ECLIPSE SURGICAL TECHNOLOGIES INC
Form 10-K/A
June 13, 2001
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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO.2
TO
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, 2000
Commission file number: 0-28288

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)

1049 Kiel Court
Sunnyvale, California 94089
(Address of principal executive officers)

(408) 548-2100
(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 [X] No [ ]

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.

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $23,923,872 as of March 30, 2001, 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.

31,696,061 shares
As of March 30, 2001

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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

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 (PTMR). TMR and PTMR 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. PTMR 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 PTMR plus medications, when compared with patients who received medications alone.

We received CE Mark approval for our TMR system in May 1997 and our PTMR 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 PTMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments. We are currently in final negotiations with the FDA in the PTMR market approval process. There can be no assurance, however, that we will receive a favorable decision from that agency.

On March 17, 1999, we merged with CardioGenesis Corporation. Under the terms of the combination, each share of CardioGenesis common stock was converted into 0.8 of a share of our common stock, and 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 1998 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, 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.

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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 PTMR, which bears the CE Marking and is currently under review at the FDA for approval in the U.S., offer potential relief to a large population of patients with severe cardiovascular disease.

The TMR and PTMR Procedure

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 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.

PTMR, or percutaneous transluminal myocardial revascularization, is an interventional procedure performed by a cardiologist. PTMR 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 PTMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments.

Business Strategy

Our objective is to become a recognized leader in the field of myocardial revascularization, with TMR and PTMR 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 initial efforts in the U.S. on the top 600 hospitals that perform the greatest number of cardiovascular procedures. To support the TMR launch, we are expanding the domestic sales force to thirty-one territory managers in four sales areas. 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 PTMR products and procedures.

Demonstrate Clinical Utility of PTMR. We are seeking to demonstrate the clinical safety and effectiveness of PTMR. We have completed a pivotal clinical trial regarding PTMR, and the study results were submitted to the FDA in a Pre Market Approval Supplemental application in December of 1999. We are currently in final negotiations with the FDA in the PMA process. 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 PTMR procedures. We are seeking to develop additional proprietary technologies for TMR, PTMR and related procedures. We have 91 foreign and U.S. patents or allowed patent applications and 51 U.S. and 27 foreign patent applications pending relating to various aspects of TMR, PTMR and other cardiovascular therapies.

Products and Technology

Eclipse TMR System

The Eclipse 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 PTMR catheter. The compact base unit occupies a 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.

Eclipse Holmium Laser. Our TMR 2000 laser base unit generates laser light of a 2-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 and SlimFlex PTMR fiber-optic delivery systems each have an easy to install connector which screws into the laser base unit, and each device is pre-calibrated in the factory so it requires no special preparation.

Eclipse PTMR System

The Eclipse PTMR System is currently sold only outside the United States. The PTMR System consists of the PTMR Laser and ECG Monitor.

Eclipse PTMR 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.

SlimFlex Catheter System. The SlimFlex PTMR system is an over-the-wire, steerable, single use catheter system that features torque control, deflection capability, infusion port and radio-opaque markers for enhanced visualization and depth control. After insertion into an artery of the leg, the PTMR catheter is advanced over the aortic arch, across the aortic valve and into the heart chamber. Visualization is achieved using standard fluoroscopic or x-ray techniques common to all hospitals doing cardiac catheterization.

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.

We submitted a PMA supplement for our PTMR system to the FDA in December 1999. The PTMR study compares PTMR to conventional medical therapy in patients with no option for other treatment. We are currently in final negotiations with the FDA in the PMA process. 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 PTMR products throughout the European Community.

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. To drive the clinical awareness and acceptance of the surgical product platform, we are expanding the domestic sales force to thirty-one territory managers in four sales regions.

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 selling lasers to hospitals outright, loaning lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price, and to begin renting lasers to hospitals.

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

We have developed, in conjunction with several major hospitals using our TMR or PTMR 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 PTMR in vivo. To date over 750 cardiothoracic surgeons have been trained on the Eclipse 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 PTMR applications.

In the fourth quarter of 2000, we increased our ownership interest in privately-held Microheart Holdings, Inc. to 32.1 percent. Microheart is a research and development company working on developing a number of full-featured clinical devices for diagnostic assessment and site-specific delivery of biopharmaceuticals and other therapeutic agents applicable to the cardiovascular and other markets.

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

Manufacturing

We manufacture and assemble our products from purchased components and subassemblies at our facility in Sunnyvale, California.

The core components of our laser units and fiber-optic handpieces are generally acquired from multiple sources. We currently purchase certain laser and fiber-optic components and subassemblies 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 our 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 and also to maintain an inventory of these items for use in the event of supply interruptions.

Competition

We expect that the market for TMR and PTMR, which is currently in the early stages of development, will be intensely competitive. Competitors include PLC Systems, Inc. (PLC), Johnson & Johnson, and Boston Scientific which are either selling FDA-approved TMR products in the U.S. and abroad, or PTMR products for investigational use in the U.S. and commercially 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 a co-marketing agreement with Edwards Life Sciences to distribute their lasers and disposables. This action will add another 18 direct domestic sales representatives involved in promoting the PLC technology.

Johnson & Johnson is a publicly traded company which uses a holmium laser and fiber-optics in its DMR (direct myocardial revascularization) products. Johnson & Johnson has acquired a ventricular mapping company to further its DMR product line and has begun U.S. trials under an IDE. Based upon recently presented trial results, the status of the regulatory submission for the Johnson & Johnson DMR system is unclear at this time.

Boston Scientific is a publicly traded company which has acquired radio frequency technology to begin a percutaneous feasibility trial in the U.S. under a preliminary IDE.

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

TMR and PTMR 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 PTMR 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

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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 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.

