PLC SYSTEMS INC.

Focused on Innovative Technologies for the Cardiac and Vascular Markets

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12-31-04

Annual Report 2004

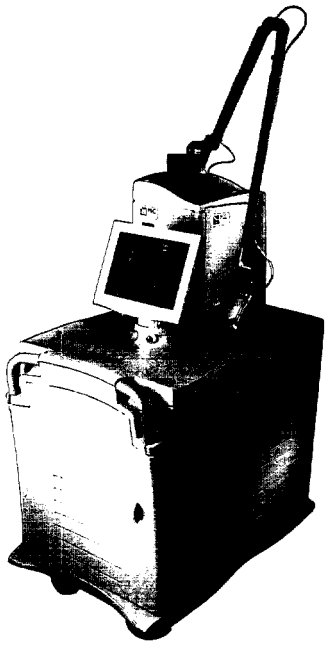
Today's PLC

PLC Systems Inc. is a medical device company specializing in innovative technologies for the cardiac and vascular markets. We currently manufacture two lasers that are used in the treatment of cardiovascular disease.

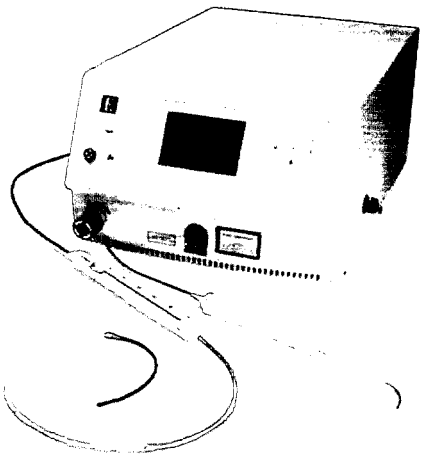
PLC pioneered the CO_2 Heart Laser System that cardiac surgeons use to perform carbon dioxide (CO_2) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. In addition, we are completing the development of and manufacturing the Optiwave 980 cardiac laser ablation system, or Optiwave 980 System, under an agreement with Edwards Lifesciences. The Optiwave 980 System is expected to be utilized by cardiac surgeons to ablate cardiac tissue as a means to treat certain heart arrhythmias.

Edwards is PLC's exclusive worldwide distributor for all surgical cardiac ablation products and, in the United States, is our exclusive distributor for TMR products.

The CO_2 TMR Heart Laser System



The Optiwave 980 System



Dear Shareholders,

Expanding and growing a business involves a significant amount of energy, effort, time and discipline. We believe the past 24 months demonstrate our progress in extending PLC beyond TMR. In fact, the past two years have two distinct phases--first we identified and evaluated new growth opportunities; and then we focused on implementing and executing our strategic decisions.

2004 was an important and exciting year for PLC. Throughout the year we continued to execute our strategic growth plan--to pursue opportunities that will provide revenue growth and product diversification. We have directed our research and development investments into programs that address the cardiac and vascular markets. Our R&D expenditures rose by more than $1 million from a year ago. We believe these significant investments in new product development will not only drive future revenue growth and profitability but also diversify our business.

We are very encouraged with our initiatives to re-shape PLC. As we entered 2004, PLC was a single product medical device company. As a result of our growth efforts, we believe that PLC is on target to end 2005 as a company with two product lines and a promising R&D pipeline.

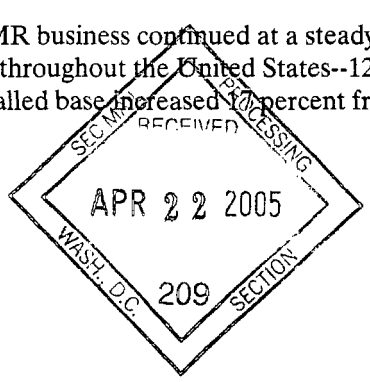
Our first move to expand our product portfolio resulted from a second agreement with Edwards Lifesciences. During the first quarter of 2004 we obtained the exclusive manufacturing rights to the Optiwave 980 cardiac laser ablation system. Throughout the year, we made significant investments to complete the development of the laser platform and we began shipping this product to Edwards in the fourth quarter. Currently, Edwards is performing marketing evaluations of the Optiwave 980 system. We believe the product is being well received by clinicians and it has exceptional technical advantages within the cardiac ablation market. Specifically, the laser diode technology allows for a very flexible handpiece, which enables cardiac surgeons to make smaller incisions. We believe that the Optiwave 980 will be well positioned in the market as soon as it becomes commercially available.

At the Society of Thoracic Surgeons (STS) Scientific Sessions held in January of 2005, there was a significant amount of interest around less invasive surgical cardiac therapies. In our opinion this less invasive trend will continue and even increase within the healthcare market. In fact, a new less invasive cardiac ablation technique using the Optiwave 980 system was presented at the STS Scientific Sessions. This less invasive approach, which may reduce hospital length of stay and improve patient outcomes, is enabled by the capabilities of the Optiwave 980 system.

CO_2 TMR

During 2004, there were two major events for the TMR therapy. The first involved the three major cardiac professional societies: STS, American College of Cardiology and American Heart Association. Each society established and published TMR practice guidelines for physicians, which we believe will be a positive influence on the adoption of the TMR therapy. Also, the Center for Medicare and Medicaid Services (CMS) reviewed the science behind the TMR therapy. We believe that anytime the organization that sets medical reimbursement policies reviews your technology or therapy it has the potential of creating uncertainty and distraction within the market, which includes physicians, patients, administrators, and even your sales channel. We believe that this effect may account for the relative flatness that we experienced in year over year kit shipments during 2004. At the end of 2004, CMS indicated to members of the STS that it has no plans to alter its TMR coverage policy. We believe that the end result of the CMS review will be a long-term positive for TMR.

Even with the uncertainty of CMS, the TMR business continued at a steady pace. We ended 2004 with 171 CO_2 Heart Lasers located at heart centers throughout the United States--124 of these being HL2s and 47 being HL1s. Overall our domestic HL2 installed base increased 10 percent from a year ago. Edwards



delivered 1,880 disposable kits to U.S. hospital sites during 2004. With the addition of 125 kits shipped internationally, worldwide kits shipped in 2004 totaled 2,005.

We believe that TMR is on a solid scientific foundation supported by clinical data and endorsed by professional societies. We believe the ongoing sales and marketing effort that Edwards applies to the product will continue to yield favorable results for CO_2 TMR.

Planning for the Future

Our efforts and energies throughout 2004 have provided the basis for the future PLC. To help the new PLC take shape, we bolstered our balance sheet during the year. In February of 2004, we amended our TMR distribution agreement. This adjustment provided $4.5 million of additional cash, which enabled us to end the year with $9.7 million in cash. The PLC management team will continue being fiscally prudent with a long-term view of your company and with the ultimate strategy of continuing to grow PLC with additional products addressing unmet medical needs.

PLC's Primary Goals for Increasing Shareholder Value

- Expanding and diversifying our product offerings,
- Growing our revenues,
- Achieving sustainable profitability, and
- Building and extending our intellectual property portfolio.

As we move into 2005, we will continue to invest in our new growth initiatives. We believe that these new initiatives will serve as a catalyst for future revenue growth and profitability for PLC and we look forward to continuing to communicate to you our progress in 2005.

Thank you for being a PLC shareholder, thank you for your interest in PLC and we invite you to continue to follow our progress and our success.

Sincerely,

Mark R. Tauscher
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period of _____ to _____

Commission file number 1-11388

PLC Systems Inc.

(Exact name of registrant as specified in its charter)

Yukon Territory, Canada	**04-3153858**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
10 Forge Park, Franklin, Massachusetts	**02038**
(Address of principal executive offices)	*(Zip Code)*

(508) 541-8800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Name of Each Exchange on which Registered*
Common stock, no par value	**American Stock Exchange**

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

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 ☒ 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2004, was $18,846,846. As of March 18, 2005, 30,067,686 shares of common stock, no par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement, which will be issued in connection with the 2005 Annual Meeting of Shareholders, are incorporated by reference in Part III of this annual report on Form 10-K.

Forward-Looking Statements

This annual report on Form 10-K (including certain information incorporated herein by reference) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements containing terms such as "believes", "plans", "expects", "anticipates", "intends", "estimates" and similar expressions contain uncertainty and are forward-looking statements. Forward-looking statements are based on current plans and expectations and involve known and unknown important risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such important factors and uncertainties include, but are not limited to the risk factors set forth in Item 7.

PART I

Item 1. *Business*

Overview

We are a medical device company specializing in innovative technologies for the cardiac and vascular markets. We currently manufacture two lasers that are used in the treatment of cardiovascular disease. We pioneered the *CO_2 Heart Laser System* that cardiac surgeons use to perform carbon dioxide (CO_2) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. In addition, we are completing the development of and manufacturing the Optiwave 980 cardiac laser ablation system, or Optiwave 980 System, under an agreement with Edwards Lifesciences LLC (Edwards). The Optiwave 980 System is expected to be utilized by surgeons to ablate cardiac tissue as a means to treat certain heart arrhythmias.

Edwards is our exclusive worldwide distributor for all surgical cardiac ablation products and, in the United States, acts as our exclusive distributor for TMR products. Edwards is our largest customer, accounting for approximately 88% and 89% of our total sales in 2004 and 2003, respectively. We expect this sales trend to continue for the foreseeable future.

Edwards is also our largest shareholder, owning approximately 18% of our outstanding common stock as of December 31, 2004, and has a representative on our Board of Directors.

The CO_2 Heart Laser System

TMR is performed by a cardiovascular surgeon, who uses a laser to create channels through the myocardium of the heart in an attempt to restore perfusion to areas of the heart not being reached by diseased or clogged arteries. This technique is used for relief of symptoms of severe angina in patients with ischemic heart disease not amenable to direct coronary revascularization interventions, such as angioplasty, stenting or coronary artery bypass grafting (bypass surgery). In addition to providing new direct pathways for blood to reach the ischemic myocardium, the creation of TMR channels is also believed to promote angiogenesis, the development of new blood vessels.

In August 1998 we received approval from the FDA to market our first generation CO_2 Heart Laser, the HL1, throughout the United States. We were the first company to receive FDA approval to commercialize a product to perform TMR. In January 2001 we received approval from the FDA to market our smaller and lighter second generation Heart Laser, the HL2.

Each TMR procedure requires a sterile, single use TMR kit containing assorted TMR handpieces, drapes and other disposable items. The HL1 and HL2 lasers each require a TMR kit as part of the system. The same TMR kit may be used with either the HL1 or HL2 laser. The combination of either an HL1 or an HL2 with a TMR kit is referred to throughout this annual report as the Heart Laser System.

We manufacture the Heart Laser Systems at our facility in Franklin, Massachusetts.

Growth Strategy and Optiwave 980

Throughout 2004 we focused on broadening and diversifying our product portfolio beyond our TMR product line by developing and acquiring new and innovative medical devices to address select cardiac and vascular related markets. As part of our overall business growth strategy, we (1) entered into an agreement with Edwards to complete the development of and manufacture the Optiwave 980 System and (2) advanced certain other longer term research projects currently under development. Our goal is to continue to seek out creative solutions for unmet clinical needs within the cardiac and vascular related markets that possess substantial revenue growth prospects.

The agreement we entered into with Edwards to complete the development of and manufacture the Optiwave 980 System was, we believe, our best first step in implementing our growth strategy. The Optiwave 980 System leverages both our existing core competencies in the field of laser technology and our existing distribution channel with Edwards and has already obtained FDA marketing clearance (510(k)).

The Optiwave 980 System consists of a diode laser power source that delivers laser energy through a flexible fiber optic single use disposable handpiece. We began manufacturing Optiwave 980 laser power sources in the third quarter of 2004 and we delivered the initial shipments to Edwards during the fourth quarter of 2004. Edwards is currently manufacturing the disposable handpieces, which are being used in ongoing marketing evaluations of the Optiwave 980 System. During these evaluations, Edwards has identified certain performance enhancement opportunities that they wish to incorporate into the product. Edwards is in the process of completing the marketing evaluations and testing and implementing these enhancements before they initiate a full marketing launch of the Optiwave 980 System.

Edwards has built a transition inventory of Optiwave 980 disposable handpieces and they believe that this inventory will be sufficient to complete the marketing evaluations. As a result, we expect that we will first begin manufacturing Optiwave 980 disposables in the second half of 2005 should the marketing evaluations prove successful.

Cardiovascular Disease and Current Therapies

According to the 2005 Heart and Stroke Statistical Update, or 2005 HSSU, which was published by the American Heart Association, an estimated 70.1 million Americans suffered from one or more types of cardiovascular disease in 2002, with an estimated 13 million suffering from coronary heart disease, 6.4 million suffering from angina pectoris (chest pain) and 2.2 million suffering from atrial fibrillation.

Cardiovascular disease is the leading cause of death in the U.S., resulting in approximately 38% (or 927,000 in 2002) of all deaths in the U.S. annually. The American Heart Association estimates that the direct and indirect costs of cardiovascular disease in the year 2005 will be approximately $393 billion.

Angina—Current Treatments

Angina is the medical term used to describe the chest pain or discomfort that an individual can experience when the heart does not receive an adequate supply of oxygen rich blood. This can occur when the arteries supplying blood flow to the heart muscle become partially blocked or narrowed by the accumulation of fatty deposits known as plaque. This condition where plaque progressively builds up in the interior walls of the arteries, resulting in reduced blood flow to the myocardium, ischemia and angina, is known as coronary atherosclerosis. Atherosclerosis is the principal form of cardiovascular disease and the primary cause of heart attacks. Traditional treatment of atherosclerosis as a means to improve blood flow to the heart includes drug therapy, angioplasty, stenting and bypass surgery.

Drug therapy alleviates some of the symptoms of atherosclerosis but is often ineffective in serious cases. Angioplasty is a less invasive treatment for arteriosclerosis than bypass surgery. The most common form of angioplasty involves inserting a catheter with a balloon at the tip into a diseased artery. By inflating the balloon at the site of blockage, the arterial plaque can be pressed against the arterial walls and reshaped, resulting in increased blood flow and decreased angina symptoms. According to the 2005 HSSU, an estimated 657,000 angioplasty procedures were performed on 640,000 patients in the U.S. in 2002.

Metallic stents were developed to help prevent abrupt closures that sometimes occur after angioplasty. These stents are inserted into the artery after balloon angioplasty to hold the expanded plaque in place. Because it is less traumatic and less costly, stenting procedures are preferred over bypass surgery when the blockages are not complicated and involve few coronary arteries. While offering certain benefits compared to bypass surgery, some studies suggest restenosis, or the reclosure of the stented portion of the artery over

time, is a serious problem. A new generation of stents that are coated with drugs targeted at preventing restenosis have recently shown some success. Early studies have shown significant reduction in restenosis when these drug eluting stents are used.

Conventional bypass surgery involves cutting open the patient's chest, cutting through the sternum, usually connecting the patient to a heart-lung machine, stopping the heart, attaching a vein or artery removed from another part of the patient's body to create a bypass around the diseased blood vessel and restarting the heart. According to the 2005 HSSU, an estimated 515,000 coronary artery bypass procedures were performed on 306,000 patients in the U.S. in 2002. Certain patients however are not suited for bypass procedures, including some who have previously undergone bypass surgery, patients with extremely diffuse diseases, patients with vessels that are too small to graft, patients with chronic obstructive pulmonary disease, some patients with diabetes, and others who are considered too ill to survive surgery.

