			631			631
Net change in unrealized gains (losses) on marketable securities				44		44
Foreign currency translation adjustment				(34)		(34)
Net loss					(14,609)	(14,609)
Balances, December 31, 2000.	30,836	161,938	(66)	(65)	(153,833)	7,974
Issuance of common stock pursuant to exercise of options	446	719				719
Issuance of common stock pursuant to stock purchased under the Employee Stock Purchase Plan	105	120				120
Issuance of common stock purchase warrants		94				94

Issuance of common stock to private entities	5,120	4,884				4,884
Deferred stock compensation		(5)	5			
Amortization of deferred compensation			61			61
Foreign currency translation adjustment				(23)		(23)
Net loss					(10,247)	(10,247)
Balances, December 31, 2001.	36,507	$167,750	$	$ (88)	$(164,080)	$ 3,582

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2001, 2000 and 1999
(in thousands)

	2001	2000	1999
Cash flows from operating activities:			
Net loss	$(10,247)	$(14,609)	$(28,333)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	450	933	1,453
Equity in net loss of investee	652	58	
Provision for doubtful accounts	904	620	1,377
Inventory reserves	1,144	1,788	1,782
Amortization of deferred compensation for options to consultants	61	631	1,174
Amortization of license fees and other assets	211	194	195
Accretion of long-term liability	31		
Loss on disposal of property and equipment	4		317
Issuance of stock to private company in lieu of payment for services		44	
Changes in operating assets and liabilities:			
Accounts receivable short term	420	3,756	551
Inventories	1,041	(694)	799
Prepaids and other current assets	346	(70)	1,195
Other assets			24
Accounts receivable long term	119	1,096	51
Accounts payable	859	(1,130)	230
Accrued liabilities	(1,322)	(3,768)	(1,907)
Current portion of long term liabilities	(5)	(375)	
Long term liabilities	(370)	(386)	(687)
Customer deposits	(132)	41	(111)
Deferred Revenue	(379)	(410)	(425)
Net cash used in operating activities	(6,213)	(12,281)	(22,315)
Cash flows from investing activities:			
Purchase of marketable securities		(3,317)	(44,702)
Maturities of marketable securities		11,108	61,473
Acquisition of property and equipment	(269)	(762)	(637)
Exercise of warrants in Microheart, Inc.		(310)	
Net cash (used in) provided by investing activities	(269)	6,719	16,134
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	839	1,452	8,580
Net proceeds from sale of common stock to private entities	4,884	1,873	
Proceeds from short term borrowings	439	319	
Repayment of note payable	(355)	(233)	(111)
Repayments of capital lease obligations	(30)	(24)	(21)
Net cash provided by financing activities	5,777	3,387	8,448
Effect of exchange rates on cash and cash equivalents	(23)	(34)	26

Net increase (decrease) in cash and cash equivalents	(728)	(2,209)	2,293
Cash and cash equivalents at beginning of year	3,357	5,566	3,273
Cash and cash equivalents at end of year	$ 2,629	$ 3,357	$ 5,566
Supplemental schedule of cash flow information:			
Interest paid	$ 21	$ 32	$ 64
Taxes paid	$ 74	$ 153	$ 112
Supplemental schedule of noncash investing and financing activities:			
Change in unrealized gain (loss) on marketable securities	$	$ 44	$ (150)
Issuance of common stock purchase warrants	$ 94	$	$
Deferred compensation	$ (5)	$ 231	$ 811

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

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations:

CardioGenesis Corporation (CardioGenesis or the Company), formerly known as Eclipse Surgical Technologies, Inc., was founded in 1989 to develop, manufacture and market surgical lasers and accessories for the treatment of disease. Currently, CardioGenesis emphasis is on the development and manufacture of products used for transmyocardial revascularization (TMR) and percutaneous myocardial revascularization (PMR), which are cardiovascular procedures. CardioGenesis markets its products for sale primarily in the U.S., Europe and Asia. CardioGenesis operates in a single segment.

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. CardioGenesis has sustained significant losses for the last several years and expects to continue to incur losses through 2002. Management believes its cash balance as of December 31, 2001 is not sufficient to meet the Company s capital and operating requirements for the next 12 months. CardioGenesis has obtained additional funding through the sale of an investment and the sale of common stock through a private placement (See Note 18 Subsequent Events).