Products manufactured or distributed by us pursuant to a PMA will be subject to pervasive and continuing regulation by the FDA, including, among other things, postmarket surveillance and adverse event reporting requirements. Failure to comply with applicable regulatory

requirements can result in, among other things, warning letters, fines, suspensions or delays of approvals, seizures or recalls of products, operating restrictions or criminal prosecutions. The Federal Food, Drug and Cosmetic Act requires us to manufacture our products in registered establishments and in accordance with Good Manufacturing Practices (GMP) regulations and to list our devices with the FDA. Furthermore, as a condition to receipt of a PMA, our facilities, procedures and practices will be subject to additional pre-approval GMP inspections and thereafter to ongoing, periodic GMP

inspections by the FDA. These GMP regulations impose certain procedural and documentation requirements upon us with respect to manufacturing and quality assurance activities. Labeling and promotional activities are subject to scrutiny by the FDA. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. Changes in existing regulatory requirements or adoption of new requirements could harm our business. We may be required to incur significant costs to comply with laws and regulations in the future and current or future laws and regulations may harm our business.

We are also regulated by the FDA under the Radiation Control for Health and Safety Act, which requires laser products to comply with performance standards, including design and operation requirements, and manufacturers to certify in product labeling and in reports to the FDA that our products comply with all such standards. The law also requires laser manufacturers to file new product and annual reports, maintain manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product. In addition, we are subject to California regulations governing the manufacture of medical devices, including an annual licensing 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 PTMR 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 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 91 U.S. and foreign patents or allowed patent applications and 78 U.S. and foreign patent applications pending relating to various aspects of TMR, PTMR and other cardiovascular therapies. On December 5, 2000 we were granted United States Patent No. 6,156,031 entitled Transmyocardial Revascularization Using Radiofrequency Energy . 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 or we may not have adequate remedies for any breach. Furthermore, our competitors may independently develop substantially equivalent proprietary information

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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 PTMR. In September 1995 we received from a competitor a notice of potential infringement of the competitor s patent regarding a method for TMR utilizing synchronization of laser pulses to the electrical signals from the heart. We concluded, following discussion with our patent counsel, that we did not utilize the process and/or apparatus which is the subject of the patent at issue. We responded to the competitor to such effect and have received no further correspondence on this matter. There can be no assurance, however, that further claims or proceedings will not be initiated by a competitor, or that claims by other parties will not arise in the future. 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 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 you 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.

Unrelated to the products used in our TMR procedure, we have received notices from three holders of patents requesting we become a licensee. Although we believe that either these patents are subject to challenge as being invalid or are not infringed by our products, we may not prevail in any such action. In one case, we have entered into a non-exclusive license to a patent involving arthroscopy use. In a second case, we buy components only from licensees of the patent holder, which we believe obviates the need for a separate license. If we determine that it is necessary to obtain a license to any patents or intellectual property, any such license may not be available on acceptable terms or at all, or we may not be able to develop or otherwise obtain alternative technology. 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,

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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 HCFA began coverage of FDA approved TMR systems for any manufacturer s TMR procedures.

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 PTMR. The lack of private insurance and health plans reimbursement may harm our business.

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, 2000 we had 123 employees, including 16 in research and development, 49 in manufacturing, 38 in sales and marketing and 20 in administration. Other than confidentiality agreements with all employees, as a general policy matter, we do not enter into employment agreements with any of our employees. In connection with the recent hirings of Michael J. Quinn as our Chief Executive Officer and Darrell Eckstein as our Vice President of Operations, we did, however, provide both officers with letter employment agreements. None of our employees is covered by a collective bargaining agreement and we have not experienced any work stoppages to date.

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Our executive officers as of March 28, 2001 are as follows:

Name	Age	Position
Michael J. Quinn	56	Chief Executive Officer, President, Chairman of the Board and Director
Darrell F. Eckstein	43	Vice President of Operations
Ian A. Johnston	46	Vice President of Finance and Treasurer
Thomas L. Kinder	38	Vice President of Worldwide Sales and Service
Richard P. Lanigan	42	Vice President of Government Affairs and Business Development
Christopher M. Owens	32	Vice President of Marketing
Ilene L. Janofsky	46	Chief Legal Counsel

Michael J. Quinn has served as our Chief Executive Officer, President and Chairman of the Board 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 major healthcare organizations including American Hospital Supply Corporation, Picker International, Cardinal Health Group and Bergen Brunswig.

Darrell F. Eckstein has served as our 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.

Ian A. Johnston has been our Vice President of Finance since July 2000 and Corporate Controller since March 1999. From 1998 to 1999 Mr. Johnston was also Controller of CardioGenesis Corporation. From 1989 to 1998 Mr. Johnston served in a variety of financial positions (most recently as Controller) at Toshiba America MRI, Inc., a medical imaging company. From 1985 to 1989 Mr. Johnston was an auditor with Arthur Andersen & Co. Mr. Johnston has a Masters in Business Administration and a Bachelor of Arts in Economics from the University of California Berkeley and is a member of the American Institute of Certified Public Accountants.

Thomas L. Kinder has served as our Vice President of Sales since March 2001 and as General Manager, West Area since November 2000. From June 2000 to November 2000, Mr. Kinder served as Vice President of Sales for Watchitwork.om. From September 1999 to November 2000, Mr. Kinder served as General Manager for Karl Storz Endoscopy. From March 1996 to September 1999, Mr. Kinder served in the roles of Business Director, Area Vice-President and, most recently, Vice President of Sales for Imagyn Medical Technologies, Inc. From March 1996 to April 1997, Mr. Kinder served as Director of Sales for Microsurg, a company that was later sold to Imagyn Medical Technologies, Inc.

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

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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.

Christopher M. Owens has been our Vice President of Marketing since March 2001. Prior to Eclipse, 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.

Ilene L. Janofsky has served as our Chief Legal Counsel since January 2001. From 1999 to 2000 Ms. Janofsky served as Patent Manager, Intellectual Property Counsel and from June 1998 to March 1999 she served as Patent Counsel. >From 1993 to 1998 Ms. Janofsky worked as an independent patent law consultant. >From 1990 to 1993 Ms. Janofsky was employed as a Patent Attorney with the Liposome Company. She has also worked as a Patent Attorney on an independent basis from 1988 to 1989 and with the New York city law firm of Ladas & Parry from 1987 to 1988. Ms. Janofsky is admitted to practice law in New York (1986), New Jersey (1986) and before the United States Patent and Trademark Office (1983). She passed the California Bar exam in July 2000 and is awaiting admission. Ms. Janofsky received her Bachelor of Science in Clinical Nutrition from the University of Florida, Gainesville in 1976 and her Juris Doctorate from St. John s University Law School in 1985.