We believe that TMR using the Heart Laser Systems is useful as a treatment for patients who have severe, stable angina and who are no longer candidates for either angioplasty or bypass surgery because of either extensive disease or small coronary arteries. The FDA has approved the Heart Laser Systems for such patients.

TMR as a sole therapy is designed to be less invasive and less expensive than traditional bypass surgery, and may avoid the restenosis problem common with bypass surgery and balloon angioplasty by not targeting the coronary arteries for treatment.

TMR Using the Heart Laser Systems

The main challenge in treating atherosclerosis is to allow adequate blood to flow to the heart muscle without significantly damaging the heart. The conventional and newer techniques described above are used to bypass, reopen or widen blocked or narrowed arteries and can eventually fail due to restenosis or natural disease progression. TMR using the Heart Laser Systems involves a different technique whereby channels are created in the myocardium as a means of supplying oxygen-rich blood from the left ventricular chamber into the ischemic myocardium. TMR does not target the coronary arteries for treatment.

Heart muscle must be constantly supplied with oxygen in order to function effectively. Oxygen is delivered to the myocardium by blood, which is distributed to the myocardium through the right and left coronary arteries. If these arteries are narrowed or blocked as a result of atherosclerosis, sufficient oxygen-rich blood may be unable to reach the heart to satisfy the metabolic demands of the myocardium. Cardiovascular disease eventually may cause myocardial ischemia, often evidenced by severe and debilitating angina caused by lack of oxygen to the heart muscle, which can progress to myocardial infarction (the death of an area of the heart muscle). Advanced multi-vessel ischemic heart disease is typically treated with bypass surgery.

During a sole therapy TMR procedure, the patient is given general anesthesia and an incision is made in the patient's side between the ribs, exposing the heart. The Heart Laser Systems are synchronized with the patient's heartbeat, firing only when the left ventricle is filled with blood and is electrically insensitive. We believe that synchronization may reduce the risk of arrhythmias (irregular heartbeats) and their associated morbidity and mortality. Research studies conducted by the Texas Heart Institute in animal models indicated that performing TMR without synchronization may be associated with an increase in life threatening arrhythmias. The synchronization technology is covered under a patent that we own. The Heart Laser Systems are capable of creating a transmural channel in less than 0.1 second with a single laser pulse in a patient whose heart has not been stopped and who has not been placed on a heart-lung bypass machine. The surgeon can vary the pulse width of the laser using a touch key control panel to accommodate for the thickness of the patient's heart wall. Transesophageal echocardiography is used to

confirm that complete channels are made by the laser. Generally, 20 to 40 new channels are created during the procedure.

We believe that, in addition to providing new direct pathways for blood to reach the ischemic myocardium, the creation of transmural channels using the Heart Laser Systems also promotes angiogenesis, the formation of new blood vessels.

Potential Benefits of TMR

In September 2001 long term follow-up data was published in *Circulation*, the official journal of the American Heart Association, on eligible patients from our FDA clinical studies. The long-term TMR analysis included 78 patients at nine hospitals. Each patient had been suffering from chronic angina and from severe coronary artery disease, or CAD, before receiving treatment with the HL1. The average age of the patients at enrollment was 61. The average preoperative angina class for the group was 3.7 out of a maximum of 4 (angina is measured in classes from one to four, one being the least painful and four being the most painful). After an average of 55 months following the TMR procedure, the group's average angina class improved from 3.7 to 1.6. This was virtually unchanged from the 1.5 average angina class reported at 12 months following the TMR procedure. In fact, five years after having the TMR procedure with the HL1, 17% of the patients reported having no angina and 64% were in angina class 1 or 2.

Based on clinical results to date, we believe that TMR using the Heart Laser Systems provides a number of benefits, although no assurance can be given that any of the mentioned benefits will be received by patients and no assurance can be given that the FDA will approve additional indications for use of the Heart Laser Systems or that the FDA will not withdraw or alter its current approval. These potential benefits include:

Therapy for Patients Not Suitable for Coronary Bypass. The FDA has approved the use of the Heart Laser Systems for patients who have stable angina (Canadian Cardiovascular Society Class III or IV) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium not amenable to direct coronary revascularization.

Potentially Reduced Hospital Readmission Costs. We believe that TMR is a cost effective treatment based on studies indicating that patients who receive TMR have fewer readmissions to the hospital for chest pain than those who receive only drug therapy.

Potential Delivery Mechanism for Angiogenic Agents. The TMR therapy utilizing the Heart Laser Systems may have the potential, with future development, to deliver angiogenic agents, which may assist in the treatment of CAD. This potentially could be accomplished through the use of stand-alone devices or by a device integrated into the current Heart Laser System handpieces that would, concomitantly with the TMR therapy, inject these agents into the myocardium.

Potential Angiogenic Response Stimulator. With additional clinical research, TMR therapy potentially could be found to be synergistic with delivered growth factors, which may prove useful in treating patients with CAD.

Cardiac Arrhythmias—Current Treatments

The heart is an electromechanical pump that contracts in a specific manner to efficiently pump blood throughout the body. The heart pumping is controlled by electrical signals that are generated in the right atrium of the heart and travel throughout the heart by way of an electrical conduction network. This system carries the electrical signals in a systematic way that results in a normal heartbeat. A failure in this conduction system usually results in an arrhythmia. An arrhythmia is an abnormal heart rhythm that can adversely affect the heart's performance.

Several different types of arrhythmias can occur in the human heart. They can occur both in the ventricles and the atria and can be either fast heart rate (tachycardia) or slow heart rate (bradycardia). The most common sustained cardiac arrhythmia is an atrial tachycardia called atrial fibrillation, or AF, that is characterized by the irregular contractions and/or very rapid beating of the atria. During AF, instead of a single smooth wave of contraction, the electrical conduction does not operate normally and a storm of electrical energy spreads in random loops across both atria causing rapid, uncoordinated contractions.

Today we believe AF affects an estimated 5 million people worldwide including an estimated 2.2 million Americans, and we estimate that there are 200,000 to 400,000 new cases diagnosed annually in the U.S. The condition can cause fatigue, dizziness, stroke and in extreme cases death if untreated. It is now understood that AF contributes to 15% to 20% of all strokes, and the need for life-long drug therapy can significantly impair the quality of life for patients.

Drug therapy is currently the standard of care for AF, and it is usually life-long. Patients are usually placed on rhythm control or rate control plus anticoagulation drugs, the former of which to manage arrhythmia and the latter to reduce the patient's stroke risk. This type of therapy does not cure AF, but does help to reduce its effects. Anti-arrhythmic drugs have not proven highly successful to date.

The surgical Cox-Maze procedure is currently the most effective cure for AF with a reported success rate of over 95%. This is an extremely invasive, open-heart procedure that involves dissecting the atrium with a scalpel and sewing it back together to block the errant electrical signals allowing the heart to return to its normal rhythm. Because of its invasiveness and technical difficulty, we believe only several hundred Cox-Maze procedures are performed annually in the U.S.

The success of the Cox-Maze procedure has led surgeons and companies to develop and refine less invasive techniques that can deliver similar outcomes without the risks and the costs. These new approaches include the substitution of alternative energy sources for the surgical incision in the Cox-Maze procedure, such as radio-frequency, microwave, laser, cryo-therapy and ultrasound. Recent clinical results indicate that these alternative energy sources can reproduce much of the success of the surgical Cox-Maze procedure with significantly less trauma, including operating through minimally invasive incisions and on a beating heart.

AF surgery with these alternative energy sources can be performed from the inside of the arrested heart (endocardially) in conjunction with other cardiac procedures or, in some cases, from the outside of the heart (epicardially) while it is beating in a minimally invasive procedure. Since AF typically occurs in 30% to 45% of patients with mitral valve disease and the atrium is usually opened to repair or replace a mitral valve, we believe the initial surgical market for these new procedures will be in combination with mitral valve surgery.

Cardiac Tissue Ablation Using the Optiwave 980 System

The Optiwave 980 System being developed is a laser-based device that uses a 60-watt, 980nm diode laser as its power source. The laser power is delivered to various handpieces through a flexible optical fiber. The diode wavelength corresponds to a water absorption peak and causes tissue ablation by dielectric heating.

The key proprietary technology for this system is in the diffusing tip, which allows the surgeon to lay a linear lesion on the atria so that lesions as long as 5 cm are possible. The tip has a gold foil reflector that directs the laser power towards the heart. The tip is also malleable to allow different shaped lesions to be made.

The goal of laser ablation on cardiac tissue is to transmurally render specific cells incapable of conducting electrical cardiac signals without damaging adjacent tissues and other structures. When infrared laser energy is directed at the target tissue, water molecules in the tissue absorb the energy,

generate heat and cause surrounding tissue to photocoagulate. The coagulated tissue forms lesions that block the conduction of errant electrical impulses, similar to the scalpel cuts in the Cox-Maze procedure.

In a study performed in 2003 at Columbia University using the Optiwave 980 System, endocardial ablations were performed on 12 dogs. All of the lesions were transmural, all were effective and there were no complications from collateral injury.

We believe some of the beneficial features of the Optiwave 980 System are:

- It lends itself to minimally invasive procedures;
- It can perform ablation either endocardially or epicardially;
- Laser technology creates uniform lesions at a precise depth;
- It produces lesions up to 5 cm in length;
- It targets tissue with a high degree of accuracy thereby avoiding damage to surrounding structures; and
- It can create lesions in fatty hearts.

Potential Benefits of Cardiac Tissue Ablation

The most time-consuming aspect of the Cox-Maze procedure is the need to create numerous incisions in the atria, essentially taking apart the tissue like a jigsaw puzzle and then meticulously sewing it back together. In addition, the procedure must be done on a stopped heart that is on cardiopulmonary bypass. As the new cardiac ablation devices are perfected, the goal will be to obtain clinically acceptable AF cure rates with a minimally invasive, easy to perform, low-cost procedure.

We believe that the Optiwave 980 System is positioned to solve problems with the Cox-Maze procedure. When using this system, the atria do not have to be cut apart and sewn back together. Electrical path blocking lesions can be made from the inside of the atria if the procedure is being done in conjunction with a valve procedure or potentially from the outside of the heart, while it is beating, without making any incisions in the atria.

We believe that the fact that this procedure has the potential to be performed minimally invasively on a beating heart and can have high cure rates, would make it an attractive alternative for many patients with AF.

Sales and Marketing Strategy

TMR Products—Sales Channel

We sell our TMR products principally through key distributors throughout the world. In the U.S., we have appointed Edwards as our exclusive distributor for the HL2 and all TMR disposable procedure kits. Edwards uses a direct sales force comprised of individuals with a high degree of professionalism and experience in the cardiovascular device business to market our TMR products in the U.S.

Outside the U.S., we have established an independent distributor network to market our TMR products, although in some areas, principally Europe, we continue to sell our TMR products directly to hospitals.

International sales (by origin) accounted for 6%, 6% and 5% of our total revenue in 2004, 2003 and 2002, respectively. We had no sales by origin in Canada, our jurisdiction of incorporation.

We sell our TMR products to both Edwards and our international distributors at a discount off list price.

Cardiac Tissue Ablation Products—Sales Channel

Edwards is our exclusive worldwide distributor for all surgical cardiac ablation products. By agreement, they are prohibited from offering for sale any directly competitive surgical products without first offering such competitive products to us to manufacture.

The Optiwave 980 System currently is only approved for marketing in the U.S. We believe we will be able to secure the regulatory approval (CE Mark) necessary to market this product throughout the European Union (EU) in 2005.

We understand that Edwards intends to use its direct sales force to market the Optiwave 980 System in the U.S. Internationally we understand that they intend to use both a direct sales force and third party distributors depending on the country in which they intend to market the product.

Edwards Marketing Programs

Edwards determines the programs, including sale, lease, rental and usage based offerings, that it believes will be most effective in the U.S. in selling our products to hospitals.

Edwards' marketing efforts are directed at cardiothoracic surgeons, whose influence is believed to be critical in a hospital's decision to purchase our products. In addition, Edwards emphasizes educating hospital administration and referring physicians, with a focus on promoting the economics and viability of the medical treatments using our products.

Edwards also currently conducts Center of Excellence TMR training programs across the country (i) to facilitate increased surgeon training for potential sales closure, (ii) to facilitate new site initiation, and (iii) to increase the number of surgeons trained in the use of our products. These TMR training programs are focused on educating prospective surgeons, as well as surgeons from new and existing customer sites. These comprehensive programs facilitate interaction among experienced users, enabling them to discuss best practices and focus on ensuring the best possible patient outcomes, including intensive discussions on patient selection and management. Course participants often view live, narrated procedures via closed circuit television. Actual hands on training is also provided in the use of our products.

Edwards' direct sales force is supported by a promotional program that consists of electronic and print media advertising, public relations, direct mail, trade shows and educational symposia, all focused on disseminating critical information to decision makers and key purchase influencers. No assurance can be given that such programs will continue or be implemented successfully by Edwards.

Products and Customers

We market one principal product line, which consists of two patented high-powered carbon dioxide laser systems known as the Heart Laser Systems. Approximately 90%, 95% and 92% of our revenues for the years ended December 31, 2004, 2003 and 2002, respectively, were derived from the sales and service of our Heart Laser Systems.

During 2004, 2003 and 2002, sales to Edwards accounted for 88%, 89% and 87%, respectively, of our total revenues.

Manufacturing

We manufacture and test our TMR products and the Optiwave 980 laser power sources at our facility in Franklin, Massachusetts, approximately 40 miles west of Boston. Optiwave 980 disposables are expected to be manufactured at a facility we lease in Billerica, Massachusetts, approximately 20 miles northwest of Boston. We believe that our manufacturing capacity will be sufficient to meet market demands anticipated in the coming year for all our products.

Some of the components for our Heart Laser Systems, most notably the power supply and certain optics and fabricated parts for the HL2, and certain components for the Optiwave 980 System, are only available from one supplier, and we have no assurance that we will be able to source any of our sole-sourced components from additional suppliers. Should the supply of certain critical components be interrupted or become unavailable, we may not be able to meet demand for our products, which could have a material adverse effect on our business and results of operations.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities to ensure compliance with FDA and European Union quality system regulations.

Government Regulation

The Heart Laser Systems and the Optiwave 980 System, as well as other medical devices that we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and abroad. The Federal Food, Drug, and Cosmetic Act (the "FDC Act") and other federal and state statutes and regulations govern the research, design, development, manufacturing, preclinical and clinical testing, installation, storage, packaging, recordkeeping, servicing, labeling, distribution and promotion of medical devices in the U.S. Our laser products are subject to additional FDA regulation under the radiation health and safety provisions of the FDC Act, which imposes labeling and other safety requirements related to radiation hazards.