CardioGenesis may require additional financing in the future. There can be no assurance that CardioGenesis will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to CardioGenesis stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on CardioGenesis business, operating results and 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 business, operating results and financial condition.

2. Summary of Significant Accounting Policies:

Basis of Presentation:

On March 17, 1999, Eclipse Surgical Technologies, Inc. (Eclipse) completed the acquisition of the former CardioGenesis Corporation pursuant to the Agreement and Plan of Reorganization (the merger) dated as of October 21, 1998. The merger was accounted for using the pooling of interests method of accounting for business combinations. Accordingly, the Company s financial statements have been restated to include the accounts of the former CardioGenesis Corporation for 1999. The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Use of Estimates:

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

Cash and Cash Equivalents:

All highly liquid instruments purchased with an original maturity of three months or less are considered cash equivalents.

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.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Patent Expenses:

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

Property and Equipment:

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

Long-Lived Assets:

CardioGenesis evaluates the recoverability of its long-lived assets in accordance with Statement of Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of (SFAS 121). SFAS 121 requires recognition of the impairment of long-lived assets in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets.

Fair Value of Financial Instruments:

The carrying amounts of certain of CardioGenesis financial instruments including cash equivalents, accounts receivable, accounts payable, accrued liabilities and customer deposits approximate fair value due to their short maturities.

The fair value of the Company s long-term liabilities is estimated by discounting future cash flows of each instrument at rates currently offered to the Company for similar debt instruments of comparable maturities. Based upon such rates currently available to the Company, the estimated fair value of the Company s long-term liabilities approximates carrying value.

Revenue Recognition:

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

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

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

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

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development:

Research and development expenses are charged to operations as incurred.

Warranties:

CardioGenesis laser products are generally sold with a one year warranty. CardioGenesis provides for estimated future costs of repair or replacement which are reflected in the accompanying financial statements.

Advertising:

CardioGenesis expenses all advertising as incurred. CardioGenesis advertising expenses were $137,000, $128,000 and $75,000 for 2001, 2000 and 1999, respectively. Advertising expenses include fees for website design and hosting, reprints from medical journals, promotional materials and sales sheets.

Income Taxes:

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

Foreign Currency Translation:

CardioGenesis international subsidiary uses its local currency as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and income and expense accounts at average exchange rates during the year. Resulting translation adjustments are recorded in accumulated other comprehensive income/loss in shareholders equity. Transaction gains and losses are included in the results of operations and have not been significant for all periods presented.

Stock-Based Compensation:

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

CardioGenesis accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue No. 96-18 Accounting for Equity Instruments that are issued to other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.

Net Loss Per Share:

Basic earnings per share (EPS) is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted EPS is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of incremental shares issuable upon the exercise of stock options and warrants using the treasury stock method.

Options to purchase 2,787,000, 3,243,000, and 4,363,000 shares of common stock were outstanding at December 31, 2001, 2000 and 1999, respectively. The range of exercise prices for these options were $0.563 $12.6875 for 2001, $0.03 $15.9375 for 2000 and $0.03 $16.09 for 1999. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of December 31, 2001. No warrants were outstanding at

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2000 and 1999. Both the options and warrants were not included in the calculation of diluted EPS because their inclusion would have been anti-dilutive.

Recent Accounting Pronouncements:

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 Business Combinations, and SFAS No. 142 Goodwill and Other Intangible Assets, which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is now prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will therefore cease upon adoption of this statement, which for the Company will be January 1, 2002. The Company does not expect the adoption of these standards will have a material effect on its consolidated financial statements.

In August 2001, the FASB issued SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 develops one accounting model for long-lived assets that are to be disposed of by sale, requires that long-lived assets that are to be disposed by sale be measured at the lower of book value or fair value less cost to sell and expands the scope of discontinued operations to include all components of an entity with operations that (1) can be distinguished from the rest of the entity and (2) will be eliminated from the on-going operations of the entity in a disposal transaction. SFAS No. 144 is effective for all fiscal years beginning after December 15, 2001 and is therefore effective for the Company beginning with its fiscal quarter ending March 31, 2002. The Company does not expect the adoption of this standard will have a material effect on its consolidated financial statements.