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

Our facilities, located in Sunnyvale, California, are comprised of 45,960 square feet under two separate leases. The manufacturing facility contains a Class 10,000 clean room for laser handpiece and catheter fabrication. The leases expire from July 2002 through September 2002. Our headquarters is located in Sunnyvale, California. 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.

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

None.

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PART II

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

(a) Our common stock has been traded on the Nasdaq National Market 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.

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

	High	Low
1999		
First Quarter	$14.25	$7.25
Second Quarter	$12.38	$7.69
Third Quarter	$18.69	$9.75
Fourth Quarter	$15.94	$5.00

As of December 31, 2000 shares of our common stock were held by 190 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.

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

The following selected consolidated statement of operations data for fiscal years ended 2000, 1999 and 1998 and the consolidated balance sheet data for 2000 and 1999 set forth below are derived from the our consolidated financial statements and are qualified by reference to our consolidated financial statements included herein.

The selected consolidated statement of operations data for fiscal year ended 1997 and 1996 and the consolidated balance sheet data for 1998, 1997 and 1996 have been derived from our audited 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 pooling of interest with 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)

	Year Ended December 31,				
	2000	**1999(1)**	**1998**	**1997**	**1996**
Statement of Operations Data:					
Net revenues	$22,210	$25,324	$15,080	$13,058	$13,718
Cost of revenues	10,055	13,246	7,868	7,295	6,424
Gross profit	12,155	12,078	7,212	5,763	7,294
Operating expenses:					
Research and development	5,065	11,353	29,861	26,217	13,323
Sales and marketing	15,349	16,553	17,663	11,542	5,949
General and administrative	6,660	8,028	10,821	9,462	4,820
Merger-related costs					5,214
Total operating expenses	27,074	41,485	58,345	47,221	24,092
Operating loss	(14,919)	(29,070)	(51,133)	(41,458)	(16,798)
Interest and other income (expense), net	3107	373	3,665	2,403	842

Net loss	$(14,609)	$(28,333)	$(47,767)	$(36,218)	$(12,956)
Net loss per share basic and diluted	$(0.48)	$(0.99)	$(1.77)	$(1.39)	$(0.65)
Shares used in per share calculation	30,166	28,629	27,000	26,027	20,019
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$3,357	$13,313	$27,941	$75,729	$110,271
Working capital	4,662	10,031	22,436	8,999	105,185
Total assets	16,965	34,019	52,978	91,714	123,003
Long-term debt, less current portion				40	58
Accumulated deficit	(153,833)	(139,224)	(110,891)	(63,124)	(26,906)
Total shareholders equity	7,974	18,573	37,276	82,374	117,061

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

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and similar expressions. In addition, any 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

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 (PTMR).

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 PTMR 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 PTMR, and study results were submitted to the FDA in a Pre Market Approval (PMA) application in December of 1999 along with subsequent amendments. We are currently in final negotiations with the FDA in the PTMR market approval process. There can be no assurance, however, that we will receive a favorable decision from the agency.

As of December 31, 2000, we had an accumulated deficit of $153,833,000. We expect to continue to incur operating losses related to the expansion of sales and marketing activities. 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, if any, of our products and the status and timing of regulatory approvals.

Results of Operations

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 revenue 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

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sales model. International sales accounted for approximately 10% and 14% of total sales for the years ended December 31, 2000 and 1999, respectively. We define international sales as sales to customers located outside of the United States. (See Risk Factors.)

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 CardioGenesis. 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.

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 has fallen through general attrition. We expect research and development expenses to continue to decline in the upcoming year with a continuing reduction in clinical and product development activities.

Sales and Marketing

Sales and marketing expenditures of $15,349,000 decreased $1,204,000 or 7% for the year ended December 31, 2000 when compared to $16,553,000 for the year ended December 31, 1999. The decrease in absolute sales and marketing dollars is mainly due to commission payments made for laser sales. Not only was laser revenue in 2000 $8,700,000 lower than in 1999, the average commission rate on the year 2000 laser sales was substantially lower due to the transition from an outside distributor to an inside sales force for a region of the US at the end of 1999. We expect that spending on sales and marketing will decrease in the upcoming year, despite continued development of the TMR and PTMR market, as the Company s focus on cost reduction becomes reflected in lower expenditures for outside services and travel costs. At year-end a sales force transition was underway which is expected to continue through the second quarter of 2001. New sales representatives are being hired to fill openings resulting from general attrition and the release of sales representatives who did not meet their sales objectives.

General and Administrative

General and administrative expenses decreased by $1,368,000 or 17% to $6,660,000 in 2000 from $8,028,000 in 1999. The decrease is due mainly to a $1,000,000 reduction of salary and wage expense associated with the elimination of redundant positions that existed between CardioGenesis and Eclipse prior to the March 17, 1999 merger and with the CEO position that was filled for only a portion of 2000. Another significant reduction was an $850,000 reduction in bad debt expenseWe expect general and administrative expenses to decline somewhat from prior year levels as we anticipate reductions in deferred compensation and bad debt expense and we plan to outsource patent work.

Merger Related Costs

There were no merger related costs in 2000 associated with the merger between us and CardioGenesis Corporation, while in 1999 there was $5,214,000 in merger related costs.

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Interest and Other Income (Expense), Net

Interest and other 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. The decrease was due to lower investments in marketable securities and cash 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 net loss of investee is a new non-cash expense in 2000. It represents our share of the net loss of Microheart Holdings, Inc., given our November 15, 2000 exercise of warrants to increase our ownership percentage to 32.1%.