As a device manufacturer, we are also required to register with the FDA. As such, we are subject to inspection on a routine basis for compliance with the FDA's Quality Systems regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements for reporting. The FDC Act and medical device reporting regulations require that we provide information to the FDA on deaths or serious injuries alleged to have been caused or contributed to by the use of our products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA also prohibits an approved device from being marketed for unapproved uses. Our product promotion and advertising is subject to continuing FDA regulation. Our laser products are subject to periodic inspection under the radiation health and safety provisions of the FDC Act for compliance with labeling and other safety regulations. The failure to comply with the applicable regulatory requirements may subject us to a variety of administrative or judicially imposed sanctions, including the FDA's refusal to approve pending or supplemental applications, withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil and criminal penalties against that company or its officers, directors or employees. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We intend to continuously improve our products after market introduction and may therefore submit future Investigational Device Exemption, Pre-Market Notification ("510(k)"), Pre-Market Approval ("PMA"), or PMA supplement applications to the FDA. No assurance can be given that clearance or approval of such new applications will be granted by the FDA on a timely basis, or at all. Furthermore, we may be required to submit extensive preclinical and clinical data depending on the nature of the changes.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products and medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

Various foreign countries in which our products are or may be sold impose additional or different regulatory and testing requirements. The international regulatory approval process varies from country to country and is subject to change in a given country as regulatory requirements change. Thus, the time required for an approval may differ and there can be substantial delays in obtaining approval after the relevant applications are filed. There is no assurance that foreign regulatory authorities will approve the use or sale of our products in a particular country on a timely basis, or at all.

The FDA has approved the use of the Heart Laser Systems for patients who have stable angina (Canadian Cardiovascular Society Class III or IV) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium not amenable to direct coronary revascularization.

The FDA has given clearance to the Optiwave 980 System under a 510(k) with indications for use as a surgical instrument for the coagulation of soft tissue, including cardiac tissue, in conjunction with or without endoscopic equipment in the contact or non-contact mode in open or closed surgical procedures.

Third-Party Reimbursement

Healthcare providers, including hospitals and physicians that purchase medical devices, such as the Heart Laser Systems and Optiwave 980 System, for use on their patients, generally rely on third-party payers, principally Medicare, Medicaid and private health insurance plans, to reimburse all or part of the costs associated with the procedures performed with these devices.

Currently Medicare coverage is provided for TMR when it is performed as a sole therapy treatment. In addition, when two or more medical procedures are performed in combination with each other, Medicare rules generally allow hospitals to bill for whichever of the two procedures carries the higher reimbursement amount. Therefore, in situations where sole therapy TMR reimbursement rates exceed that provided for bypass surgery alone, if hospitals perform a combination procedure where both bypass surgery and adjunctive TMR are performed on a patient, the hospital is able to bill for the higher TMR procedure reimbursement payment. In these instances, the doctor also can bill an additional amount for performing multiple procedures.

Certain private insurance companies and health maintenance organizations also currently provide reimbursement for TMR procedures performed with our products and physician reimbursement codes have been established for both surgical procedures; however, we have limited data as to the breadth of this coverage for the TMR procedure by private insurance companies and health maintenance organizations.

Cardiac tissue ablation procedures, such as those that would be performed using the Optiwave 980 System, are also currently reimbursed by Medicare when performed as a sole therapy. In instances where a surgeon might perform a cardiac tissue ablation procedure in combination with another heart related procedure, such as a valve replacement or repair, we believe the other procedure will normally carry a higher reimbursement and, therefore, will be the procedure that the hospital bills to Medicare.

No assurance can be given, however, that these payers will continue to reimburse healthcare providers who perform TMR or cardiac tissue ablation procedures using our products now or in the future. Further, no assurance can be given that additional payers will reimburse healthcare providers who perform TMR or cardiac tissue ablation procedures using our products or that reimbursement, if provided, will be timely or adequate. In addition, the market for our products could be adversely affected by future legislation to reform the nation's healthcare system or by changes in industry practices regarding reimbursement policies and procedures.

Proprietary Processes, Patents, Licenses and Other Rights

It is our policy to file patent applications to protect our technology, inventions and product improvements. We also rely on trade secret protection for certain confidential and proprietary information.

Since April 1992, we have received 30 U.S. patents. These patents have terms which expire from 2009 through 2020 and cover, among other things, laser technology to create a pulsed, fast-flow laser system, the use of a laser on a beating heart to revascularize the heart using TMR related disposable components, and the system used to time the heart's contractions to synchronize the laser firing at the correct time. We also have U.S. patent applications pending relating to technology used in the Heart Laser Systems and technologies associated with percutaneous myocardial revascularization. Edwards is the owner of the intellectual property rights in the Optiwave 980 System.

In January 1999, CardioGenesis Corporation, the only other current competitor in the TMR market, agreed to the validity and enforceability of certain of our patents in connection with a settlement of certain litigation between the companies. The patents, U.S. Patent No. 5,125,926 and related international patents, cover our proprietary synchronization technology, which we believe is a critical factor in increasing the safety of TMR procedures. We granted CardioGenesis a non-exclusive worldwide license to the patents in exchange for payment of a license fee and ongoing royalties over the life of the patents.

Although we believe our patents and the patents that we license from Edwards to be strong, litigation by a competitor seeking to invalidate these patents could have a material adverse effect on our business, financial condition and results of operations. No assurance can be given that the existing patents will be held valid if challenged, that any additional patents will be issued or that the scope of any patent protection will exclude competitors. The breadth of claims in medical technology patents involves complex legal and factual issues and therefore can be highly uncertain.

We also rely upon unpatented proprietary technology and trade secrets that we seek to protect, in part, through confidentiality agreements with employees and other parties. No assurance can be given that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop or otherwise acquire substantially equivalent proprietary technology and trade secrets or disclose such technology or that we can meaningfully protect our rights in such unpatented technology. In addition, others may hold or receive patents that contain claims covering products developed by us or by Edwards.

We believe our patents, as well as those that we license from Edwards, to be valid and enforceable. However, there has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which could result in substantial cost and diversion of our efforts, may be necessary to enforce our patents, to protect our trade secrets, to defend ourselves against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Adverse determinations in litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties and prevent us from manufacturing, selling or using our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

Competition

TMR Products

Our only direct competitor in the TMR market at this time is CardioGenesis. Although we do not believe it likely, because of the length of time and significant cost involved to conduct the necessary human clinical trials that would be required to secure approval from the FDA to market new TMR products, other companies may enter the TMR market in the future.

CardioGenesis has received FDA approval to market its holmium laser in the U.S. to perform TMR. CardioGenesis has also received CE Mark approval for their TMR system, which allows them to sell their product commercially in the European Union. CardioGenesis recently introduced in December 2004 a new model of their TMR laser and is promoting the advantages they believe their TMR system provides surgeons who wish to perform minimally invasive or robotically assisted TMR procedures. It is unclear at this time how successful, if at all, CardioGenesis will be with this new marketing program or what impact their new line of TMR products will have in terms of competing with our present Heart Laser System design.

In addition to their TMR system, CardioGenesis has pursued a "percutaneous" method of performing myocardial revascularization, known as PMR. PMR procedures are performed via a catheter inserted through an incision in a patient's leg. PMR is a less invasive method than TMR of creating channels in a human heart. CardioGenesis' PMR system was reviewed by the FDA Circulatory System Devices Panel in July 2001. That panel, in a 7-2 vote, found the PMA application for their PMR system to be not approvable. Presently there are no FDA approved PMR devices in the marketplace.

We believe that the primary competitive factors in the medical treatment of CAD are clinical safety and efficacy, product safety and reliability, regulatory approval, availability of reimbursement from insurance companies and other payers, product quality, price, reputation for quality, customer service and ease of use. We believe that our competitive success will be based on our ability to create and maintain scientifically effective and safe technology, obtain and maintain required regulatory approvals, obtain and maintain third party reimbursement for use of our products, attract and retain key personnel, obtain and maintain patent or other protection for our products and successfully differentiate, price, manufacture and market our products either directly or indirectly through outside parties.

The medical care products industry is characterized by extensive research efforts and rapid technological progress. New technologies and developments are expected to continue at a rapid pace in both industry and academia. Competition in the market for surgical lasers and for the treatment of cardiovascular disease is intense and is expected to increase. We believe that the Heart Laser Systems must compete not only with other TMR systems and potentially PMR systems, but also with medical management (drugs) and other coronary procedures (e.g., coronary bypass surgery, balloon angioplasty, atherectomy, laser angioplasty and stents, including new drug eluting stents that may significantly reduce restenosis). Many of the companies manufacturing these products have substantially greater resources and experience than we do. Such companies may succeed in developing products that are more effective, less invasive or less costly in treating coronary disease than the Heart Laser Systems and may be more successful than us in manufacturing and marketing their products. No assurance can be given that our competitors or others will not succeed in developing technologies, products or procedures that are more effective than any being developed by us or that would render our technology and products obsolete or noncompetitive. Although we will continue to work to develop new and improved products, the advent of either new devices or new pharmaceutical agents could hinder our ability to compete effectively and have a material adverse effect on our business, financial condition and results of operations.

Cardiac Tissue Ablation Products

Drug therapy currently accounts for nearly half of the current treatment for AF. The therapy is individualized to the patient and usually focuses on number, duration and/or severity of symptoms instead of achieving a cure, which remains elusive. In addition, many patients do not respond to drug treatment. These and other factors have created an environment in which new therapies that cure the condition in a safe and cost effective manner are likely to be adopted. Because of this, a number of companies have developed or are in the process of developing new devices for the treatment of AF.

Aside from drugs, there are a number of methods for treating AF, including surgical management, cardioversion, implantable devices and catheter-based ablation.

Surgical management includes the Cox-Maze procedure performed with either a scalpel or surgical ablation devices such as the Optiwave 980 System. We believe that the Optiwave 980 System, at the time that it becomes commercially available, will be the only laser based surgical ablation system then on the market. Other surgical ablation systems exist using other sources of energy such as radio-frequency (RF), microwave, cryo-ablation and ultrasound. Each of these systems has advantages and disadvantages. A number of companies supply such devices, which will compete directly with the Optiwave 980 System when it becomes commercially available.

Surgical RF ablation can be performed using several different devices and techniques, including unipolar and bipolar devices and with or without irrigation. Companies with RF ablation devices include: Boston Scientific, Medtronic and AtriCure. A microwave surgical ablation device is currently being sold by Guidant/Afx. A cryo-ablation device is being sold by Cryocath. In addition, St. Jude Medical announced that it has invested in Epicor, a company which is developing a high intensity focused surgical ultrasound ablation device for treating AF. Since the surgical ablation business is relatively new, none of these devices has established itself as the market leader and the business is still evolving.

Cardioversion is another technique that is used to treat AF. In this procedure the patient's heart is given a shock, either externally using a defibrillator device or internally using a catheter. This shock usually causes the heart to return to normal rhythm. It has been successfully used for secondary AF which has not persisted for a long time and is caused by a specific event such as surgery.

Implantable devices consist of pacemakers and internal cardioverter defibrillators (ICD's). Pacemakers can be used in atrial overdrive pacing to try to overpower errant electrical signals or where the atrium electrical system is ablated and replaced with a pacemaker. ICDs are implanted in the patient to provide automatic internal cardioversion during episodes of AF. While this appears to work, patient intolerance for shock therapy for a non-life threatening condition has emerged as a serious limitation.

Catheter-based ablation technologies are similar to the surgical ablation technologies, except the ablation energy is delivered percutaneously through a catheter. A number of companies are developing devices for this procedure.

Research and Development

Research and development expenses were $2,130,000, $980,000 and $889,000 for the years ended December 31, 2004, 2003 and 2002, respectively. We expect to continue to incur significant new research and development expenditures in the future in pursuit of our business strategy to broaden and diversify our product portfolio beyond our current TMR offerings. In particular, we expect our 2005 research and development expenditures to increase approximately $600,000 compared to 2004 as we attempt to complete the development of the Optiwave 980 System and advance certain other longer term research and development projects.

We continue to monitor technologies that may be applicable to TMR or cardiac ablation systems. No assurance can be given that our research and development goals will be implemented successfully.

Employees

As of March 18, 2005, we had 29 full-time employees worldwide, including our executive officers. Of these, 8 are in general and administrative positions, 2 are involved in sales, 6 are involved in research and development, 7 are involved in manufacturing, 5 are involved in service and 1 is involved in quality and regulatory affairs. We also employ 3 part-time employees, 1 in administration and 2 in quality and

regulatory affairs. None of our employees are represented by a union. We consider our relationship with our employees to be good.

Company Information

We were incorporated pursuant to the COMPANY ACT of British Columbia, Canada on March 3, 1987. We transferred our jurisdiction of incorporation to the Yukon Territory of Canada in March 1999. Our principal offices and manufacturing facilities are located at 10 Forge Park, Franklin, Massachusetts 02038. Our telephone number is (508) 541-8800. Our Internet address is *www.plcmed.com*. As used herein, the references to PLC, we, our and the Company mean, unless the context requires otherwise, PLC and its subsidiaries, PLC Medical Systems, Inc. and PLC Sistemas Medicos Internacionais (Deutschland) GmbH.

Item 2. ***Properties***

We maintain our principal executive offices and manufacturing and development operations in 24,000 square feet of leased space in Franklin, Massachusetts. The lease expires on August 31, 2009. We also lease 1,900 square feet of office and manufacturing space in a second facility located in Billerica, Massachusetts. The lease for this space expires on February 28, 2006. The total base rental payments for the fiscal years ending December 31, 2005, 2006, 2007, 2008 and for the eight months ending August 31, 2009 are approximately $318,000, $260,000, $255,000, $261,000 and $176,000, respectively. We are also responsible for certain operating and maintenance costs and real estate taxes.

Item 3. ***Legal Proceedings***

We are not presently involved in any material litigation proceedings.

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

Not applicable.

PART II

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

Since September 17, 1992, our common stock has traded on the American Stock Exchange ("AMEX") under the symbol "PLC". On March 16, 2005, the closing sale price of our common stock was $0.62 per share.

For the periods indicated, the following table sets forth the range of high and low sales prices for our common stock from January 1, 2003.

2003	High	Low
First Quarter	$0.64	$0.40
Second Quarter	$0.74	$0.41
Third Quarter	$1.09	$0.62
Fourth Quarter	$1.85	$0.88

2004	High	Low
First Quarter	$2.00	$1.10
Second Quarter	$1.50	$0.73
Third Quarter	$0.96	$0.60
Fourth Quarter	$0.94	$0.71

As of March 16, 2005, there were 768 record holders of our common stock. We believe that there are approximately 10,483 beneficial owners of our common stock.

Dividends

We have never paid cash dividends. We currently intend to retain all future earnings, if any, for use in our business and we do not anticipate paying any cash dividends in the foreseeable future.

Canadian Tax Matters

This summary is applicable to a holder or prospective purchaser of our common stock who is not (and is not deemed to be) a resident in Canada, does not (and is not deemed to) use or hold the common stock in, or in the course of, carrying on a business in Canada, and is not an insurer that carries on an insurance business in Canada and elsewhere.

This summary is based on the current provisions of the Income Tax Act (Canada) and the regulations thereunder. This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice to any holder of the common stock and no representation with respect to Canadian federal income tax consequences to any holder of common stock is made herein. Accordingly, prospective purchasers and holders of the common stock should consult their own tax advisers with respect to their individual circumstances.

Sales or Other Dispositions of Shares

A capital gain realized on the disposition of common stock by a person resident in the United States (a "non-resident") will not be subject to tax under the Income Tax Act (Canada) unless the shares held by the non-resident are "taxable Canadian property". In general, common stock will be taxable Canadian property if the particular non-resident used (or in the case of a non-resident insurer, used or held) the common stock in carrying on business in Canada or where at any time during the five-year period immediately preceding the realization of the gain, not less than 25% of the issued and outstanding shares

of any class or series of shares of the company, which were listed on a prescribed stock exchanged, were owned by the particular non-resident, by persons with whom the particular non-resident did not deal at arms' length, or by any combination thereof. If common stock constitutes taxable Canadian property, relief nevertheless may be available under the reciprocal tax treaty between Canada and the United States. Under the treaty, gains from the alienation of common stock owned by a non-resident who has never been resident in Canada generally will be exempt from Canadian capital gains tax if the shares do not relate to a permanent establishment or fixed base which the non-resident has or had in Canada, and if not more than 50% of the value of the shares was derived from real property situated in Canada.