3. Business Combination

On March 17, 1999, Eclipse Surgical Technologies, Inc. and the former CardioGenesis Corporation announced the completion of their business combination. Under the terms of the combination, each share of common stock of the former CardioGenesis Corporation was converted into 0.80 of a share of Eclipse common stock, and the Company assumed all outstanding stock options of the former CardioGenesis Corporation. Additionally, the former CardioGenesis Corporation became a wholly-owned subsidiary of Eclipse and its shares were no longer publicly traded. As a result of the transaction, the Company increased its outstanding shares by approximately 9.9 million shares. The transaction was structured to qualify as a tax-free reorganization and was accounted for as a pooling of interests.

The former CardioGenesis Corporation was a medical device company like Eclipse, which developed, manufactured, and marketed cardiac revascularization products for the treatment of advanced cardiovascular disease and severe angina pain through TMR and PTMR. This company also manufactured and marketed disposable products to perform intraoperative transmyocardial revascularization (ITMR), catheter-based percutaneous myocardial revascularization (PMR), and thorascopic transmyocardial revascularization (TTMR) to treat patients afflicted with debilitating angina.

There were merger-related costs in 1999 of $5,214,000 associated with the merger between the Company and the former CardioGenesis Corporation. In March 1999, the Company recognized merger-related costs of $6,893,000 for financial advisory and legal fees, personnel severance, terminated relationships and other costs including write-offs of fixed assets and inventory. A majority of the 40 terminated employees as a result of the merger were located in California and worked in operations, sales, marketing, quality, research and development and administrative functions. In addition, the Company recognized merger-related costs of $844,000, which were mainly due to an upgrade program to replace customer owned equipment rendered unusable by the merger. The total merger-related costs for the twelve months ended December 31, 1999 were

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

$7,737,000, which included costs attributed to inventory write-offs and a laser upgrade program totaling $2,523,000 that were recorded as a component of cost of revenues.

The following table summarizes the merger-related costs:

Description	Amount
	(in thousands)
Financial advisory and legal fees	$ 2,528
Personnel severance	1,190
Terminated relationships/contracts	910
Other costs including fixed asset and inventory write-offs	3,109
Subtotal	7,737
Less: Amount included in cost of revenues	(2,523)
Total	$ 5,214

The following table summarizes the fiscal year 1999 net revenues and net loss of Eclipse and the former CardioGenesis Corporation through March 31, 1999:

	Quarter Ended March 31, 1999
	(in thousands)
The former CardioGenesis Corporation:	
Net revenues	$ 675
Net loss	$(8,317)
Eclipse:	
Net revenues	$ 3,799
Net loss	$(6,849)

The following table summarizes the Company s merger related reserve balances:

	(in thousands)
Merger Related Cost (for the twelve month period ended December 31, 1999)	$7,737
Less:	
Non-cash charges	2,060
Cash payments	5,163
Merger reserve balance at December 31, 1999	514
Less:	
Cash payments	244

Merger reserve balance at December 31, 2000	270
Less:	
Change in estimate	270
Merger reserve balance at December 31, 2001	$

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Restructuring Costs:

During the year ended December, 31 2001, the Company recognized restructuring charges of $1,303,000, which were partially offset by a change in estimate of $270,000 in connection with merger-related costs that were incurred in 1999. The current year restructuring charges related to the company-wide restructuring which began in the second quarter of 2001. The restructuring included a reduction in headcount, the closing of the Company s facilities in Sunnyvale, California and the move to a new facility located in Foothill Ranch, California. As a result of the restructuring, 48 employees were identified to be terminated under the original restructuring plan and have since been terminated, primarily from the finance and manufacturing departments.

The following table summarizes the restructuring activity and the remaining restructuring reserve balance:

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
		(in thousands)		
Provisions	$ 655	$ 344	$ 304	$ 1,303
Payments	(655)	(252)	(176)	(1,083)
Non-cash charges		(52)	(116)	(168)
Balance as of December 31, 2001	$	$ 40	$ 12	$ 52

The restructuring reserve balance is included in accrued liabilities.

Personnel and severance costs are comprised of severance, retention and relocation costs. Certain employees were offered a retention incentive to stay employed through a certain date while the Company was going through the restructuring phase. Lease and other contractual commitments are comprised primarily of the termination penalties associated with the early lease termination on the Company s manufacturing and office facilities.