Year Ended December 31, 1999 Compared to Year Ended December 31, 1998

Net Revenues

Net revenues of $25,324,000 for the year ended December 31, 1999 increased $10,244,000 or 68% when compared to net revenues of $15,080,000 for the year ended December 31, 1998. The increase in revenues was due to $7,300,000 in higher sales of laser systems and $2,580,000 in higher sales of disposable products resulting from the receipt of FDA approval on our TMR products and an increase in research revenue associated with the sale of intellectual property of $310,000. Export sales accounted for approximately 14% and 24% of total sales for the years ended December 31, 1999 and 1998, respectively. The percentage decrease relative to total sales is mainly due to higher domestic sales from the receipt of FDA approval on our TMR products, as international sales fell by only $30,000. We define export sales as sales to customers located outside of the United States. (See Risk Factors.)

Gross Profit

Gross profit increased to $12,078,000, $14,601,000 net of the merger related inventory write-offs and a laser upgrade program or 58% of net revenues for the year ended December 31, 1999, as compared to $7,212,000 or 48% of net revenues for the year ended December 31, 1998, an increase of $7,389,000. This increase both in percentage and in absolute terms resulted from greater unit sales volume and a higher average sales price on lasers and disposables; these factors increased gross margin by approximately $3,100,000 and $3,800,000, respectively. Lower unit cost contributed an additional $500,000 towards gross margin, as the fixed manufacturing expense were applied over higher production volumes. Gross profit percentage, including the inventory and upgrade program write-off related to the merger, was 48% of net revenues.

Research and Development

Research and development expenditures of $11,353,000 decreased $18,508,000 or 62% for the year ended December 31, 1999 when compared to $29,861,000 for the year ended December 31, 1998. The decrease in these expenses reflects cost savings resulting from the merger with CardioGenesis by the elimination of redundant TMR and PTMR clinical trials, engineering and clinical support activity of $2 million, $8 million and $2 million, respectively. There was an additional $6 million of clinical expense reductions during 1999 attributed to the completion of major trials in 1998 and early 1999.

Sales and Marketing

Sales and Marketing expenditures of $16,553,000 decreased $1,110,000 or 6% for the year ended December 31, 1999 when compared to $17,663,000 for the year ended December 31, 1998. The decrease in absolute dollars is mainly due to cost efficiencies realized from the merger. Prior to the merger, both Eclipse and

CardioGenesis were operating separate sales units in Europe. Cost savings from the elimination of this redundancy was approximately $1.5 million. This savings is partially offset by $250,000 in increased general marketing expenses supporting the commercial TMR products and $200,000 in increased commissions.

General and Administrative

General and administrative expenses decreased by $2,793,000 or 26% to $8,028,000 in 1999 from $10,821,000 in 1998. The decrease is due to a $3.5 million reduction in litigation expenses offset by a $700,000 increase in deferred compensation to consultants.

Merger Related Costs

CardioGenesis was a medical device company like us, which developed, manufactured, and marketed cardiac revascularization products for the treatment of advanced cardiovascular disease and severe angina pain through TMR and PTMR. CardioGenesis also manufactured and

marketed disposable products to perform intraoperative transmyocardial revascularization, catheter-based percutaneous myocardial revascularization, and thorascopic transmyocardial revascularization to treat patients afflicted with debilitating angina. During the quarter ended March 31, 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 terminated employees were located in California and worked in operations, sales, marketing, quality, research and development and administrative functions. A total of 40 employees were terminated.

During the remaining three quarters in the year ended December 31, 1999, we recognized additional merger-related costs of $844,000, which was mainly due to an upgrade program to replace customer owned equipment rendered unusable by the merger. This increase brought the total of merger related costs for the twelve months ended December 31, 1999 to $7,737,000; this includes inventory write-offs and the laser upgrade program totaling $2,523,000 that are accounted for in our cost of revenues. We do not expect any further charges for merger related expense and anticipate the last merger-related payment to occur in the second part of 2001. The following table summarizes the merger-related costs (in thousands).

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

Interest and Other Income (Expense), Net

Interest and other income of $801,000 decreased $2,653,000 or 77% for the year ended December 31, 1999 when compared to $3,454,000 for the year ended December 31, 1998. The decrease was due to lower investments in marketable securities and cash and cash equivalents.

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Interest expense of $64,000 decreased $24,000 or 27% for the year ended December 31, 1999 when compared to $88,000 for the year ended December 31, 1998. This decrease reflects a lower level of debt outstanding.

Liquidity and Capital Resources

Cash, cash equivalents and short and long-term marketable securities were $3,357,000 at December 31, 2000 compared to $13,313,000 at December 31, 1999, a decrease of 75%. We used $12,281,000 of cash for operating activities, including funding our operating loss and decreases in accrued liabilities in 2000.

Accounts receivable of $3,654,000 at December 31, 2000 decreased 56% to $8,119,000 at December 31, 1999, even though annual sales only decreased by 12% when comparing the same periods. The decrease in accounts receivable is attributed to a decrease in sales in the three month period ending December 31, 2000 as compared to the same period ending in 1999. Non-current accounts receivable of $119,000 at December 31, 2000 decreased 89% to $1,125,000 at December 31, 1999. Non-current accounts receivable is comprised of leases that were recognized in prior years.

Inventories decreased by $1,583,000 or 23% to $5,400,000 at December 31, 2000 from a level of $6,983,000 at December 31, 1999. This decrease is mainly due to a reduction of $900,000 in gross inventory from lower purchases of raw materials relative to inventory outflows via cost of revenues, along with the addition of $670,000 of inventory reserves.

Inventory reserves increased by $182,000 to $2,180,000 at December 31, 2000 compared to $1,998,000 at December 31, 1999. During the year, approximately $673,000 of new reserves were accrued, with $360,000 of this amount attributed to lasers in Europe for which there was no intent to sell and $180,000 of the reserve being attributed to raw materials held in excess of current requirements. Reserve balances were reduced during the year by write-offs of approximately $491,000 for obsolete and out-of-date material.

As of December 31, 2000, there were reserves of $2,180,000 against gross inventory of $7,580,000 for a reserve percentage of 29%. Approximately $980,000 of these reserves relates to lasers in Europe for which there was no intent to sell, while $600,000 is reserved for raw materials in excess of current requirements and $440,000 is reserved for service/obsolete inventory. The Company is closely monitoring its inventory levels with a view to balancing outlays for raw materials with sales requirements.