Passive Foreign Investment Company Implications

Because we are incorporated outside the United States, and our cash and investments are significant to our total assets, we must monitor rules regarding possible classification as a passive foreign investment company under U.S. Federal tax rules. While currently not classified as such, future classification as a passive foreign investment company could result in certain adverse tax consequences including, but not limited to, the allocation of a portion of the Company's taxable income to our shareholders.

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

The following selected financial data for the five years ended December 31, 2004 are derived from our audited consolidated financial statements. This data should be read in conjunction with the consolidated financial statements, related notes and other financial information included elsewhere herein.

	For the years ended December 31,				
	2004	2003	2002	2001	2000
	(All amounts are in thousands except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales	$ 5,982	$ 6,899	$ 7,425	$ 7,975	$ 6,803
Placement and service fees	1,591	1,435	1,413	1,805	3,437
Total revenues:	7,573	8,334	8,838	9,780	10,240
Cost of revenues	3,069	3,343	4,092	5,591	7,220
Gross profit	4,504	4,991	4,746	4,189	3,020
Operating expenses:					
Selling, general and administrative	3,329	3,297	3,626	7,438	9,143
Research and development	2,130	980	889	904	1,680
Total operating expenses	5,459	4,277	4,515	8,342	10,823
Income (loss) from operations	(955)	714	231	(4,153)	(7,803)
Liquidation of subsidiary:					
Foreign currency loss	—	(257)	—	—	—
Other income, net	175	60	74	251	393
Income (loss) before income taxes	(780)	517	305	(3,902)	(7,410)
Provision for income taxes	53	—	—	—	—
Net income (loss)	$ (833)	$ 517	$ 305	$ (3,902)	$ (7,410)
Basic and diluted earnings (loss) per share	$ (0.03)	$ 0.02	$ 0.01	$ (0.13)	$ (0.32)
Average shares outstanding:					
Basic	30,025	29,826	29,696	29,248	23,266
Diluted	30,025	30,414	29,784	29,248	23,266

	As of December 31,				
	2004	2003	2002	2001	2000
Balance Sheet Data:					
Working capital	$10,658	$7,405	$ 6,470	$ 5,785	$ 5,010
Total assets	13,327	9,849	10,328	12,298	15,078
Secured borrowings, long-term	—	—	408	1,446	3,079
Stockholders' equity	6,829	7,556	6,725	6,310	6,216

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

Overview

We are a medical device company specializing in innovative technologies for the cardiac and vascular markets. We currently manufacture two lasers that are used in the treatment of cardiovascular disease. Our Heart Laser Systems are used to treat patients with severe angina and the Optiwave 980 System, when commercially introduced, is expected to be used to ablate cardiac tissue as a means to treat certain heart arrhythmias.

Edwards is our exclusive worldwide distributor for all surgical cardiac ablation products and, in the United States, acts as our exclusive distributor for TMR products. Edwards is our largest customer, accounting for approximately 88% and 89% of our total sales in 2004 and 2003, respectively. We expect this sales trend to continue for the foreseeable future.

Approximately 90% of our revenues in 2004 came from the sale and service of TMR lasers and related disposable kits. Although not a direct measure, we believe a leading indicator of the adoption rate of TMR as a treatment for severe angina is TMR kit shipments to hospitals. TMR kit shipments to hospitals were relatively flat from 2003 to 2004. We remain largely dependent on the success of Edwards' sales and marketing efforts to increase our installed base of TMR lasers and increase TMR procedure volumes and revenues.

Our management reviews a number of key performance indicators to assist them in determining how to allocate resources and run our day to day operations. These indicators include (1) actual prior quarterly sales trends, (2) projected TMR laser and kit sales for the next four quarters, as provided by Edwards in a rolling twelve month sales forecast, (3) research and development progress as measured against internal project plan objectives, (4) budget to actual financial expenditure results, (5) inventory levels (both our own and Edwards') and (6) short term and long term projected cash flows of the business.

Critical Accounting Policies and Estimates

Our financial statements are based on the application of significant accounting policies, many of which require us to make significant estimates and assumptions (see Note 2 to the Consolidated Financial Statements). We believe that the following are some of the more material judgment areas in the application of our accounting policies that currently affect our financial condition and results of operations.

Inventories

Inventories are stated at the lower of cost or market value. A specific obsolescence allowance is provided for slow moving, excess and obsolete inventory based on our best estimate of the net realizable value of inventory on hand taking into consideration factors such as (1) actual trailing twelve month sales, (2) expected future product line demand, based in part on sales forecast input received from Edwards, and (3) service part stocking levels which, in management's best judgment, are advisable to maintain in order to meet warranty, service contract and time and material spare part demands. Historically, we have found our reserves to be adequate.

Allowance for Doubtful Accounts

For our accounts receivable, we continuously monitor collections from customers, our principal customer being Edwards, and we maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues that we have identified. Historically, we have not experienced significant losses related to our accounts receivable. Collateral is not generally required. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Warranty and Preventative Maintenance Costs

We warranty our products against manufacturing defects under normal use and service during the warranty period. We obtain similar warranties from a majority of our suppliers, including those who supply critical Heart Laser System components. In addition, under the terms of our TMR distribution agreement with Edwards, we are able to bill Edwards for actual warranty costs, including preventative maintenance services, up to a specified amount during the warranty period.

We evaluate the estimated future unrecoverable costs of warranty and preventative maintenance services for our installed base of lasers on a quarterly basis and adjust our warranty reserve accordingly. We consider all available evidence, including historical experience and information obtained from supplier audits.

Revenue Recognition

We record revenue from the sale of TMR kits and Optiwave 980 Systems at the time of shipment to Edwards. TMR kit revenues include the amount invoiced to Edwards for kits shipped pursuant to purchase orders received, as well as an amortized portion of deferred revenue related to Edwards' payment to us of $4,533,333 in February 2004 in exchange for a reduction in the prospective purchase price we receive from Edwards upon a sale of the kits. We expect to amortize this payment from Edwards into our Consolidated Statement of Operations as revenue over a seven year period under the units-of-revenue method as prescribed by Emerging Issues Task Force (EITF) 88-18, *Sales of Future Revenue*. We determined that a seven year timeframe was the most appropriate amortization period based on a valuation model we used to assess the economic fairness of the payment. Factors we considered in developing this valuation model included the estimated foregone revenues over a seven year period resulting from the reduction in the prospective purchase price payable to us by Edwards, a discount rate deemed appropriate to this

transaction and an estimate of the remaining economic useful life of the current TMR kit design, without any benefit being given to potential future product improvements we may make. For the year ended December 31, 2004, we recorded amortization of $183,000.

TMR lasers are billed to Edwards in accordance with purchase orders that we receive. Invoiced TMR lasers are recorded as other current assets and deferred revenue on our consolidated balance sheet until such time as the laser is shipped to a hospital, at which time we record revenue and cost of revenue.

Under the terms of the Edwards TMR distribution agreement, once Edwards has recovered a prescribed amount of revenue from a hospital for the use or purchase of a TMR laser, any additional revenues earned by Edwards are shared with us pursuant to a formula established in the distribution agreement. We only record our share of such additional revenue, if any, at the time the revenue is earned.

We record revenue from the sale of TMR kits and TMR lasers to international distributors or hospitals at the time of shipment.

Prior to entering into the Edwards TMR distribution agreement, we installed TMR lasers in hospitals under placement contracts that did not transfer substantial ownership of the equipment to the customer. Revenues from these transactions are recognized over the life of the placement agreement in accordance with the specific terms of the contract.

Revenues from service and maintenance contracts are recognized ratably over the life of the contract.

Installation revenues related to a TMR laser transaction are recorded as a component of placement and service fees when the laser is installed.

Results of Operations

Results for the past three years and the related percent of revenues were as follows:

	2004		2003		2002	
	$	%	$	%	$	%
			(dollars in thousands)			
Total revenues	$7,573	100.0%	$8,334	100.0%	$8,838	100.0%
Total cost of sales	3,069	40.5	3,343	40.1	4,092	46.3
Gross profit	4,504	59.5	4,991	59.9	4,746	53.7
Selling, general & administrative	3,329	44.0	3,297	39.6	3,626	41.0
Research & development	2,130	28.1	980	11.8	889	10.1
Income (loss) from operations	(955)	(12.6)	714	8.6	231	2.6
Other income	175	2.3	60	0.7	74	0.8
Liquidation of subsidiary:						
Foreign currency loss	—	0.0	(257)	(3.1)	—	0.0
Income (loss) before income taxes	(780)	(10.3)	517	6.2	305	3.4
Provision for income taxes	53	0.7	—	—	—	—
Net income (loss)	$ (833)	(11.0)%	$ 517	6.2%	$ 305	3.4%

	2004	Increase (decrease) over 2003		2003	Increase (decrease) over 2002		2002
	$	$	%	$	$	%	$
	(dollars in thousands)						
Product sales	$5,982	$ (917)	(13)%	$6,899	$(526)	(7)%	$7,425
Placement and service fees	1,591	156	11	1,435	22	2	1,413
Total revenues	7,573	(761)	(9)	8,334	(504)	(6)	8,838
Product cost of sales	2,346	(478)	(17)	2,824	(736)	(21)	3,560
Placement and service fees cost of sales	723	204	39	519	(13)	(2)	532
Total cost of revenues	3,069	(274)	(8)	3,343	749	(18)	4,092
Gross profit	4,504	(487)	(10)	4,991	245	5	4,746
Selling, general & administrative expenses	3,329	32	1	3,297	(329)	(9)	3,626
Research & development expenses	2,130	1,150	117	980	91	10	889
Total operating expenses	5,459	1,182	28	4,277	(238)	(5)	4,515
Liquidation of subsidiary: Foreign currency loss	—	257	(100)	(257)	(257)	—	—
Other income	175	115	192	60	(14)	(19)	74
Income (loss) before income taxes	(780)	(1,297)	(251)	517	212	70	305
Provision for income taxes	53	53	100	—	—	—	—
Net income (loss)	$ (833)	$(1,350)	(261)%	$ 517	$ 212	70%	$ 305

Product Sales

TMR laser revenues, the largest component of product sales in 2004, decreased by $1,020,000, or 23%, as compared to 2003. This decrease is primarily attributable to a $950,000, or 22%, decrease in domestic TMR laser revenues generated through our Edwards sales channel. The $950,000 decline in domestic TMR laser revenues is primarily a result of both a decrease in the number of new TMR laser units sold by Edwards in 2004 (20) compared to 2003 (29) and a lower average domestic selling price on TMR laser sales (down 8% in 2004).

International TMR laser revenues decreased by $70,000, or 46%, in 2004. Although we shipped a greater number of HL1 TMR lasers in 2004 (2) compared to 2003 (1), the lasers we did sell were at a lower average selling price. We believe the HL1 will continue to have some ability to be sold in price sensitive foreign countries; however, we expect the number to be in limited quantities similar to the past two years.

Disposable TMR kit revenues, the second largest component of product sales, decreased by $236,000, or 12%, in 2004 as compared to 2003. The decrease is primarily related to a $143,000, or 8%, decrease in domestic disposable revenue. This $143,000 decrease resulted from a lower volume of kit shipments to Edwards coupled with a reduced share of revenue on TMR kits. The reduced share of revenue on TMR kits is a result of a modification to the TMR distribution agreement in February 2004, whereby the Company's share of the revenue on TMR kits sold to hospitals was reduced from 45% to 36.5% in exchange for a payment by Edwards of $4,533,333. The impact of this reduction to 36.5% compared to what disposable revenue would have been at 45% was a reduction of $327,000 in 2004. This impact was offset in part by the recognition of $183,000 of deferred revenue amortization in 2004 related to the $4,533,333 payment by Edwards.

International disposable revenue decreased by $93,000, or 46%, due to a decrease in the number of TMR kits shipped to international customers in 2004 (125) compared to 2003 (135) and a lower overall average selling price this year on those kits that were sold. The decline in average sale price is the result of a greater number of kits being sold outside the European Union in 2004 compared to 2003. A greater number of the kits sold this year were to countries located in Latin America and the Middle East, where we believe pricing pressures are greater and where we sell through distributors at a discount off of list price.

Optiwave 980 System revenues to Edwards, a new component of product sales in 2004, increased $249,000 as compared to 2003 when we had no such sales.

Other product sales, relating to sales of new and refurbished surgical tubes, increased $90,000, or 20%, in 2004.

TMR laser revenues, the largest component of product sales in 2003, decreased by $905,000, or 17%, as compared to 2002. This decrease is primarily attributable to a $1,035,000, or 19%, decrease in domestic TMR laser revenues generated through our Edwards sales channel. The $1,035,000 decline in domestic TMR laser revenues is primarily attributable to a decrease in the number of new TMR laser units sold by Edwards in 2003 (29) as compared to 2002 (41). This decrease in the number of new TMR lasers sold was offset in part by (1) a higher average domestic selling price on TMR laser sales (up 9% in 2003) and (2) increased revenue sharing on TMR laser transactions earned under the distribution agreement with Edwards.

International laser revenues increased by $130,000, or 565%, in 2003, principally due to the revenue generated from one HL1 laser sale.

Disposable TMR kit revenues, the second largest component of product sales, increased by $623,000, or 45%, in 2003 as compared to 2002. This increase is attributable to an increase in the number of TMR kits shipped to Edwards.

Royalty revenue, a component of product sales, decreased $231,000, or 92%, in 2003 as compared to 2002. This decrease is due to a decline in the guaranteed minimum royalties due from CardioGenesis. Minimum royalties were in effect through June 30, 2002, but ceased thereafter. Although CardioGenesis is required to pay an ongoing royalty on actual sales of covered products after June 30, 2002, we expect that until such time, if ever, that CardioGenesis obtains FDA approval for its PMR device, and provided that device remains a covered product under the terms of the license agreement, royalty revenue will be insignificant.

Other product sales, relating to sales of new and refurbished surgical tubes, decreased $13,000, or 3%, in 2003.

Placement and Service Fees

Placement fees declined $82,000, or 33%, in 2004 as compared to 2003. Domestic placement fees declined $195,000, or 90%, while international placement fees increased $113,000, or 377%. Domestic placement fees are generated from a declining HL1 installed base in the U.S. and totaled only $22,000 in 2004. We believe they will continue to be relatively insignificant to our total revenues in the years ahead. The $113,000 increase in international placement fees is due to a new HL2 placement contact customer in 2004.

Service fees increased $238,000, or 20%, in 2004 as compared to 2003. This increase is primarily attributable to a $196,000, or 18%, increase in domestic service revenues. This increase in domestic service revenues is due to more domestic lasers being in service throughout 2004, which resulted in increased

billings to Edwards for service contracts, installations and other service related calls. International service revenues also increased $42,000, or 50%, compared to 2003.