5. Inventories:

Inventories consist of the following:

	December 31,	
	2001	2000
	(in thousands)	
Raw materials	$ 917	$2,045
Work in process	323	715
Finished goods	1,975	2,640
	$3,215	$5,400

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Property and Equipment:

Property and equipment consists of the following:

	December 31,	
	2001	2000
	(in thousands)	
Computers and equipment	$ 2,715	$ 2,508
Manufacturing and demonstration equipment	2,210	2,216
Assets in progress	62	183
Leasehold improvements	157	198
	5,144	5,105
Less accumulated depreciation and amortization	(4,281)	(4,057)
	$ 863	$ 1,048

CardioGenesis leases certain equipment under a capital lease which expires in December 2003. Accordingly, capitalized costs of $138,000, net of accumulated amortization of $83,000 and $57,000 at December 31, 2001 and 2000, respectively, are included in computers and equipment.

7. Other Assets:

On January 5, 1999, CardioGenesis entered into a Settlement and License Agreement (the PLC agreement) with PLC Medical Systems, Inc. (PLC) which granted CardioGenesis a non-exclusive worldwide license to certain PLC patents. In return, CardioGenesis agreed to pay PLC a license fee and minimum royalties totaling $2.5 million over an approximately forty-month period. The present value of these payments of $2.3 million was recorded as a prepaid license fee in other assets, and is being amortized over the life of the underlying patents. The Company has recorded accumulated amortization of $584,000 and $389,000 for the years ended December 31, 2001 and 2000, respectively (See Note 10).

At December 31, 2001 and 2000, CardioGenesis had a 30.3% and 32.1% ownership interest in Microheart, Inc., formerly known as Microheart Holdings, Inc., (Microheart), respectively, which is accounted for under the equity method. The investment in Microheart was originally recorded at cost and subsequently adjusted for the Company s share of Microheart s loss. For the year ended December 31, 2001 and 2000, CardioGenesis recorded net losses of $652,000 and $58,000, respectively, which represents CardioGenesis equity in the loss incurred by Microheart subsequent to obtaining the equity interest. As of December 31, 2001 the investment in Microheart has been fully written down. CardioGenesis recorded no income or loss related to Microheart under the equity method in 1999 (See Note 18 Subsequent Events).

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. Accrued Liabilities:

Accrued liabilities consists of the following:

	December 31,	
	2001	**2000**
	(in thousands)	
Accrued research support	$2,192	$2,356
Accrued accounts payable and related expenses	989	1,256
Accrued merger expenses		270
Accrued restructuring expenses	52	
Accrued withholdings on exercised options	196	74
Accrued salaries and related expenses	248	472
Accrued commissions	213	235
Accrued consulting fees and related expenses	50	43
Accrued warranty	16	158
Accrued legal expense	308	30
Accrued other	203	895
	$4,467	$5,789

9. Notes Payable:

In May 2001, CardioGenesis financed insurance premiums for Directors & Officers insurance with a $339,000 note payable to a finance company at 6.1% per annum, with an outstanding balance of $70,000 at December 31, 2001. In May 2000, CardioGenesis financed insurance premiums for Directors & Officers insurance with a $319,000 note payable to a finance company at 8.0% per annum, with an outstanding balance of $86,000 at December 31, 2000.

In August 2001, CardioGenesis established a receivables financing arrangement with a finance company. As of December 31, 2001, the Company has borrowing capacity of approximately $1.2 million based on qualifying accounts receivable and has outstanding borrowings of $100,000. The term of this arrangement is one year from the date of inception, July 25, 2001, and is renewable annually at the mutual consent of both parties. The agreement provides the Company with the option of borrowing at an annual rate of 12% plus an administrative fee of 0.50% on all outstanding borrowings.

10. Other Current Liability:

Pursuant to the PLC agreement, which grants CardioGenesis a non-exclusive worldwide license to certain PLC patents, CardioGenesis agreed to pay PLC a license fee and minimum royalties totaling $2.5 million over an approximately forty-month period. As of December 31, 2001, the liability for outstanding payments due to PLC is $495,000, net of interest of $5,000, and has been reflected in other current liability on the accompanying balance sheet (See Note 7).