Investing activities, consisting primarily of purchases and sale of marketable securities and additions to property and equipment, provided cash of $6,700,000, $16,100,000 and $28,400,000 in fiscal years 2000, 1999, and 1998 respectively. In the fourth quarter of 2000, we increased our ownership interest in privately-held MicroHeart Holdings, Inc. to 32.1% for cash compensation of $310,000. The investment in MicroHeart is accounted for under the equity method. As of December 31, 2000, we recorded a net loss of $58,000, which represents Eclipse s equity in the loss incurred by MicroHeart. Financing activities provided cash of $3,400,000, $8,400,000 and $1,300,000 in fiscal years 2000, 1999 and 1998 respectively primarily from the issuance of common stock pursuant to exercise of stock options and warrants and the issuance of common stock.

Since our inception, we have satisfied our capital requirements primarily through sales of our equity securities. In addition, our operation has been funded in part through sales of our products.

In September 2000, we sold 526,496 shares of our common stock to Acqua Wellington at a negotiated purchase price of $3.7987 per share. We did not pay any other compensation in conjunction with the sale of our common stock.

In March 2001, we sold 898,202 shares of common stock to Acqua Wellington at a negotiated purchase price of $1.1133 per share. We did not pay any other compensation in conjunction with the sale of our common stock. In April 2001, the Board adopted an amendment to our Bylaws which precludes the Company from

entering into or exercising any rights under any equity line agreement, including the Acqua Wellington equity line agreement, unless approval from the shareholders holding a majority of the shares is obtained.

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. We did not pay any other compensation in conjunction with the sale of our common stock.

We have incurred significant losses for the last several years and at December 31, 2000 have an accumulated deficit of $153,833,000. The accompanying 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 under clinical trials. We have recognized the need for infusion of cash. In September 2000, March 2001 and April 2001, we raised approximately $1,873,000, $1,000,000 and $1,925,000, respectively, net of estimated offering costs, from the sale of shares of common stock. In April 2001, we received a non-binding letter of intent

from a business credit financing company regarding an asset-based financing agreement current level of which will provide an estimated $1,000,000 of additional financing based upon current level of our qualified domestic accounts receivable which will serve as collateral. 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 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							
	2000				1999			
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Net revenues	$5,677	$6,608	$5,014	$4,911	$4,474	$7,190	$6,085	$7,575
Gross profit	3,346	3,910	2,542	3,451	177(a)	3,695(b)	2,954(c)	4,252(d)
Operating loss	(4,546)	(3,398)	(3,800)	(3,175)	(15,474)(a)	(4,339)(b)	(4,982)(c)	(4,275)(d)
Net loss	(4,439)	(3,262)	(3,744)	(3,164)	(15,166)(a)	(4,201)(b)	(4,906)(c)	(4,060)(d)
Net loss per share:								
Basic and diluted	(0.15)	(0.11)	(0.13)	(0.10)	(0.55)	(0.15)	(0.17)	(0.14)
Weighted average shares outstanding	29,664	30,064	30,191	30,729	27,576	28,086	28,591	29,425

(a) Gross profit includes cost of revenues of $1,392,000 related to inventory and fixed asset write-offs in connection with the merger. Operating loss includes merger-related costs of $5,501,000. Net loss includes cost of revenues of $1,392,000 related to inventory write-offs in connection with the merger and merger-related costs of $5,501,000.

(b) Gross profit includes cost of revenues of $625,000 related to a laser upgrade program in connection with the merger. Operating loss includes a reversal of a previously recorded reserve of $541,000. Net loss includes cost of revenues of $625,000 related to a laser upgrade program in connection with the

merger and a reversal of a previously recorded reserve of $541,000.(c) Gross profit includes cost of revenues of $179,000 related to a laser upgrade program in connection with the merger. Operating loss includes merger-related costs of $257,000. Net loss includes cost of revenues of $179,000 related to a laser upgrade program in connection with the merger and merger-related costs of $257,000.(d) Gross profit includes cost of revenues of $327,000 related to a laser upgrade program in connection with the merger. Operating loss includes a reversal of a previously recorded reserve of $4,000. Net loss includes cost of revenues of $327,000 related to a laser upgrade program in connection with the merger and a reversal of a

previously recorded reserve of $4,000.

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Recently Issued Accounting Standards

In June 1998, the Financial Accounting Standards Board issued SFAS 133, Accounting for Derivative Instruments and Hedging Activities . SFAS 133 establishes new standards of accounting and reporting for derivative instruments and hedging activities. SFAS 133 requires that all derivatives be recognized at fair value in the statement of financial position, and that the corresponding gains or losses be reported either in the statement of operations or as a component of comprehensive income, depending on the type of hedging relationship that exists. We do not currently hold derivative instruments or engage in hedging activities. We will adopt SFAS 133 in the first quarter of 2001 and we do not believe that the initial adoption will have a material impact on the financial statements.

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB 25. FIN 44 provides updated accounting guidance regarding implementing and interpreting APB 25, and should be applied on a prospective basis from July 1, 2000. The Company s adoption of this pronouncement had no impact on the Company s financial position or results of operations.

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.

We may not be able to secure additional financing in the future. In the future, we may require additional funds for operating expenses. Our capital requirements may vary and will depend on both internal and external factors. Internal factors affecting our capital requirements include our ability to generate increased sales, profits and cash flow from operations. External factors affecting our capital requirements include the progress of our PTMR submission with the FDA, and competing technological and market developments. 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. If this occurs, we may have to significantly reduce our operations until an appropriate solution is implemented.

We may fail to obtain required regulatory approvals to market our products in the United States. Our business, financial condition and results of operations could be harmed by any of the following events, circumstances or occurrences related to the regulatory process:

the failure to obtain regulatory approvals for our PTMR system;

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

substantial costs incurred in obtaining regulatory approvals.