Placement fees declined $211,000, or 46%, in 2003 as compared to 2002. Approximately $124,000 of this $211,000 decline is attributable to a reduction in domestic placement fees. The $124,000 reduction in domestic placement fees is in part the result of various U.S. HL1 customers upgrading to the newer HL2. Each upgrade results in a laser sale to Edwards and a corresponding shift in recorded disposable TMR kit sales to these new HL2 customers which are recognized as product sales instead of placement fees. The remaining $87,000 reduction in international placement fees was the result of lower contract fees due to decreased kit shipments to international placement contract customers.

Service fees increased $233,000, or 24%, in 2003 as compared to 2002 due to more domestic lasers in service throughout 2003, which resulted in increased billings to Edwards for service contracts, installations and other service related calls.

Gross Profit

Total gross profit was $4,504,000, or 59.5%, of total revenues, for the year ended December 31, 2004 as compared with gross profit of $ 4,991,000, or 59.9%, of total revenues, for the year ended December 31, 2003. The decrease in gross profit dollars in 2004 as compared to 2003 is due to (1) a decrease in the number of new TMR lasers sold, (2) lower disposable TMR revenues, (3) lower revenues on HL1 transactions and (4) a $40,000 decrease in benefit derived from reducing our warranty accrual. These decreases were offset in part by new 2004 product sales of Optiwave 980 Systems and an increase in service related revenues.

Total gross profit was $4,991,000, or 59.9%, of total revenues, for the year ended December 31, 2003 as compared with gross profit of $4,746,000, or 53.7%, of total revenues, for the year ended December 31, 2002. The improvement in gross profit in 2003 as compared to 2002 is due to (1) higher disposable TMR revenues, (2) an increase in service related revenues and (3) higher average selling price and additional shared revenue on laser transactions. These increases were offset in part by (1) lower royalty revenues from CardioGenesis (2) a decrease in the number of new TMR lasers sold, (3) a $136,000 decrease in benefit derived from reducing our warranty accrual and (4) reduced placement fees.

Selling, General and Administrative Expenses

The overall increase in 2004 as compared to 2003 is primarily a result of increased expenditures related to legal fees of $167,000 offset in part by reduced international expenditures of $111,000 due to the closing of our Swiss subsidiary in late 2003 and other general corporate expenditures.

The overall decrease in 2003 as compared to 2002 is primarily a result of reduced expenditures related to compensation, related benefits, depreciation, telephone and general corporate expenditures.

Research and Development Expenses

The largest component of our research and development expenses in the fiscal years ended December 31, 2004, 2003 and 2002 was the salaries and associated fringe benefits paid to our development staff, which amounted to 46%, 64% and 69% of expenditures.

The increased expenditures in 2004 were incurred in connection with the development of the Optiwave 980 System due to increased salaries and associated fringe benefits, project materials and depreciation related to this program and additional product development work on longer term research and development projects. These increases were offset in part by a $56,000 reduction in an accrued liability related to a past clinical trial that we no longer deemed necessary.

We expect to continue to incur significant new research and development expenditures in 2005 in pursuit of our business strategy to broaden and diversify our product portfolio. In particular, we expect our 2005 research and development expenditures to increase in the aggregate approximately $600,000 compared to 2004 as we complete the development of the Optiwave 980 System and advance other longer term research and development projects.

The overall increase in 2003 as compared to 2002 is primarily related to consulting expenditures incurred in conjunction with our investigation and evaluation of new product development opportunities.

Other Income

The largest component of other income is interest income earned on our cash balances. Interest income increased in 2004 due to higher average cash balances.

In 2003, interest income remained relatively consistent compared to 2002. In addition, other income was lower due to a reduction in foreign currency transaction gains realized in our international operations.

Liquidation of Subsidiary—Foreign Currency Loss

In 2003, we decided to close our Swiss subsidiary. In closing that subsidiary, we realized a non-recurring foreign currency translation loss of $257,000 in the year ended December 31, 2003.

Net Income (Loss)

The change from net income in 2003 to a net loss in 2004 resulted primarily from lower gross margin dollars generated on lower overall sales coupled with higher research and development expenses.

The increase in net income in 2003 as compared to 2002 resulted primarily from higher gross margin dollars generated and lower operating expenses, offset by the non-recurring foreign currency translation loss.

In 2004, we recorded a provision for income taxes due to limitations on the utilization of U.S. net operating loss carryforwards being available to reduce taxable income.

There was no provision for income tax for the year ended December 31, 2003 or 2002, despite a recorded net profit of $517,000 and $305,000, respectively, due to the utilization of U.S. net operating loss carryforwards being available to reduce taxable income.

We expect to incur a net loss in 2005, primarily as a result of our planned increased investments in research and development expenses, as discussed above.

Kit Shipments

We view disposable kit shipments to end users as an important metric in evaluating our business. We believe kit shipments, although not a direct measure, are a reasonable indicator for the adoption of TMR as a therapy in the marketplace. Disposable kit shipments to end users are as follows:

	2004	% Increase (Decrease) Over 2003	2003	% Increase (Decrease) Over 2002	2002
Domestic (by Edwards)	1,880	1%	1,866	33%	1,407
International	125	(7)	135	(44)	242
Total	2,005	0	2,001	21%	1,649

We believe the limited growth in domestic kit shipments in 2004 was in part a result of some uncertainty surrounding reimbursement for the TMR procedure that was created when the Centers for Medicare and Medicaid Services (CMS) convened an advisory panel meeting in July 2004 to review and discuss the evidence and clinical data regarding TMR. We believe this uncertainty adversely impacted Edwards' sales. We believe that, following the advisors panel meeting, Medicare decided to leave reimbursement for TMR in place and unchanged.

The limited growth in TMR kit shipments in 2004 may also be partly attributable to what we believe may be an ongoing downward trend in the number of bypass surgeries being performed. We believe the proliferation in the number of interventional cardiac procedures being performed, particularly with the recent advent in the use of drug eluting stents, is causing a delay in the number of patients being referred to cardiac surgeons for treatment of their cardiovascular disease. Because a significant number of the total TMR procedures performed each year by cardiac surgeons are done in combination with bypass surgery, we believe the growth in the number of TMR procedures in 2004 may have been adversely impacted.

We believe the increase in domestic kit shipments in 2003 compared to 2002 is due primarily to (1) an increase in the total number of installed lasers in 2003 and (2) lasers installed and available for only a portion of the 2002 being available to hospitals for all of 2003 to perform TMR procedures. Management believes the decline in international kit shipments in 2003 is primarily due to our limited efforts to drive adoption of TMR in international markets.

Liquidity and Capital Resources

At December 31, 2004, we had cash and cash equivalents of $9,678,000. We have no debt obligations.

During the year ended December 31, 2004, we recorded a net loss of $833,000. The net loss was offset by net favorable working capital changes (primarily an increase in deferred revenue of $4,548,000) which resulted in net cash provided by operating activities of approximately $3,358,000. Cash used in investing activities was approximately $180,000, consisting of the purchase of equipment. Cash provided by financing activities was approximately $95,000, consisting of the proceeds from the exercise of stock options and shares purchased under our employee stock purchase plan. We believe that our existing cash resources will meet our working capital requirements for at least the next 12 months.

We are largely dependent on the success of Edwards' sales and marketing efforts in the U.S. to continue to increase the installed base of HL2 lasers and substantially increase TMR procedural volumes and revenues. Should the installed base of HL2 lasers or TMR procedural volume not increase sufficiently, our liquidity and capital resources will be negatively impacted. Additionally, other unanticipated decreases in operating revenues or increases in expenses or further changes or delays in third-party reimbursement to healthcare providers using our products may adversely impact our cash position and require further cost reductions or the need to obtain additional financing. It is not certain that we, working with Edwards and our international distributors, will be successful in achieving broad commercial acceptance of the Heart Laser Systems, or that we will be able to operate profitably in the future on a consistent basis, if at all.

Some hospital customers prefer to acquire the Heart Laser Systems on a usage basis rather than as a capital equipment purchase. We believe this is the result of limitations many hospitals currently have on acquiring expensive capital equipment as well as competitive pressures in the marketplace. A usage business model likely will result in a longer recovery period for Edwards to recoup its investment in lasers it purchases from us. This could result in (1) a delay in our ability to receive additional shared revenue, if any, that we otherwise are entitled to receive under the terms of our distribution agreement with Edwards (see "Critical Accounting Policies and Estimates—Revenue Recognition") and (2) a delay in the purchase of new lasers by Edwards if its installed base of lasers placed under usage contracts are under-performing and it chooses to re-deploy these lasers to other hospital sites in lieu of purchasing a new laser from us. Our cash position and our need for additional financing to fund operations will be dependent in part upon the number of hospitals that acquire Heart Laser Systems from Edwards on a usage basis and the number and frequency of TMR procedures performed by these hospitals. We cannot predict whether a usage based sales model will be successful, whether implemented by us or Edwards.

Furthermore, we have recently undertaken a new business strategy that involves broadening and diversifying our product portfolio beyond our current TMR offerings, by developing or acquiring new and innovative medical devices to address cardiac and vascular related markets. We believe this strategy will result in our incurring losses for at least the next 12-24 months as we increase our investments in both manufacturing and research and development staff necessary to pursue these new strategic initiatives, including, but not limited to, the Optiwave 980 System. We cannot be certain that we will be successful in implementing our new business strategy or that future sales, if any, from these planned new products will recover the investments we plan to make. If we are unsuccessful in implementing our new business strategy our liquidity and capital resources will be adversely affected and we may need to obtain additional financing.

There can be no assurance that, should we require additional financing, such financing will be available on terms and conditions acceptable to us. Should additional financing not be available on terms and conditions acceptable to us, additional actions may be required that could adversely impact our ability to continue to realize assets and satisfy liabilities in the normal course of business. The consolidated financial statements set forth in this annual report do not include any adjustments to reflect the possible future effects of these uncertainties.

Contractual Obligations

Our long-term contractual commitments consist of operating leases for our two facilities in Billerica and Franklin, Massachusetts and purchase commitments to make payments to suppliers. Our two facility operating leases expire in February 2006 and August 2009, respectively. Future annual minimum payments for these contractual obligations are as follows:

	Payment due by period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
		(dollars in thousands)			
Operating Lease Obligations	$1,270	$ 318	$515	$437	—
Purchase Obligations	967	967	—	—	—
Total	$2,237	$1,285	$515	$437	—

Off-Balance Sheet Arrangements

None.

Certain Factors that May Affect our Future Results

The risks and uncertainties described below are not the only risks we face. Additional risks and uncertainties not presently known to us or currently deemed immaterial may also impair our business operations. If any of the following risks actually occur, our financial condition and operating results could be materially adversely affected.

We expect to incur significant operating losses in the near future

We incurred a net loss of $833,000 for the year ended December 31, 2004. We expect to continue to incur net losses for at least the next 12-24 months as we increase our spending in the areas of manufacturing and research and development for the Optiwave 980 System and other strategic research and development programs. Moreover, as we continue to pursue our new business strategy of acquiring or developing new medical devices to address cardiac and vascular related markets, we may continue to incur expenses that exceed the revenues we generate. We cannot provide any assurance that we will be successful with our new business strategy or that we will ever return to profitability.

Our company is currently dependent on one principal product line to generate revenues

We currently market one product line, which consists of two patented high-powered carbon dioxide lasers and related TMR disposable kits known as the Heart Laser Systems, which account for the majority of our total revenue. Approximately 90% and 95%, of our revenues in the years ended December 31, 2004 and December 31, 2003, respectively, were derived from the sales and service of our Heart Laser Systems. This absence of a diversified product line means that we are directly and materially impacted by changes in the market for Heart Laser Systems.

Our company is dependent on one principal customer

Pursuant to the terms of our TMR distribution agreement with Edwards, Edwards is our exclusive distributor for our HL2 TMR laser and TMR kits in the United States. In addition, pursuant to the terms of our new distribution agreement with Edwards for the Optiwave 980 System (as well as any other additional surgical products that we may develop for the treatment of AF), Edwards is our exclusive worldwide distributor of those products. As a result of these exclusive distribution arrangements, Edwards accounted for 88% and 89% of our total revenue in the years ended December 31, 2004 and December 31, 2003, respectively, and we expect Edwards to account for the significant majority of our revenue in the

future. If our relationship with Edwards does not progress as anticipated, or if Edwards' sales and marketing strategies fail to generate sales of our products in the future, our revenue will decrease significantly and our business, financial condition and results of operations will be seriously harmed.

Our company is dependent on certain suppliers

Some of the components for our Heart Laser Systems, most notably the power supply and certain optics and fabricated parts for the HL2, and certain components for the Optiwave 980 System, are only available from one supplier, and we have no assurance that we will be able to source any of our sole-sourced components from additional suppliers. We are dependent upon our sole suppliers to perform their obligations in a timely manner. In the past, we have experienced delays in product delivery from our sole suppliers and, because we do not have an alternative supplier to produce these products for us, we have little leverage to enforce timely delivery. Any delay in product delivery or other interruption in supply from these suppliers could prevent us from meeting our commercial demands for our products, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, we do not require significant quantities of any components because we produce a limited number of our products each year. Our low-quantity needs may not generate substantial revenue for our suppliers. Therefore, it may be difficult for us to continue our relationships with our current suppliers or establish relationships with additional suppliers on commercially reasonable terms, if at all, and such difficulties may seriously harm our business, financial condition and results of operations.

Edwards must successfully complete their marketing evaluations of the Optiwave 980 System before they commit to launch the product

Edwards is currently conducting marketing evaluations of the Optiwave 980 System at hospitals across the country. Edwards must complete these marketing evaluations and judge them to be successful before they will commit to launch the product into the market. Although we believe the evaluations of the product to date have been positive and we expect to begin manufacturing of the Optiwave disposable handpieces in the second half of 2005, we cannot assure you that Edwards will successfully complete these marketing evaluations of the Optiwave 980 System or that they will not decide to cancel the program in the future. Should Edwards decide for whatever reason not to market the Optiwave 980 System, our revenue growth prospects, financial condition and results of operations will be materially and adversely affected.

We must transition manufacturing of the Optiwave 980 disposable handpieces from Edwards and be able to manufacture them in required volumes at commercially reasonable costs

Assuming Edwards successfully completes their marketing evaluations of the Optiwave 980 System, we must successfully transition production of the Optiwave 980 disposable handpieces to our leased manufacturing space in Billerica, Massachusetts. We must hire new skilled manufacturing employees and we must develop and validate our manufacturing processes with respect to building these disposable handpieces. We expect to incur expenses to outfit our manufacturing space with the necessary production and test equipment and to train our employees on how to build the product. We will need to be able to manufacture these highly specialized disposable handpieces for which we have no comparable prior experience producing at any volume. Until such time as we become more proficient in these manufacturing methods, if ever, we may encounter problems, including those related to:

- production yields;
- quality control;
- training;
- shortages of qualified personnel; and
- potential capacity constraints.

Such problems could severely affect our ability to adequately scale up production and meet demand for our products on a timely basis, which could harm our business, financial condition and results of operations.

We are dependent upon our key personnel and will need to hire additional key personnel in the near future

Our ability to operate our business successfully depends in significant part upon the retention and motivation of certain key technical, regulatory, production and managerial personnel and consultants and our ongoing ability to hire and retain additional qualified personnel in these areas. Competition for such personnel is intense, particularly in the Greater Boston area. We cannot be certain that we will be able to attract such personnel and the loss of any of our current key employees or consultants could have a significant adverse impact on our business.