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Commitments and Contingencies:

CardioGenesis has entered into an operating lease for an office facility with terms extending through October 2006. The minimum future rental payments are as follows:

Year Ending December 31,	(in thousands)
2002	$ 498
2003	498
2004	498
2005	498
2006	436
	$2,428

Rent expense was approximately $1,154,000, $950,000 and $1,089,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

At December 31, 2001, the Company held a capital lease which bears interest at 6.8% and expires in December 2003. Future minimum lease payments under this capital lease are as follows:

Year Ending December 31,	(in thousands)
2002	$ 32
2003	32
Total minimum lease payments	64
Less: Amount representing interest	(2)
Present value of capital lease obligations	62
Less: Current portion	(30)
Long-term portion of capital lease obligations	$ 32

CardioGenesis is engaged in certain legal and administrative proceedings incidental to its normal business activities. While it is not possible to determine the ultimate outcome of these actions at this time, management believes that any liabilities resulting from such proceedings, or claims which are pending or known to be threatened, will not have a material adverse effect on the Company s financial position, cash flows or results of operations.

12. Shareholders Equity:

Issuances of Common Stock:

In March 2001 and September 2000, the Company sold 898,202 shares and 526,496 shares, respectively, of common stock to a private company. The March 2001 sale was at a negotiated purchase price of $1.1133 per share and the September 2000 sale was at a negotiated price of $3.7987 per share. The Company did not pay any other compensation in conjunction with these sales of common stock.

In December 2001 and April 2001, the Company sold 2,222,225 shares and 2,000,000 shares, respectively, of common stock to a governmental entity. The December 2001 sale was at a negotiated purchase price of $0.90 per share and the April 2001 sale was at a negotiated purchase price of $1.00 per share. The Company did not pay any other compensation in conjunction with these sales of common stock. Certain bylaws were amended as a condition of these sales.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Warrants:

During the year ended December 31, 2001, the Company issued warrants to purchase 75,000 shares of common stock at a price of $1.63 per share in connection with a facilities lease agreement executed in 2001. The warrants were fair valued at $94,000 using the Black-Scholes pricing model and are being amortized over the five-year lease term. For the year ended December 31, 2001, the Company recorded a charge of $9,000 in connection with these warrants. The warrants expire in May 2006 and were outstanding at December 31, 2001. At December 31, 2000, no warrants were outstanding. During the years ended December 31, 2001 and 2000, no warrants were exercised. During the year ended December 31, 1999, 448,799 warrants were exercised, generating proceeds of approximately $833,000.

Options Granted to Consultants:

At December 31, 2001, 2000 and 1999, options for consultants to purchase a total of 86,000, 371,000 and 678,000 shares of common stock, respectively, at exercise prices ranging from $1.38 to $8.75 per share were outstanding. The termination of this plan and terms under which stock options are exercised are the same as CardioGenesis Stock Option Plan which is described below. At December 31, 2001, CardioGenesis had reserved 86,000 shares of common stock for issuance upon exercise of these options. CardioGenesis recorded deferred stock compensation of $61,000, $231,000 and $811,000 for the years ended December 31, 2001, 2000 and 1999, respectively, related to these options. These options are included in the Stock Option Plan disclosures below.

Stock Option Plan:

CardioGenesis maintains a Stock Option Plan, which includes the Employee Program under which incentive and nonstatutory options may be granted to employees and the Consultants Program, under which nonstatutory options may be granted to consultants of the Company. As of December 31, 2001, CardioGenesis had reserved a total of 5,600,000 shares of common stock for issuance under this plan. Under the plan, options may be granted at not less than fair market value (110% of fair market value for options granted to 10% shareholders), as determined by the Board of Directors. Options generally vest over a period of three years and expire ten years from date of grant (five years for options granted to 10% shareholders). No shares of common stock issued under the plan are subject to repurchase.

Directors Stock Option Plan:

CardioGenesis maintains a Directors Stock Option Plan which provides for the grant of nonstatutory options to directors who are not officers or employees of the Company. As of December 31, 2001, CardioGenesis had reserved 325,000 shares of common stock for issuance under this plan. Under this plan, options are granted at the trading price of the common stock at the date of grant. Options generally vest over twelve to thirty-six months and expire ten years from date of grant. No shares of common stock issued under the plan are subject to repurchase.