In 1997, we submitted a PMA application to the FDA for certain applications of our TMR laser system. On October 27, 1998, an advisory panel of the FDA recommended that the FDA approve our PMA application for the TMR laser system. Along with our approval, the FDA panel requested that we conduct postmarket surveillance in a form to be determined through further discussions with the FDA. On February 11, 1999, we received final approval from the FDA for use of 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.

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 coronary artery bypass graft, known as 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 FDA for an expanded indication to our approved TMR labeling to include TMR in conjunction with CABG. In January

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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. In December, 1999, we submitted a PMA application to the FDA seeking marketing clearance for PTMR in the United States. To date, the FDA has not granted approval of this application. The FDA may not approve this application in a timely manner, if ever.

The Medical Community has not broadly adopted our products, and unless our products are broadly adopted, our business will suffer. Our TMR products have not yet achieved broad commercial adoption, and our PTMR products are experimental and have not yet achieved broad 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 PTMR systems fail to achieve significant market acceptance.

Positive endorsements by physicians are essential for clinical adoption of our TMR and PTMR laser systems. Even if the clinical efficacy of TMR and PTMR laser systems is established, physicians may elect not to recommend TMR and PTMR laser systems for any number of reasons. The reasons why TMR or PTMR laser systems may effectively treat coronary artery disease are not fully understood. Although we intend to use research, development and clinical efforts to understand better the physiological effects of TMR and PTMR treatment, we may not achieve such understanding on a timely basis, or at all. TMR and PTMR laser systems may not be clinically adopted unless we:

understand thoroughly the physiological effects of the products;

provide scientific evidence of long term benefits for treated patients, and

disseminate such understanding within the medical community.

Clinical adoption of these products will also depend upon:

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

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

raising the awareness of TMR and then PTMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

physician recommendations;

the degree of invasiveness;

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, and we have limited experience to dates establishing these operations. 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 PTMR lasers and disposable catheters for investigational use only.

In the fourth quarter of 1999, we changed our U.S. sales strategy to include both selling lasers to hospitals outright, as well as loaning lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. During the current year, the

majority of lasers shipped have been under this loan program. The purpose of this strategy is to focus our sales force on increasing market penetration and selling disposable handpieces used in connection with our TMR procedure. If the sales force is not successful in increasing market share and selling our disposable handpieces our business will suffer.

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With FDA approval of our TMR laser system, we are marketing our products primarily through our direct sales force. We have been expanding our operations by hiring additional sales and marketing personnel. This has required and will continue to require substantial management efforts and financial resources. If we are not able to establish effective sales and marketing capabilities our business will suffer.

The expansion of our business may put added pressure on our management and operational infrastructure and could create numerous risks and challenges. The growth in our business may place a significant strain on our limited personnel, management and other resources. The evolving growth of our business involves numerous risks and challenges, including:

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

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.

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;

continue to attract, train and motivate additional qualified personnel in all areas; and

achieve manufacturing efficiencies as production volume increases.

We may not be able to manage these activities and implement these strategies successfully, and any failure to do so could harm our operating results.

Our operating results will 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 FDA and other regulatory approval processes;

personnel changes;

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. Our operating results have, in the past, fallen below expectations and 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, the price of our common stock may fall again, perhaps substantially.

We will be able to obtain FDA approval only for those products that are proven safe and effective in clinical sites. The FDA has not approved our PTMR laser systems for any indication in the United States. We submitted a PMA Supplement for our Axcis PTMR system to the FDA in December 1999. The PTMR study

compares PTMR to conventional medical therapy in patients with no option for other treatment. The FDA may not accept the study as safe and effective, and PTMR may not be approved for commercial use in the United States. Responding to FDA requests for additional information could require substantial financial and management resources and take several years.

In October 2000, preliminary results from a competitor s clinical trial of a catheter-based device employing Direct Myocardial Revascularization (DMR) were presented at a medical conference in Washington D.C. The trial s principal investigator concluded that the DMR device did not show significant evidence of clinical benefit with regard to angina class reduction or exercise tolerance, and questioned the efficacy of other devices and procedures relying on TMR. We believe that the preliminary results of the DMR device study should not call the results of our PTMR study into question because the devices and procedures are substantially different. We cannot assure you, however, that the preliminary results of the DMR device study will not impact our submission for the Axcis PTMR system to the FDA.

We may not be able to successfully market our products if we fail to obtain third party reimbursement for the procedures performed with our products. 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. A failure by third party payors to provide adequate reimbursement for the TMR and PTMR procedures that use our products would harm our business.

Effective July 1, 1999 the Health Care Financing Administration commenced Medicare coverage for TMR systems for any manufacturer s TMR procedures. Hospitals are now eligible to receive Medicare reimbursement for TMR procedures. The Health Care Financing Administration may not approve reimbursement for PTMR. If it does not provide reimbursement, our business will suffer. 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 PTMR procedures. If they do not provide reimbursement, our business will suffer.

Third party payors may deny reimbursement if they determine that the device used in a treatment is:

unnecessary;

inappropriate;

experimental;

used for a non-approved indication; or

not cost-effective.

Potential purchasers must determine whether the clinical benefits of our TMR and PTMR laser systems justify:

the additional cost or the additional effort required to obtain prior authorization or coverage; and

the uncertainty of actually obtaining such authorization or coverage.

We face intense competition and competitive products could render our products obsolete. The market for TMR and PTMR laser systems is intensely competitive and is constantly becoming more competitive. If our competitors are more effective in developing new products and procedures and marketing existing and future products, our business will suffer.

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

are more effective than our products;

are more effectively marketed than our products; or

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may render our products or technology obsolete.

We currently compete with PLC Systems, Inc., Johnson & Johnson and Boston Scientific. PLC is currently selling TMR commercially in the United States and abroad, while Johnson & Johnson is currently selling PTMR products for investigational use. Boston Scientific has acquired radio frequency technology to begin a percutaneous feasibility trial in the United States under a preliminary IDE. PLC recently announced a co-marketing agreement with Edwards Life Sciences to distribute their lasers and disposables. This action will add another 18 direct domestic sales representatives involved in promoting the PLC technology.