Our company may be unable to raise needed funds

As of December 31, 2004, we had cash and cash equivalents totaling $9,678,000. Based on our current operating plan, we anticipate that our existing capital resources should be sufficient to meet our working capital requirements for at least the next 12 months. However, if our business does not progress in accordance with our current business plan, we may need to raise additional funds in the future. We may not be able to raise additional capital upon satisfactory terms, or at all, and our business, financial condition and results of operations could be materially and adversely affected. To the extent that we raise additional capital by issuing equity or convertible securities, ownership dilution to our shareholders will result. To the extent that we raise additional capital through the incurrence of debt, our activities may be restricted by the repayment obligations and other restrictive covenants related to the debt.

In order to compete effectively, our current and future products need to gain commercial acceptance

TMR and surgical ablation for cardiac arrhythmias are still both emerging technologies. Our current and planned future products may never achieve widespread commercial acceptance. To be successful, we need to:

- demonstrate to the medical community in general, and to heart surgeons and cardiologists in particular, that TMR and surgical tissue ablation for cardiac arrhythmias are procedures that are effective, relatively safe and cost effective;
- support third-party efforts to document the medical processes by which TMR procedures relieve angina and surgical tissue ablation cures cardiac arrhythmias;
- have more heart surgeons trained to perform TMR procedures using the Heart Laser Systems and surgical tissue ablation procedures using the Optiwave 980 System; and
- maintain and expand third-party reimbursement for the TMR procedure.

To date, only a limited number of heart surgeons have been trained in the use of TMR using the Heart Laser Systems and cardiac tissue ablation procedures using the Optiwave 980 System. We are dependent on Edwards to expand related marketing and training efforts in the U.S. for the use of our current and planned future products.

Although the Heart Laser Systems have received FDA approval and the CE Mark, they have not yet received widespread commercial acceptance. We believe that concerns over the lack of a consensus view on the reason or reasons why a TMR procedure relieves angina in patients who undergo the procedure has limited demand for and use of the Heart Laser Systems. Until there is consensus, if ever, of the medical processes by which TMR procedures relieve angina, we believe some hospitals may delay the implementation of a TMR program.

In addition, although the Optiwave 980 System has received FDA clearance, it has not yet secured the CE Mark and it is therefore not yet ready for worldwide commercialization. If we are unable to maintain regulatory clearances, secure the CE Mark for the Optiwave 980 System or achieve widespread commercial acceptance of the Heart Laser Systems or the Optiwave 980 System, our business, financial condition and results of operations will be materially and adversely affected.

Our competitor in TMR may obtain FDA approval to market a new device, the impact of which is uncertain on the future adoption rate of TMR

Our primary TMR competitor, CardioGenesis, is attempting to obtain FDA approval to market their "percutaneous" method of performing myocardial revascularization, previously known as PMR, and recently rebranded as PMC (percutaneous myocardial channeling), which would provide a less invasive method of creating channels in the heart. If PMC can be shown to be safe and effective and is approved by the FDA, it would eliminate the need in certain patients to make an incision in the chest, reducing costs and speeding recovery. It is unclear what impact, if any, an approval of a PMC device would have on the future adoption rate for TMR procedures. If PMC is approved, it could erode the potential TMR market which would have a material adverse effect on our business, financial condition and results of operations.

Rapid technological changes in our industry could make our products obsolete

Our industry is characterized by rapid technological change and intense competition. New technologies and products and new industry standards will develop at a rapid pace, which could make our current and future planned products obsolete. The advent of new devices and procedures and advances in new drugs and genetic engineering are especially concerning competitive threats. Our future success will depend upon our ability to develop and introduce product enhancements to address the needs of our customers. Material delays in introducing product enhancements may cause customers to forego purchases of our products and purchase those of our competitors.

Many potential competitors have substantially greater financial resources and are in a better financial position to exploit marketing and research and development opportunities. In addition, we are aware that other companies are developing or already have developed proprietary systems for the treatment of cardiac arrhythmias, and specifically AF, that may be safer, clinically more effective, easier and more cost effective to use and, in the case of percutaneous devices, less invasive than the system we are developing.

We must receive and maintain government clearances or approvals in order to market our products

Our products and our manufacturing activities are subject to extensive, rigorous and changing federal and state regulation in the U.S. and to similar regulatory requirements in other major international markets, including the European Union and Japan. These regulations and regulatory requirements are broad in scope and govern, among other things:

- product design and development;
- product testing;
- product labeling;
- product storage;
- premarket clearance and approval;
- advertising and promotion; and
- product sales and distribution.

Furthermore, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, Quality Systems regulations, and recordkeeping requirements. The FDA's Quality Systems regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Edwards, our distributor, depending on its activities, is also subject to certain requirements under the FDC Act and the regulations promulgated thereunder, and state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies that could affect our regulatory responsibilities or the regulatory responsibilities of a distributor like Edwards. We may be slow to adapt or may not be able to adapt to these changes or new requirements.

Later discovery of previously unknown problems with our products, manufacturing processes, or our failure to comply with applicable regulatory requirements may result in enforcement actions by the FDA and other international regulatory authorities, including, but not limited to:

- warning letters;
- patient or physician notification;
- restrictions on our products or manufacturing processes;
- voluntary or mandatory recalls;
- product seizures;
- refusal to approve pending applications or supplements to approved applications that we submit;
- refusal to permit the import or export of our products;
- fines;
- injunctions;
- suspension or withdrawal of marketing approvals or clearances; and
- civil and criminal penalties.

Should any of these enforcement actions occur, our business, financial condition and results of operations could be materially and adversely affected.

To date, we have received the following regulatory approvals for our products:

Heart Laser Systems

United States—We received FDA approval to market the HL1 Heart Laser System in August 1998 and the HL2 Heart Laser System in January 2001. However, although we have received FDA approval, the FDA:

- has restricted the use of the Heart Laser Systems by not allowing us to market these products to treat patients whose condition is amenable to conventional treatments, such as heart bypass surgery, stenting and angioplasty; and
- could impose additional restrictions or reverse its ruling and prohibit use of the Heart Laser Systems at any time.

Europe—We received the CE Mark from the European Union for the HL1 and HL2 in March 1995 and February 2001, respectively. However:

- the European Union could impose additional restrictions or reverse its ruling and prohibit use of the Heart Laser Systems at any time; and
- France has prohibited, and other European Union countries could prohibit or restrict, use of the Heart Laser Systems.

Japan—We cannot market our product in Japan until we receive government approval.

Prior to marketing the Heart Laser Systems in Japan, we must receive approval from the Japanese government. This approval requires a clinical study in Japan with at least 60 patients. A study was completed in 1998 with the HL1. Although the results of this study have been submitted to the Japanese government, we do not know whether the clinical study will be sufficient or when, if ever, we will receive approval to sell the HL1 in Japan. In addition, it is unclear what impact the introduction of the HL2 into the U.S. and other international markets will have on our ability to market the HL1 in Japan.

Optiwave 980 System

United States—The FDA has given clearance to the Optiwave 980 System through the 510(k) premarket notification process with indications for use as a surgical instrument for coagulation of soft tissue, including cardiac tissue, in conjunction with or without endoscopic equipment in the contact or non-contact mode in open or closed surgical procedures.

Although we have received clearance from the FDA only for the indications of use stated above, physicians, under the practice of medicine exception, may use the Optiwave 980 System in any manner they choose in treating an individual patient, including using the device to treat patients with AF. However, neither we nor Edwards have conducted any clinical trials designed to obtain data to submit to the FDA for the purpose of obtaining a specific indication for use of the Optiwave 980 System that would allow us to make claims or otherwise market this device for the treatment of AF. We are aware of at least one company which has indicated they have submitted data to the FDA in support of a labeling claim that, if clearance is obtained, would allow them to market their device for the treatment of AF.

In the event this company or other competitors are successful in obtaining specific indications of use for their devices in the treatment of AF, the Optiwave 980 System may be at a competitive marketing disadvantage until such time, if ever, that Edwards conducts a clinical trial, submits sufficient data to the FDA by means of a new 510(k) and obtains clearance to market the Optiwave 980 System for the treatment of AF. We cannot provide any assurance that Edwards will ever conduct such a clinical trial or, if they do, that the data they obtain and submit to the FDA will be sufficient for the FDA to expand the current indications of use and provide clearance for the Optiwave 980 System to be marketed for the treatment of AF. Also, we cannot assure you that even if such clearance is obtained, that it will be obtained in a timely enough fashion for our products to remain competitive in the marketplace.

Europe—The Optiwave 980 System cannot be marketed in the EU until such time as it receives CE Mark approval. We need to complete and submit the relevant technical documentation to the appropriate certifying body in order to be able to apply the CE Mark that, if granted, will enable the product to be distributed in the EU.

Changes in third party reimbursement for our TMR procedure could materially affect future demand for our TMR products

Currently, Medicare and Blue Cross Blue Shield provide coverage for TMR when it is performed as both a sole therapy treatment and when used as an adjunct to bypass surgery. Certain other private insurance companies and health maintenance organizations also currently provide reimbursement for these TMR procedures performed with our products, and physician reimbursement codes have been established for both surgical procedures; however, we have limited data as to the breadth of this coverage for the TMR procedures by private insurance companies and health maintenance organizations. Should third party insurance reimbursement for our TMR products be reduced or eliminated in the future, our business, financial condition and results of operations would be materially and adversely affected.

In July 2004, CMS convened the Medicare Coverage Advisory Committee (MCAC) to review and discuss the evidence and clinical data regarding TMR. The MCAC is an advisory panel consisting of clinicians and other medical experts which CMS utilizes to supplement their own internal expertise. Although the MCAC was not convened for the purpose of making a reimbursement coverage recommendation, we believe CMS has reviewed the information presented at the MCAC meeting and has decided to continue existing Medicare coverage for TMR without any modification. No assurance can be given that CMS will not choose to alter Medicare coverage in the future, which could include (1) issuing new guidelines clarifying the patient criteria for Medicare reimbursement, (2) reducing, modifying or eliminating the existing reimbursement coverage for TMR or (3) requesting additional clinical studies to be performed.

Asserting and defending intellectual property rights may impact our results of operations

In our industry, competitors often assert intellectual property infringement claims against one another. The success of our business depends on our ability to successfully defend our intellectual property. Future litigation may have a material impact on our financial condition even if we are successful in marketing our products. We may not be successful in defending or asserting our intellectual property rights.

An adverse outcome in any litigation or interference proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. In addition, a finding that any of our intellectual property is invalid could allow our competitors to more easily and cost-effectively compete with us. Thus, an unfavorable outcome in any patent litigation or interference proceeding could have a material adverse effect on our business, financial condition or results of operations.

The cost to us of any patent litigation or interference proceeding could be substantial. Uncertainties resulting from the initiation and continuation of patent litigation or interference proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and interference proceedings may also absorb significant management time.

We may be subject to product liability lawsuits; our insurance may not be sufficient to cover damages

We may be subject to product liability claims. Such claims may absorb significant management time and could degrade our reputation and the marketability of our products. If product liability claims are made with respect to our products, we may need to recall the implicated product which could have a material adverse effect on our business, financial condition and results of operations. In addition, although we maintain product liability insurance, we cannot be sure that our insurance will be adequate to cover potential product liability lawsuits. Our insurance is expensive and in the future may not be available on acceptable terms, if at all. If a successful product liability claim or series of claims exceeds our insurance

coverage, it could have a material adverse effect on our business, financial condition and results of operations.

We are subject to risks associated with international operations

A portion of our product sales are generated from operations outside of the U.S. Establishing, maintaining and expanding international sales can be expensive. Managing and overseeing foreign operations are difficult and products may not receive market acceptance. Risks of doing business outside the U.S. include, but are not limited to, the following: agreements may be difficult to enforce and receivables difficult to collect through a foreign country's legal system; foreign customers may have longer payment cycles; foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade; U.S. export licenses may be difficult to obtain; and the protection of intellectual property rights in foreign countries may be more difficult to enforce. There can be no assurance that our international business will grow or that any of the foregoing risks will not result in a material adverse effect on our business or results of operations.

Because we are incorporated in Canada, you may not be able to enforce judgments against us and our Canadian directors

Under Canadian law, you may not be able to enforce a judgment issued by courts in the U.S. against us or our Canadian directors. The status of the law in Canada is unclear as to whether a U.S. citizen can enforce a judgment from a U.S. court in Canada for violations of U.S. securities laws. A separate suit may need to be brought directly in Canada.

Our stock price has historically fluctuated and may continue to fluctuate significantly in the future which may result in losses for our investors

Our stock price has been and may continue to be volatile. Some of the factors that can affect our stock price are:

- the announcement of new products, services or technological innovations by us or our competitors;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- speculation or actual news announcements in the media or industry trade journals about our company, our products, the TMR or cardiac ablation procedures or changes in reimbursement policies by Medicare and/or private insurance companies;
- announcements relating to strategic relationships or mergers;
- conditions or trends in the medical device industry;
- changes in the economic performance or market valuations of other medical device companies; and
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance.

The market price of our stock may fall if shareholders sell their stock

Certain current shareholders hold large amounts of our stock, which they could sell in the public market from time to time. Sales of a substantial number of shares of our common stock within a short period of time could cause our stock price to fall. In addition, the sale of these shares could impair our ability to raise capital through the sale of additional stock.

We have no intention to pay dividends

We have never paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not expect to pay any dividends in the foreseeable future.

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

A portion of our operations consists of sales activities in foreign jurisdictions. We manufacture our products exclusively in the U.S. and sell our products in the U.S. and abroad. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in exchange rates between the U.S. dollar and foreign currencies, especially the Euro. When the U.S. dollar strengthens against the Euro, the value of foreign sales decreases. When the U.S. dollar weakens, the functional currency amount of sales increases. No assurance can be given that foreign currency fluctuations in the future may not adversely affect our business, financial condition and results of operations, although at the present we do not believe that our exposure is significant as international sales represented only 6% of our consolidated sales in 2004. We do not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates.

Our interest income and expense are sensitive to changes in the general level of U.S. and foreign interest rates. In this regard, changes in U.S. and foreign interest rates affect the interest earned on our cash and cash equivalents. We do not believe that a 10% change to the applicable interest rates would have a material impact on our future results of operations or cash flows.

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

All financial statements and other information required to be filed hereunder are filed as Appendix A hereto, are listed under Item 15(a) and are incorporated herein by reference.

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

Not applicable.

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

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2004. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2004, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

On March 23, 2005, the Compensation Committee of our Board of Directors adopted bonus arrangements for our executive officers for 2005. Mark R. Tauscher, our President and Chief Executive Officer, James G. Thomasch, our Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer, Michael F. Adams, our Vice President, New Ventures, Kenneth J. Luppi, our Vice President, Operations and Development, and Robert I. Rudko, our Chief Scientist, will receive a bonus based one-third on the profitability of our TMR business and two-thirds on the attainment of defined program milestones during the fiscal year ending December 31, 2005. The target bonus payment for Mr. Tauscher is 50% of his base salary, for Mr. Thomasch is 40% of his base salary, and for Messrs. Adams and Luppi and Dr. Rudko is 30% of each of their respective base salaries. The target bonus payments may be adjusted downwards if the profitability of our TMR business does not meet the targets or we do not attain the defined program milestones.