Employee Stock Purchase Plan:

CardioGenesis maintains an Employee Stock Purchase Plan (ESPP), under which 878,400 shares of common stock have been reserved for issuance. CardioGenesis adopted the ESPP in April 1996. The purpose of the ESPP is to provide eligible employees of CardioGenesis with a means of acquiring common stock of CardioGenesis through payroll deductions. Eligible employees are permitted to purchase common stock at 85% of the fair market value through payroll deductions of up to 15% of an employee s compensations, subject to certain limitations. During fiscal years 2001, 2000 and 1999, approximately 105,000, 172,000, and 74,000 shares, respectively, were sold through the ESPP.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation:

The Company has adopted the disclosure only provisions of SFAS 123. CardioGenesis, however, continues to apply APB 25 and related interpretations in accounting for its plans. Had compensation cost for the Stock Option Plan, the Director s Stock Option Plan and the ESPP been determined based on the fair value of the options at the grant date for awards in 2001, 2000 and 1999 consistent with the provisions of SFAS 123, CardioGenesis net loss and net loss per share would have increased to the pro forma amounts indicated below:

	Year Ended December 31,		
	2001	2000	1999
	(in thousands, except per share amounts)		
Net loss as reported	$(10,247)	$(14,609)	$(28,333)
Pro forma net loss	$(11,609)	$(17,993)	$(32,362)
Basic and diluted net loss per share as reported	$ (0.31)	$ (0.48)	$ (0.99)
Pro forma basic and diluted net loss per share	$ (0.35)	$ (0.60)	$ (1.13)

The above pro-forma disclosures are not necessarily representative of the effects on reported net income for future years. The aggregate fair value and weighted average fair value per share of options granted in the years ended December 31, 2001, 2000 and 1999 were $1.4 million, $2.5 million, and $7.9 million, and $1.53, $1.44, and $5.25, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for grants in 2001, 2000 and 1999:

	December 31,		
	2001	2000	1999
Expected life of option	7 years	7 years	7 years
Risk-free interest rate	5.26%	5.85%	5.00%
Expected dividends			
Expected volatility	193%	165%	100%

The aggregate fair value and weighted average fair value per share of purchase rights under the ESPP in fiscal years 2001, 2000 and 1999 was $61,000, $167,000 and $157,000, and $0.64, $3.01, and $3.42, respectively. The fair value for the purchase rights under the ESPP is estimated using the Black-Scholes option pricing model, with the following assumptions for the rights granted in 2001, 2000 and 1999:

	December 31,		
	2001	2000	1999
Expected life	.5 years	.5 years	.5 years
Risk-free interest rate	5.26%	5.85%	5.00%
Expected dividends			
Expected volatility	193%	165%	100%

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Option activity under the Stock Option Plan and the Directors Stock Option Plan is as follows:

		Outstanding Options	
	Shares Available For Grant	Number of Shares	Weighted Average Price per Share
	(in thousands, except per share amounts)		
Balance, December 31, 1998	437	4,539	$4.36
Additional shares reserved	1,225		
Options granted	(1,494)	1,494	$7.57
Options canceled	133	(222)	$8.11
Options exercised		(1,448)	$5.11
Balance, December 31, 1999	301	4,363	$5.35
Options granted	(1,081)	1,081	$2.34
Options canceled	780	(1,561)	$7.36
Options exercised		(640)	$1.66
Balance, December 31, 2000		3,243	$4.99
Additional shares reserved	500		
Options granted	(2,075)	2,075	$1.61
Options canceled	2,085	(2,085)	$5.27
Options exercised		(446)	$1.58
Balance, December 31, 2001	510	2,787	$2.42

The following table summarizes information about the Company s stock options outstanding and exercisable under the Stock Option Plan and the Director s Stock Option Plan at December 31, 2001:

	Options Outstanding			Options Exercisable	
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
	(in thousands)			(in thousands)	
$0.56-$1.02	480	9.47	$ 0.92	75	$ 0.81
$1.10-$1.19	530	9.67	$ 1.18	86	$ 1.19
$1.22-$1.67	312	8.39	$ 1.40	80	$ 1.44
$1.69-$1.75	749	8.81	$ 1.69	283	$ 1.69
$2.57-$4.00	364	9.34	$ 2.91	63	$ 3.26
$5.00-$8.75	264	7.36	$ 7.13	211	$ 7.25
$9.13-$12.69	88	6.62	$11.69	74	$11.33
	2,787	8.90	$ 2.42	872	$ 3.81

The Company s stock options exercisable under the Stock Option Plan and the Director s Stock Option Plan at December 31, 2000 and 1999 were 2,477,000 and 2,509,000 shares, respectively.