Even with the FDA approval for our TMR 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 also compete with alternative treatment methods and our products must replace these methods to be commercially successful. Many of the medical indications that may be treatable with TMR and PTMR laser systems are currently being treated by drug therapies or surgery and other interventional therapies, including PTCA and CABG.

Our business would be materially harmed if TMR technology fails to replace or augment existing therapies or to be more effective, safer or more cost effective than new therapies. A number of the existing therapies are widely accepted in the medical community, have a long history of use and continue to be enhanced rapidly.

Procedures using TMR and PTMR technology may not be able to replace or augment such established treatments.

Others are developing new surgical procedures and new drug therapies to treat coronary artery disease. These new procedures and drug therapies could be more effective, safer or more cost effective than TMR and PTMR laser systems.

The market acceptance and commercial success of our TMR and PTMR laser systems will depend not only upon their safety and effectiveness, but also upon the relative safety and effectiveness of alternative treatments.

Our products depend on TMR technology that is rapidly changing which could require us to incur substantial product development expenditure. TMR and PTMR laser systems are our only products. Accordingly, if we fail to develop and commercialize successfully our TMR and PTMR laser systems, then our business would suffer.

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. In addition, we must expand the indications and applications for our products by developing and introducing enhanced and new versions of our TMR and PTMR 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.

Even if we identify and develop such products, we may not receive regulatory approval and may not be commercially successful.

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 can not 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.

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 FDA and other regulatory approvals for our PTMR laser systems; and

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

We may not achieve or sustain profitability in the future.

If we experience increased demand for our products, we may not be able to expand our business to meet such demand. We may be required to expand our business to:

respond to increasing clinical adoption of the TMR procedure;

develop future products;

generally compete successfully;

complete the clinical trials that are currently in progress; and

prepare additional products for clinical trials.

Such expansion could place a significant strain on managerial, operational and financial systems and resources. To accommodate such expansion and compete effectively, we must improve information systems, procedures and controls and expand, train, motivate and manage our employees.

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 PTMR procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other

TMR or PTMR technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

In September 1995, one of our competitors sent us a notice of potential infringement of their patent regarding a method for TMR utilizing synchronization of laser pulses to the electrical signals from the heart. After discussion with patent counsel, we concluded that we did not utilize the process and/or apparatus that was the subject of the patent at issue, and we provided a response to the competitor to that effect. We have not received any additional correspondence from this competitor on these matters.

In 1996, prior to the merger with us, CardioGenesis initiated a suit in the United States against PLC seeking a judgment that the PLC patent is invalid and unenforceable. In 1997, PLC counterclaimed in that suit alleging infringement by CardioGenesis of the PLC patent. Also in 1997, PLC initiated suit in Germany against CardioGenesis and CardioGenesis former German sales agent alleging infringement of a European counterpart to the PLC patent. In 1997, CardioGenesis filed an Opposition in the European Patent Office to a European counterpart to the PLC patent, seeking to have the European patent declared invalid.

On January 5, 1999, before trial on the United States suit commenced, CardioGenesis and PLC settled all litigation between them, both in the United States and in Germany, with respect to the PLC patent and the European patents. Under the Settlement and License Agreement signed by the parties, CardioGenesis stipulated to the validity of the PLC patents and PLC granted CardioGenesis a non-exclusive worldwide license to the PLC patents. CardioGenesis agreed to pay PLC a license fee, and minimum royalties, totaling $2.5 million over an approximately forty-month period, with a running royalty credited against the minimums.

The Settlement and License Agreement applies only to those products or that technology covered by the PLC patents, and the agreement does not provide PLC any rights to any CardioGenesis intellectual property. The Eclipse TMR 2000 laser system does not use the technology associated with the PLC patents.

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

We may not be able to protect our intellectual property because:

patents may not be issued;

patents may be challenged, invalidated or designed around by competitors; or

patent protection may not continue to be available for surgical methods in the future.

Costly litigation may be necessary 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;

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.

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, until recently, maintained in secrecy until patents issue, 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.

The United States patent laws 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 amendment will materially affect our ability to protect our proprietary methods and procedures.

Competitors may independently develop proprietary information substantially equivalent to our proprietary information and techniques, or otherwise gain access to our proprietary technology.

In addition to our patents, we rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We may not be able to meaningfully protect our unpatented technology because:

- our employees, consultants and advisors may breach their confidentiality and invention assignment agreements and there may not be an adequate remedy for such breach;
- our competitors may independently develop substantially equivalent proprietary information and techniques; or
- competitors may otherwise gain access to our proprietary technology. Our inability to protect our unpatented intellectual property could materially harm our business.

We depend on single source suppliers for certain key components and production would be interrupted if a key supplier had to be replaced. We currently purchase certain critical laser and fiber-optic components from single sources. Although we have identified alternative suppliers, a lengthy process would be required to qualify them as additional or replacement suppliers. Any significant interruption in the supply of critical materials or

components could delay our ability to manufacture our products and could harm our manufacturing operations, business and results of operations.

We anticipate that products will be manufactured based on forecasted demand and will seek to purchase subassemblies and components in anticipation of the actual receipt of purchase orders from customers. Lead times for materials and components vary significantly and depend on factors such as the business practices of each specific supplier and the terms of particular contracts, as well as the overall market demand for such materials and components at any given time. If the forecasts are inaccurate, we could experience fluctuations in inventory levels, resulting in excess inventory, or shortages of critical components, either of which could cause our business to suffer.

Certain of our suppliers could have difficulty expanding their manufacturing capacity to meet our needs if demand for our TMR and PTMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers could cause a delay in regulatory approvals or adversely affect product acceptance. We can not predict if:

materials obtained from outside suppliers will continue to be available in adequate quantities; or

alternative suppliers can be located on a timely basis.

We operate on a purchase order basis with most of our suppliers. Such vendors could at any time determine to cease the supply and production of such components.

We have limited manufacturing experience which could prevent us from successfully increasing capacity in response to market demand. We have limited experience in manufacturing products. Manufacturers often encounter difficulties in increasing production, including problems involving:

production yields;

adequate supplies of components;

quality control and assurance (including failure to comply with good manufacturing practices regulations, international quality standards and other regulatory requirements); and

shortages of qualified personnel.