PART III

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

The information required by this item is incorporated herein by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2005 Annual Meeting of Shareholders (referred to as our Definitive Proxy Statement) under the caption "Item No. 1—Election of Directors".

We have adopted a code of ethics that applies to all employees, including our principal executive officer, principal financial officer and principal accounting officer. We undertake to provide a copy of our code of ethics to any person without charge, upon request to PLC Systems Inc., c/o Chief Financial Officer, 10 Forge Park, Franklin, Massachusetts 02038. We intend to disclose waivers and amendments of provisions of the code, if any, for our principal executive officer, principal financial officer and principal accounting officer and that relates to any element of the code of ethics definition enumerated in applicable SEC rules by posting such information, if any, on our Internet website, *www.plcmed.com*.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "Item No. 1—Election of Directors". The information specified in Item 402(k) and (1) of Regulation S-K and set forth in our Definitive Proxy Statement is not incorporated herein by reference.

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

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the captions "Securities Authorized for Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management".

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

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "Certain Relationships and Related Transactions".

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

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "Principal Accountant Fees and Services".

PART IV

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

(a) *Financial Statements.* The following documents are filed as Appendix A hereto and are included as part of this annual report on Form 10-K.

All other schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

(b) *Exhibits.*

The exhibits filed as part of this annual report on Form 10-K are set forth on the Exhibit Index immediately preceding such exhibits, and are incorporated herein by reference.

(c) *Financial Statement Schedules.*

See Item 15(a) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLC SYSTEMS INC.

Date: March 25, 2005

By: /s/ MARK R. TAUSCHER
Mark R. Tauscher
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ MARK R. TAUSCHER Mark R. Tauscher	President and Chief Executive Officer (Principal Executive Officer)	March 25, 2005
/s/ JAMES G. THOMASCH James G. Thomasch	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 25, 2005
/s/ EDWARD H. PENDERGAST Edward H. Pendergast	Chairman of the Board of Directors	March 25, 2005
/s/ DONALD E. BOBO Donald E. Bobo	Director	March 25, 2005
/s/ KEVIN J. DUNN Kevin J. Dunn	Director	March 25, 2005
/s/ BENJAMIN HOLMES Benjamin Holmes	Director	March 25, 2005
/s/ ALAN H. MAGAZINE Alan H. Magazine	Director	March 25, 2005
/s/ H.B. BRENT NORTON, M.D. H.B. Brent Norton, M.D.	Director	March 25, 2005
/s/ ROBERT I. RUDKO, PH.D. Robert I. Rudko, Ph.D.	Director	March 25, 2005

APPENDIX A

PLC SYSTEMS INC.
CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2004, 2003 and 2002

PLC SYSTEMS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
PLC Systems Inc.

We have audited the accompanying consolidated balance sheets of PLC Systems Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of PLC Systems Inc. at December 31, 2004 and 2003, and the consolidated results of its operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 10, 2005

PLC SYSTEMS INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2004 and 2003

	2004	2003
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,678	$ 6,377
Accounts receivable—Edwards	1,144	1,101
Accounts receivable—other, net of allowance of $104 and $115 in 2004 and 2003, respectively	261	138
Inventories, net	1,112	885
Prepaid expenses and other current assets	592	490
Lease receivables	—	376
Total current assets	12,787	9,367
Equipment, furniture and leasehold improvements, net	293	206
Other assets	247	276
Total assets	$ 13,327	$ 9,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 328	$ 297
Accrued compensation	430	376
Accrued other	301	358
Deferred revenue—Edwards	999	524
Deferred revenue—other	71	31
Secured borrowings	—	376
Total current liabilities	2,129	1,962
Deferred revenue—Edwards	4,181	143
Deferred revenue—other	188	188
Total long-term liabilities	4,369	331
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, unlimited shares authorized, none issued and outstanding		
Common stock, no par value, unlimited shares authorized, and 30,068 and 29,896 shares issued and outstanding in 2004 and 2003, respectively	93,731	93,636
Accumulated deficit	(86,582)	(85,749)
Accumulated other comprehensive loss	(320)	(331)
Total stockholders' equity	6,829	7,556
Total liabilities and stockholders' equity	$ 13,327	$ 9,849

The accompanying notes are an integral part of the consolidated financial statements.

PLC SYSTEMS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For The Years Ended December 31, 2004, 2003 and 2002

	2004	2003	2002
	(In thousands, except per share data)		
Revenues:			
Product sales—Edwards	$ 5,328	$ 6,123	$ 6,505
Product sales—other	654	776	920
Placement and service fees—Edwards	1,322	1,328	1,099
Placement and service fees—other	269	107	314
Total revenues	7,573	8,334	8,838
Cost of revenues:			
Product sales—Edwards	1,987	2,551	3,379
Product sales—other	359	273	181
Placement and service fees—Edwards	556	513	532
Placement and service fees—other	167	6	—
Total cost of revenues	3,069	3,343	4,092
Gross profit	4,504	4,991	4,746
Operating expenses:			
Selling, general and administrative	3,329	3,297	3,626
Research and development	2,130	980	889
Total operating expenses	5,459	4,277	4,515
Income (loss) from operations	(955)	714	231
Other income (expense):			
Liquidation of subsidiary: foreign currency loss	—	(257)	—
Other income, net	175	60	74
Income (loss) before income taxes	(780)	517	305
Provision for income taxes	53	—	—
Net income (loss)	$ (833)	$ 517	$ 305
Basic and diluted earnings (loss) per share	$ (0.03)	$ 0.02	$ 0.01
Average shares outstanding:			
Basic	30,025	29,826	29,696
Diluted	30,025	30,414	29,784

The accompanying notes are an integral part of the consolidated financial statements.

PLC SYSTEMS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For The Years Ended December 31, 2004, 2003 and 2002

	Common Stock		Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Deficit	Loss	Total
			(In thousands)		
Balance, December 31, 2001	29,527	$93,419	$(86,571)	$(538)	$6,310
Exercise of stock options	185	129	—	—	129
Issuance of common stock	86	38	—	—	38
Comprehensive income:					
Net income	—	—	305	—	305
Foreign currency translation	—	—	—	(57)	(57)
Total comprehensive income					248
Balance, December 31, 2002	29,798	$93,586	$(86,266)	$(595)	$6,725
Exercise of stock options	19	10	—	—	10
Issuance of common stock	79	40	—	—	40
Comprehensive income:					
Net income	—	—	517	—	517
Foreign currency translation, including $257 of realized foreign currency losses	—	—	—	264	264
Total comprehensive income					781
Balance, December 31, 2003	29,896	$93,636	$(85,749)	$(331)	$7,556
Exercise of stock options	159	86	—	—	86
Issuance of common stock	13	9	—	—	9
Comprehensive income:					
Net loss	—	—	(833)	—	(833)
Foreign currency translation	—	—	—	11	11
Total comprehensive income					(822)
Balance, December 31, 2004	30,068	$93,731	$(86,582)	$(320)	$6,829

The accompanying notes are an integral part of the consolidated financial statements.

PLC SYSTEMS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For The Years Ended December 31, 2004, 2003 and 2002

	2004	2003	2002
		(In thousands)	
Operating activities:			
Net income (loss)	$ (833)	$ 517	$ 305
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	122	122	211
Foreign currency loss on liquidation of subsidiary	—	257	—
Change in assets and liabilities:			
Accounts receivable—Edwards	(43)	119	949
Accounts receivable—other	(134)	(13)	248
Inventory	(226)	22	89
Prepaid expenses and other assets	(102)	(120)	(149)
Accounts payable	30	(104)	(571)
Deferred revenue—Edwards	4,514	258	20
Deferred revenue—other	34	20	16
Accrued liabilities	(4)	(471)	(181)
Net cash provided by operating activities	3,358	607	937
Investing activities:			
Purchase of equipment	(180)	(91)	(2)
Net cash used for investing activities	(180)	(91)	(2)
Financing activities:			
Net proceeds from sales of common shares	95	50	167
Secured borrowings	—	(137)	(121)
Net cash provided by (used for) financing activities	95	(87)	46
Effect of exchange rate changes on cash and cash equivalents	28	16	(26)
Net increase in cash and cash equivalents	3,301	445	955
Cash and cash equivalents at beginning of year	6,377	5,932	4,977
Cash and cash equivalents at end of year	$9,678	$6,377	$5,932

The accompanying notes are an integral part of the consolidated financial statements.

1. *Business*

PLC Systems Inc. ("PLC" or the "Company") is a medical device company specializing in innovative technologies for the cardiac and vascular markets. The Company currently manufactures two lasers that are used in the treatment of cardiovascular disease. PLC pioneered the *CO_2 Heart Laser System* ("The Heart Laser System") that cardiac surgeons use to perform carbon dioxide (CO_2) transmyocardial revascularization ("TMR") to alleviate symptoms of severe angina. In addition, PLC is completing the development of and manufacturing the Optiwave 980 cardiac laser ablation system ("Optiwave 980 System") under an agreement with Edwards Lifesciences LLC ("Edwards"). Following commercial release, the Optiwave 980 System is expected to be utilized by surgeons to ablate cardiac tissue as a means to treat certain heart arrhythmias.

Edwards is the Company's exclusive worldwide distributor for all surgical cardiac ablation products and, in the United States, acts as the Company's exclusive distributor for TMR products. Edwards is also the Company's largest shareholder, owning approximately 18% of its outstanding common stock as of December 31, 2004, and has a representative on the Board of Directors.

2. *Significant Accounting Policies*

Basis of Presentation

The consolidated financial statements include the accounts of PLC and its two wholly owned subsidiaries, PLC Medical Systems, Inc. and PLC Sistemas Medicos Internacionais (Deutschland) GmbH. During 2003, PLC Medical Systems AG was substantially liquidated resulting in the recognition of $257,000 of foreign currency translation losses. All intercompany accounts and transactions have been eliminated. Certain prior year amounts have been reclassified to conform to the current year's presentation.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents at December 31, 2004 and 2003 consist of investments in money market funds. These investments are carried at cost, which approximates fair value.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing its cash equivalents in high-quality financial instruments

2. Significant Accounting Policies (Continued)

with a high quality institution. At December 31, 2004 and 2003, the majority of the cash and cash equivalents balance was invested in a single financial institution.

The Company has a concentration of credit risk due to its exclusive distributorship arrangements with Edwards. Edwards accounted for 88%, 89% and 87% of the Company's revenues for the years ended December 31, 2004, 2003 and 2002, respectively. Collateral is not required on sales to Edwards.

Concentration of Revenues

Approximately 90%, 95% and 92% of the Company's revenues for the years ended December 31, 2004, 2003 and 2002, respectively, were derived from the sales and service of the Heart Laser System.

Allowance for Doubtful Accounts

For the Company's accounts receivable, the Company continuously monitors collections from customers, its principal customer being Edwards, and maintains a provision for estimated credit losses based upon historical experience and any specific customer collection issues that the Company has identified. Historically, the Company has not experienced significant losses related to its accounts receivable. Collateral is generally not required. If the financial condition of its customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Inventories

Inventories are stated at the lower of cost (computed on a first-in, first-out method) or market value. A specific obsolescence allowance is provided for slow moving, excess and obsolete inventory based on management's best estimate of the net realizable value of inventory on hand taking into consideration factors such as actual trailing twelve month sales, expected future product line sales and estimated required service part stocking levels needed to meet warranty, service contract and time and material spare part demands.

Equipment, Furniture, Leasehold Improvements and Long-Lived Assets

Equipment, fixtures and leasehold improvements are stated on the basis of cost. Depreciation is computed principally on the straight-line method for financial reporting purposes and on accelerated methods for income tax purposes.

Depreciation and amortization are based on the following useful lives:

Equipment	3-5 years
Equipment under placement agreements	Life of contract
Office furniture and fixtures	5 years
Leasehold improvements	Shorter of life of lease or useful life

The Company reviews and evaluates long-lived assets for impairment on a regular basis. In the Company's opinion, long-lived assets are not impaired as of the balance sheet dates presented.

2. *Significant Accounting Policies (Continued)*

Warranty and Preventative Maintenance Costs

The Company warranties its products against manufacturing defects under normal use and service during the warranty period. The Company obtains similar warranties from a majority of its suppliers, including those who supply critical Heart Laser System components. In addition, under the terms of our TMR distribution agreement with Edwards, the Company is able to bill Edwards for actual warranty costs, including preventative maintenance services, up to a specified amount during the warranty period.

The Company evaluates the estimated future unrecoverable costs of warranty and preventative maintenance services for its installed base of lasers on a quarterly basis and adjusts its warranty reserve accordingly. The Company considers all available evidence, including historical experience and information obtained from supplier audits.

Changes in the warranty accrual were as follows (in thousands):

	Year Ended December 31,	
	2004	2003
Balance, beginning of period	$60	$100
Change in liability for warranties issued during the period	4	19
Change in liability for pre-existing warranties	(4)	(59)
Balance, end of period	$60	$ 60

Revenue Recognition

The Company records revenue from the sale of TMR kits and Optiwave 980 Systems at the time of shipment to Edwards. TMR kit revenues include the amount invoiced to Edwards for kits shipped pursuant to purchase orders received, as well as an amortized portion of deferred revenue related to Edwards' payment of $4,533,333 in February 2004. This payment was made by Edwards in exchange for a reduction in the prospective purchase price the Company receives from Edwards upon a sale of the kits (see Note 3). The Company expects to amortize this payment from Edwards into its Consolidated Statement of Operations as revenue over a seven year period under the units-of-revenue method as prescribed by Emerging Issues Task Force (EITF) 88-18, *Sales of Future Revenue*. Management determined that a seven year timeframe was the most appropriate amortization period based on a valuation model they used to assess the economic fairness of the payment. Factors management considered in developing this valuation model included the estimated foregone revenues over a seven year period resulting from the reduction in the prospective purchase price payable to the Company by Edwards, a discount rate deemed appropriate to this transaction and an estimate of the remaining economic useful life of the current TMR kit design, without any benefit being given to potential future product improvements the Company may make. For the year ended December 31, 2004, the Company has recorded amortization of $183,000.

TMR lasers are billed to Edwards in accordance with purchase orders that the Company receives. Invoiced TMR lasers are recorded as other current assets and deferred revenue on the Company's Consolidated Balance Sheet until such time as the laser is shipped to a hospital, at which time the Company records revenue and cost of revenue.

2. Significant Accounting Policies (Continued)

Under the terms of the Edwards TMR distribution agreement, once Edwards has recovered a prescribed amount of revenue from a hospital for the use or purchase of a TMR laser, any additional revenues earned by Edwards are shared with the Company pursuant to a formula established in the distribution agreement. The Company only records its share of such additional revenue, if any, at the time the revenue is earned.

The Company records revenue from the sale of TMR kits and TMR lasers to international distributors or hospitals at the time of shipment.

Prior to entering into the Edwards TMR distribution agreement, the Company installed TMR lasers in hospitals under placement contracts that did not transfer substantial ownership of the equipment to the customer. Revenues from these transactions are recognized over the life of the placement agreement in accordance with the specific terms of the contract.

Revenues from service and maintenance contracts are recognized ratably over the life of the contract.

Installation revenues related to a TMR laser transaction are recorded as a component of placement and service fees when the laser is installed.