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Employee Retirement Plan:

CardioGenesis maintains a 401(k) plan for its employees. The plan allows eligible employees to defer up to 15% of their earnings, not to exceed the statutory amount per year on a pretax basis through contributions to the plan. The plan provides for employer contributions at the discretion of the Board of Directors. For the year ended December 31, 2001, $110,000 of employer contributions were made to the plan. For the years ended December 31, 2000 and 1999, no such contributions were made.

14. Segment Disclosures

The Company operates in the cardiovascular medical device segment. The principal markets for the Company s products are in the United States of America. International sales occur in Europe, the Middle East and Asia and amounted to $1.0 million, $2.2 million and $3.5 million for the years ended December 31, 2001, 2000 and 1999, respectively. The international sales represent 7%, 10% and 14% of total sales for the years ended December 31, 2001, 2000 and 1999, respectively. The majority of international sales are denominated in US dollars.

15. Income Taxes:

Significant components of CardioGenesis deferred tax assets are as follows:

	December 31	
	2001	2000
	(in thousands)	
Net operating losses	$ 56,931	$ 50,734
Research and development and other credits	3,823	3,697
Capitalized research and development		806
Reserves	1,950	2,038
Accrued liabilities	680	1,118
Depreciation	243	259
Other	304	763
Net deferred tax asset	63,931	59,415
Less valuation allowance	(63,931)	(59,415)
Net deferred tax assets	$	$

The Company has established a valuation allowance to the extent of its deferred tax asset since it is not certain that a benefit can be realized in the future due to the Company s recurring operating losses.

As of December 31, 2001, the Company had federal and state net operating loss carryforwards of approximately $149 million and $68 million, respectively, to offset future taxable income. In addition, the Company had federal and state credit carryforwards of approximately $2,548,000 and $1,275,000 available to offset future tax liabilities. The Company s net operating loss carryforwards, as well as credit carryforwards, will expire at various dates beginning in 2002 through 2020, if not utilized.

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

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CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. Related Party Transactions:

The Company paid $3,875 for consulting fees to certain stockholders during the year ended December 1999. The Company did not enter into any other related party transactions in 2001, 2000 and 1999.

17. Risks and Concentrations:

CardioGenesis sells its products primarily to hospitals and other healthcare providers in North America, Europe and Asia. CardioGenesis performs ongoing credit evaluations of its customers and generally does not require collateral. Although CardioGenesis maintains allowances for potential credit losses that it believes to be adequate, a payment default on a significant sale could materially and adversely affect its operating results and financial condition. At December 31, 2001, one customer individually accounted for more than 10% of gross accounts receivable. No other customers individually accounted for 10% or more of accounts receivable at December 31, 2001 and 2000. For the years ended December 31, 2001, 2000 and 1999, no customer individually accounted for 10% or more of net revenues.

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.

18. Subsequent Events:

In April 2002, the Company sold its ownership interest in Microheart, Inc. for $2,285,150 and will recognize a gain of an equal amount in the second quarter of 2002. The Company did not pay any other compensation in conjunction with the sale of this investment.

In April 2002, the Company sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. The Company did not pay any other compensation in conjunction with the sale of our common stock. These securities carry registration rights. If a registration statement is not declared effective by the SEC on or before July 10, 2002, the Company will be required to pay liquidated damages in the amount of 0.25% of the total purchase price of the shares for each week after July 10, 2002 that the registration statement is not declared effective.