We also may not be able to successfully increase manufacturing capacity or avoid manufacturing difficulties or product recalls.

Our products may 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 PTMR laser systems. Any such occurrence could cause a delay in regulatory approvals or adversely affect the commercial acceptance of our products and could cause harm to our business.

We must comply with FDA manufacturing standards or face fines or other penalties including suspension of production. We are required to demonstrate compliance with the FDA s current good manufacturing practices regulations if we market devices in the United States or manufacture finished devices in the United States. The FDA inspects manufacturing facilities on a regular basis to determine compliance. If we fail to comply with applicable FDA or other regulatory requirements, we can be subject to:

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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,

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manufacture and marketing of medical devices. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death, and we could be subject to product liability claims if the use of our TMR or PTMR laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective.

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

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. Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel.

Our future business and results of operations also depend in significant part upon our ability to attract and retain additional qualified management, manufacturing, 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.

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. The 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.

Our products will be subject to other regulatory requirements in the European Union and other countries. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer.

The time required to obtain approval for sale in foreign countries may be longer or shorter than required for FDA approval, and the requirements may differ. In addition, there may be foreign regulatory barriers other than regulatory approval. Except as stated in the following sentence, the FDA must approve exports of devices that require a PMA but are not yet approved domestically. An unapproved device may be exported without prior FDA approval to any member country of the European Union and the other listed countries, including Australia, Canada, Israel, Japan, New Zealand, Switzerland and South Africa:

if the device is approved for sale by that country; or

for investigational use in accordance with the laws of that country.

We received the CE Mark for our TMR laser system in May 1997 and for our PTMR laser system in April 1998. In the European Economic Area, we will be:

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subject to continued supervision;

required to report any serious adverse incidents to the appropriate authorities; and

required to comply with additional national requirements that are outside the scope of the Medical Device Directive.

We became ISO 9001 certified in May 1997. We may not be able to:

achieve or maintain the compliance required for CE marking on all or any of our products; and

produce our products profitably and in a timely manner while complying with the requirements of the Medical Device Directive and other regulatory requirements.

If we fail to comply with applicable regulatory requirements we could face:

fines, injunctions, civil penalties;

recalls or seizures of products;

total or partial suspensions of production;

refusals by foreign governments to permit product sales; and

criminal prosecution.

Furthermore, if existing regulations are changed or new regulations or policies are adopted, we may:

not be able to obtain, or affect the timing of, future regulatory approvals or clearances;

not be able to obtain necessary regulatory clearances or approvals on a timely basis or at all; and

be required to incur significant costs in obtaining or maintaining such foreign regulatory approvals.

We sell our products internationally which subjects us to certain risks of transacting business in foreign countries. Our international revenue is subject to the following risks:

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.

Any of these factors could have an adverse effect on our international sales revenues. In future quarters, international sales could become a significant portion of our revenue.

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 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 TMR products in the international markets in which such approvals are sought.

We may engage in future acquisitions that 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

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technologies. While there are currently no commitments with respect to any particular acquisition or investment, our management frequently evaluates the strategic opportunities available related to complementary 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 amortization expenses related to goodwill and other intangible assets, any of which could materially harm our operating results and financial condition.

The price of our Common Stock may fluctuate significantly, which may result in losses for investors. The market price for our common stock has been and may continue to be volatile. For example, during the 52-week period ended December 31, 2000, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $11.050 to a low of $0.50. 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.

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 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 existing long-term debts and any future financing requirements. The long-term debt at December 31, 2000 consists of outstanding balances on a note payable and lease obligations.

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:

	2001	2002	2003	2004	2005	Total Fair Value
In Thousands						
Assets Cash, cash equivalents	$3,357	$	$	$		$3,357
Weighted average interest rate	4.7%					4.7%
Liabilities Fixed Rate Debt Note payable	$86	$	$	$		$86
Weighted average interest rate	8.0%					8.0%
Lease obligation	$32	$32	$32	$		$96
Weighted average interest rate	6.8%	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 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.

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PART III

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

The following table and discussion sets forth certain information concerning our current directors. Certain of the information concerning our executive officers required by this Item is contained in the Section of Part I of our Annual Report on Form 10-K filed April 17, 2001 entitled Item 1. Business Employees.

Name	Age	Position
Michael J. Quinn	56	Chief Executive Officer, President, Chairman of the Board
Jack M. Gill, Ph.D. 65DirectorAlan L. Kaganov, Sc.D 62DirectorRobert L. Mortensen (1)(2) 66DirectorRobert C. Strauss (1)(2) 59Director		

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.

All directors hold office until the next annual meeting of shareholders or until their successors have been elected and qualified. Officers serve at the discretion of our Board of Directors and are appointed annually. There are no family relationships between any of our directors or officers.

Michael J. Quinn has served as our Chief Executive Officer, President and Chairman of the Board since October 2000. From 1978 to 1988, Mr. Quinn held senior operating management positions at the level of Vice President, Chief Operating Officer and President at major healthcare organizations including American Hospital Supply Corporation, Picker International, Cardinal Health Group, Bergen Brunswig and Fisher Scientific. Most recently Mr. Quinn served as President and Chief Executive Officer of Premier Laser Systems, a manufacturer of surgical and dental products. Prior to that position, he served as President of Imagyn Medical Technologies, a manufacturer of minimally invasive surgical specialty products.

Jack M. Gill, Ph.D. has been one of our directors since March 1999. Dr. Gill formerly served as Chairman of the Board of Directors of CardioGenesis Corporation from November 1993 to March 1999. Dr. Gill is a founding general partner of Vanguard Venture Partners and has served in such capacity since 1981. Dr. Gill is a director of a number of privately held medical device companies. Dr. Gill received his B.S. degree in Engineering from Lamar University and his Ph.D. in Organic Chemistry from Indiana University.

Alan L. Kaganov, Sc.D. has been one of our directors since January 1997. From December 1999 to October 2000, Dr.&nbs