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CARDIOGENESIS CORPORATION

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

	Balance at Beginning of Period	Additions(1)	Deductions(2)	Balance at End of Period
Allowance for doubtful accounts:				
Year ended December 31, 1999				
Allowance for doubtful accounts	$ 2,669	$1,377	$2,170	$ 1,876
Year ended December 31, 2000				
Allowance for doubtful accounts	$ 1,876	$ 620	$1,700	$ 796
Year ended December 31, 2001				
Allowance for doubtful accounts	$ 796	$ 904	$ 346	$ 1,354
Inventory reserve:				
Year ended December 31, 1999				
Inventory reserve	$ 403	$1,782	$ 187	$ 1,998
Year ended December 31, 2000				
Inventory reserve	$ 1,998	$1,788	$1,606	$ 2,180
Year ended December 31, 2001				
Inventory reserve	$ 2,180	$1,144	$2,078	$ 1,246
Warranty reserve:				
Year ended December 31, 1999				
Warranty reserve	$ 178	$ 114	$ 67	$ 225
Year ended December 31, 2000				
Warranty reserve	$ 225	$ 95	$ 162	$ 158
Year ended December 31, 2001				
Warranty reserve	$ 158	$ 28	$ 170	$ 16
Valuation allowance:				
Year ended December 31, 1999				
Valuation allowance	$46,733	$9,564	$	$56,297
Year ended December 31, 2000				
Valuation allowance	$56,297	$3,118	$	$59,415
Year ended December 31, 2001				
Valuation allowance	$59,415	$4,516	$	$63,931

(1) Charged to costs and expenses.

(2) Amounts written off against the reserve.

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE YEAR ENDED DECEMBER 31, 2001 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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Exhibit Number	Description
2.1(1)	Agreement and Plan of Reorganization among the Company, the former CardioGenesis Corporation and RW Acquisition Corporation dated October 21, 1998.
3.1(2)	Certificate of Amendment and Restated Articles of Incorporation of Registrant.
3.2	Certificate of Amendment to Articles of Incorporation of Registrant (incorporated by reference to the Registrant s Form 10-Q filed August 14, 2001).
3.3	Amended and Restated Bylaws of Registrant.
4.1	Form of Rights Agreement, dated as of August 17, 2001, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent, which includes as Exhibit A the Form of Right Certificate, Form of Assignment and Form of Election to Purchase (incorporated by reference to the Registrant s Form 8-K filed August 20, 2001).
4.2	First Amendment to Rights Agreement, dated as of January 17, 2002, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent (incorporated by reference to the Registrant s Form 8-K filed January 18, 2001).
4.3	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Centre Dr., Suite 320, Foothill Ranch California (incorporated by reference to the Registrant s Form 10-Q/A, Exhibit 10.1, filed August 16, 2001).
4.4	Share Purchase Agreement dated April 11, 2001 between the Company and the State of Wisconsin Investment Board (incorporated by reference to Exhibit 4.1 of the Registrant s Form 8-K filed April 23, 2001).
4.5	Share Purchase Agreement dated December 21, 2001 between the Company and the State of Wisconsin Investment Board (incorporated by reference to Exhibit 4.1 of the Registrant s Form 8-K filed January 18, 2002).
10.1(2)	Form of Director and Officer Indemnification Agreement.
10.2	Stock Option Plan, as amended and restated.
10.3	Director Stock Option Plan, as amended and restated.
10.4(2)	1996 Employee Stock Purchase Plan of CardioGenesis Corporation.
10.5(2)	Facilities Lease for 1049 Kiel Court, Sunnyvale, California.
10.6(2)	Facilities Lease for 1139 Karlstad Drive, Sunnyvale, California.
10.7	Facilities Lease for 26632 Towne Centre Dr., Suite 320, Foothill Ranch, California (incorporated herein by reference to the Registrant s Form 10-Q/A, Exhibit 10.1, filed August 16, 2001).
10.8(2)	401(k) Plan.
10.9(3)	1993 Equity Incentive Plan of the former CardioGenesis Corporation
10.10(4)	1996 Equity Incentive Plan of the former CardioGenesis Corporation
10.11	Employment agreement dated September 27, 2001 between the Company and Michael J. Quinn, Chief Executive Officer.
10.12	Employment Letter Agreement dated December 19, 2000 between the company and Darrell F. Eckstein, Vice President of Operations (incorporated by reference to the Registrant s Form 10-K, filed April 17, 2001).
21.1	List of Subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP
24.1	Power of Attorney (see signature page)

(1) Incorporated herein by reference to Appendix 1 to the Company s Registration Statement on S-4 filed with the Securities and Exchange Commission on February 9, 1999 (File No. 333-72063).

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

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(3) Incorporated herein by reference from the former CardioGenesis Corporation s Form SB-2, (File No. 333-3752-LA), declared effective on May 21, 1996.

(4) Incorporated herein by reference from the former CardioGenesis Corporation s Form S-8, (File No. 333-35095, dated September 8, 1997).