Foreign Currency Translation

Assets and liabilities are translated into U.S. dollars at current exchange rates, while income and expense items are translated at average rates of exchange prevailing during the year. Exchange gains and losses arising from translation are accumulated as a separate component of stockholders' equity. During 2003, the liquidation of PLC Medical Systems AG was substantially complete, resulting in the recognition of $257,000 of foreign currency translation losses. Gains and losses from foreign currency transactions are recorded as other income, net, in the accompanying statements of operations and are not material.

Earnings (Loss) per Share

In 2004, basic and diluted loss per share have been computed using only the weighted average number of common shares outstanding during the period without giving effect to any potential future issuances of common stock related to stock option programs and warrants since their inclusion would be antidilutive.

In 2003 and 2002, basic earnings per share have been computed using only the weighted average number of common shares outstanding during the period, while diluted earnings per share was computed using the weighted average number of common shares outstanding during the period plus the effect of outstanding stock options and warrants using the treasury stock method. In calculating diluted earnings per share, the dilutive effect of stock options and warrants is computed using the average market price for the respective period.

2. Significant Accounting Policies (Continued)

For the years ended December 31, 2004 and 2003, 6,170,000 and 3,866,000 shares attributable to outstanding stock options and warrants were excluded from the calculation of diluted earnings per share because the effect was antidilutive. The following table sets forth the computation of basic and diluted earnings per share:

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except per share data)		
Net income (loss) available for common shareholders	$ (833)	$ 517	$ 305
Weighted average outstanding shares of common stock	30,025	29,826	29,696
Dilutive effect of employee stock options and warrants	—	588	88
Common stock and common stock equivalents	30,025	30,414	29,784
Earnings (loss) per share:			
Basic	$ (0.03)	$ 0.02	$ 0.01
Diluted	$ (0.03)	$ 0.02	$ 0.01

Stock Based Compensation

The Company grants stock options for a fixed number of shares to employees and certain other individuals with exercise prices equal to the fair value of the shares at the dates of grant. The Company has adopted the disclosure only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-based Compensation* ("SFAS No. 123"), and will continue to account for its stock option plans in accordance with the provisions of Accounting Principles Board Opinion 25, *Accounting for Stock Issued to Employees* ("APB Opinion No. 25"). Under APB Opinion No. 25, compensation expense with respect to such awards is not recognized if on the date the awards were granted the exercise price was equal to or greater than the fair market value of the underlying common shares.

2. Significant Accounting Policies (Continued)

The following table illustrates the effect on net income (loss) and basic earnings (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except per share data)		
Net income (loss) attributable to common stockholders—As reported	$ (833)	$ 517	$ 305
Deduct total stock-based compensation expense determined under fair value based method for all stock option awards	(470)	(147)	(582)
Net income (loss) attributable to common stockholders—Pro forma	$(1,303)	$ 370	$ (277)
Earnings (loss) per basic and diluted share attributable to common stockholders—As reported	$ (0.03)	$ 0.02	$ 0.01
Earnings (loss) per basic and diluted share attributable to common stockholders—Pro forma	$ (0.04)	$ 0.01	$(0.01)

The fair value of options issued at the date of grant were estimated using the Black-Scholes model with following weighted average assumptions:

	2004	2003	2002
Expected life (years)	3	3	3
Interest rate	1.47%-2.53%	1.59%-2.98%	3.82%
Volatility	.734-.803	.585-.788	.738
Expected dividend yield	None	None	None
Weighted average fair value of options granted during the year	$0.41	$0.25	$0.32

Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payments ("SFAS 123R"), which is a revision of SFAS No. 123. SFAS 123R supersedes APB Opinion No. 25. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. The disclosure only approach permitted by SFAS 123 and elected by the Company, is no longer an alternative. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on the results of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS 123R in prior

2. Significant Accounting Policies (Continued)

periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of Accounting Research Bulletin (ARB) No. 43, Chapter 4* ("SFAS 151"). SFAS 151 amends the guidance in ARB No 43, Chapter 4, *Inventory Pricing*, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current-period charges. In addition, SFAS 151 requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS 151 are effective for fiscal years beginning after June 15, 2005. The Company is currently evaluating the provisions of SFAS 151 and does not believe that its adoption will have a material impact on the Company's financial condition, results of operations or liquidity.

3. Edwards Transaction

In February 2004, the Company signed an agreement with Edwards to assume development of the Optiwave 980 System. Under the terms of the agreement, the Company will have exclusive manufacturing rights to build the Optiwave 980 System and other related surgical products. The Company will be responsible, among other things, for ongoing research and development and manufacture of the product and for obtaining regulatory approvals. Edwards will be responsible for the approval, funding and conduct of any clinical studies designed to obtain data in support of a new product approval or clearance as required by the FDA or other regulatory body.

In conjunction with signing this new agreement, the terms of the Company's TMR distribution agreement with Edwards were modified to (1) extend the term of the agreement until at least October 17, 2017 and (2) reduce the Company's share of revenue on TMR kits sold to hospitals. The Company received as consideration from Edwards, a lump-sum payment of $4,533,333, which initially was recorded as deferred revenue in the Company's Consolidated Balance Sheet. See Note 2, "Revenue Recognition".

4. Inventories

Inventories consist of the following at December 31 (in thousands):

	2004	2003
Raw materials	$ 889	$668
Work in process	130	70
Finished goods	93	147
	$1,112	$885

At December 31, 2004 and 2003, inventories are stated net of a reserve of $528,000 and $806,000, respectively, for potentially obsolete inventory.

5. Equipment, Furniture and Leasehold Improvements

Equipment, furniture and leasehold improvements consist of the following at December 31 (in thousands):

	2004	2003
Equipment	$2,437	$2,256
Equipment under placement agreements	1,176	2,292
Office furniture and fixtures	582	582
Leasehold improvements	346	346
	4,541	5,476
Less accumulated depreciation and amortization	4,248	5,270
	$ 293	$ 206

Depreciation expense was $94,000, $89,000 and $180,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

6. Stockholders' Equity

In January 2001, the Company issued 5,333,333 shares of common stock to Edwards at $.75 per share resulting in net proceeds of approximately $3,898,000. Edwards has certain preemptive rights to maintain their ownership position relative to future stock offerings. The Company also issued 1,000,000 warrants to purchase shares of common stock at $1.50 per share, 1,000,000 warrants to purchase shares of common stock at $2.50 per share, and 1,000,000 warrants to purchase shares of common stock at $3.50 per share. These warrants expire in January 2004, January 2005 and January 2006, respectively. The 1,000,000 warrants due to expire in January 2004 and January 2005 did so unexercised. In connection with this transaction, the Company issued to a financial advisor a warrant to purchase 100,000 shares at $1.00 per share, expiring January 2006.

At December 31, 2004, there were 6,670,675 shares of authorized but unissued common stock reserved for issuance under all stock option plans, the employee stock purchase plan and stock warrants.

The Company has unlimited authorized shares of preferred stock. The Board of Directors is authorized to fix designations, relative rights, preferences and limitations in the preferred stock at the time of issuance.

The Company has never declared nor paid dividends on any of its capital stock and does not expect to do so in the foreseeable future.

7. Stock Option and Stock Purchase Plans

The Company's 1995 Stock Option Plan ("1995 Plan"), 1997 Executive Stock Option Plan ("1997 Executive Plan"), 2000 Employee Stock Purchase Plan ("Purchase Plan"), 2000 Equity Incentive Plan ("2000 Plan"), 2000 Non-Statutory Stock Option Plan ("2000 Non-Statutory Plan") and 2000 Non-Qualified Retention and Performance Equity Plan ("2000 Retention Plan"), collectively referred to as the

7. Stock Option and Stock Purchase Plans (Continued)

"Plans", allow for the granting of options aggregating 4,236,144 shares of common stock. Incentive stock options are issuable only to employees of the Company, while non-qualified options may be issued to non-employee directors, consultants, and others, as well as to employees. The options granted under all the Plans generally become exercisable ratably over one to four years from the date of grant, or based on the attainment of specific performance criteria, and expire ten years from the date of grant.

Annually, the Company grants 15,000 options to each of its non-employee directors who have vested in their initial option grant of 30,000 options. A director must attend at least 60% of all Board meetings, as well as committee meetings, to receive the grant. In addition, the Chairman of the Board receives an annual grant of 30,000 options. The options generally vest either immediately or over one year on a quarterly basis and expire ten years from the date of grant. The exercise price is the fair market value of the Company's common stock on the date of grant.

The per share exercise price of the common stock subject to an incentive stock option may not be less than the fair market value of the common stock on the date the option is granted. The Company must grant non-qualified options at an exercise price of at least 85% of the fair market value of the common stock.

In May 2004, the Company granted new options to purchase 895,000 shares of the Company's common stock to employees and non-employee directors which vested immediately upon granting.

In August 2002, the Company communicated to its domestic employees an offer to exchange certain employee stock options having an exercise price of $.75 or more per share previously granted to them in return for nonqualified stock options of the Company at an exchange ratio of one new option share for one eligible option share surrendered (the "Exchange Offer"). Each employee who accepted the Exchange Offer was required to exchange all option shares subject to each option grant that the employee surrendered for exchange and to forfeit certain stock options granted to him or her on or after February 26, 2002. Generally, the new options granted in this exchange vest on a cumulative basis with one-sixth of the new option vesting on the date the new option was granted and the remaining portion of the new option vesting in five equal installments at the end of each six-month period thereafter.

The Company issued on or about March 26, 2003 new options to purchase 999,345 shares of the Company's Common Stock in exchange for the options surrendered in this option exchange program. Because the new options were granted six months and a day from the cancellation, no compensation expense resulted from the grant of the new options.

7. Stock Option and Stock Purchase Plans (Continued)

The following is a summary of option activity under all Plans (in thousands, except per option data):

	2004	2003	2002
Outstanding at beginning of year	3,346	2,149	3,855
Options canceled upon termination of expired stock option plans	(22)	(90)	(300)
Granted	927	1,378	5
Exercised	(158)	(20)	(185)
Canceled	(23)	(71)	(1,226)
Outstanding at end of year	4,070	3,346	2,149
Exercisable at end of year	3,539	2,258	1,824
Available for grant at end of year	166	1,070	1,387

	2004	2003	2002
Weighted average exercise price:			
Outstanding at beginning of year	$1.51	$2.25	$2.47
Options canceled upon termination of expired stock option plans	$4.63	$4.00	$4.00
Granted	$0.82	$0.53	$0.64
Canceled	$1.15	$1.74	$2.77
Exercised	$0.54	$0.51	$0.62
Outstanding at end of year	$1.38	$1.51	$2.25
Exercisable at end of year	$1.50	$1.97	$2.53

	Range of Exercise Prices		
	$0.45 – $0.90	$1.25 – $3.00	$3.88 – $8.88
Options Outstanding:			
Number (in thousands)	3,172	335	563
Weighted average remaining contractual life (years)	8.01	5.56	2.96
Weighted average exercise price	0.62	2.16	5.19
Options Exercisable:			
Number (in thousands)	2,681	295	563
Weighted average exercise price	0.63	2.27	5.19

The weighted average remaining contractual life of all outstanding options as of December 31, 2004 is 7.11 years.

The Company has an Employee Stock Purchase Plan for all eligible employees. Under the Company's Purchase Plan, shares of the Company's common stock may be purchased at six-month intervals at 85% of the lower of the fair market value on the first or the last day of each six-month period. Employees may purchase shares having a value not exceeding 10% of their gross compensation during an offering period, subject to certain additional limitations. Under the Purchase Plan, employees of the Company purchased 13,390 shares of commons stock in 2004, 78,832 shares of common stock in 2003 and 85,495 shares of

7. Stock Option and Stock Purchase Plans (Continued)

common stock in 2002 at average prices of $0.70, $0.51 and $0.44 per share, respectively. At December 31, 2004, 334,531 shares were reserved for future issuance under the Purchase Plan.

8. Lease Receivables and Secured Borrowings

Prior to 2001, the Company entered into third-party financing arrangements whereby the Company received payment from a leasing company equal to the present value of guaranteed minimum procedure payments due from the customer after customer acceptance of the HL1. In transactions where the Company had transferred substantially all of the risks and rewards of ownership to the customer and the customer had accepted the HL1, the Company recognized revenues, which were reported as a component of product sales. The Company recognized a lease receivable equal to the present value of the guaranteed minimum lease payments until such time as the Company can legally isolate the lease receivables. The payment received from the leasing company was recognized as a secured borrowing. Interest income and interest expense related to the lease receivables and secured borrowing, respectively, are recognized over time using the effective interest method. Equal amounts of interest income and interest expense are included as a component of other income, net in the Consolidated Statement of Operations. All such arrangements had expired as of December 31, 2004.

9. Lease Commitments

The Company leases its corporate office under an operating lease agreement which expires in August 2009. In addition to the minimum lease payments, the agreements require payment of the Company's pro-rata share of property taxes and building operating expenses. The Company also leases additional manufacturing space under an operating lease which expires in February 2006.

As of December 31, 2004, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments
2005	$ 318
2006	260
2007	255
2008	261
2009	176
	$1,270

Total rent expense was $294,000 in 2004, $296,000 in 2003 and $299,000 in 2002.

10. Income Taxes

The provision for income taxes shown in the Consolidated Statement of Operations represents federal income taxes currently payable.

10. Income Taxes (Continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows (in thousands):

	2004	2003
Net U.S. operating loss carryforwards	$ 20,138	$ 20,399
Net foreign operating loss carryforwards	377	460
Accrued expenses and reserves	585	688
Tax credits	1,039	1,005
Other	2,403	617
Total deferred tax assets	24,542	23,169
Valuation allowance	(24,542)	(23,169)
Net deferred tax assets	$ —	$ —

The valuation allowance increased by approximately $1,373,000 in 2004 primarily due to a net loss and an increase in temporary differences associated with deferred revenue in 2004. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset of $24,542,000.

Income (loss) before taxes consisted of the following (in thousands):

	2004	2003	2002
Domestic	$(4,496)	$1,098	$ 638
Foreign	3,663	(581)	(333)
	$ (833)	$ 517	$ 305

The amounts reported above for domestic and foreign income (loss) before taxes include the effects of the write-off of all unsettled intercompany receivables and payables carried on the books of the Company's U.S. and Swiss operating subsidiaries at the time the Swiss operating subsidiary was formally liquidated in 2004. As such, the U.S. operating subsidiary recorded an expense of approximately $3,800,000 and the Swiss operating subsidiary recorded income of the same amount.

Income taxes (benefit) computed at the federal statutory rate differ from amounts provided as follows (in thousands):

	2004	2003	2002
Statutory income tax expense (benefit)	$ (283)	$ 471	$ 267
Utilization of loss carryforwards	(1,398)	(471)	(267)
Unbenefited U.S. losses	1,529	—	—
Unbenefited foreign losses	152	—	—
Benefit for income taxes	$ —	$ —	$ —

10. Income Taxes (Continued)

At December 31, 2004, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately $50 million, which expire at various dates through 2024. In addition, the Company had foreign net operating loss carryforwards of approximately $900,000.

11. Segment Information

The Company operates in one industry segment - the development, manufacture and sales of medical lasers and related products. Net sales to unaffiliated customers (by origin) are summarized below (in thousands):

	North America	Europe	Total
2004			
Net sales	$7,111	$462	$7,573
2003			
Net sales	$7,864	$470	$8,334
2002			
Net sales	$8,420	$418	$8,838

All of the Company's long-lived assets are located in North America.

12. Selected Quarterly Data (unaudited)

	March 31	June 30	September 30	December 31	Total
	(In thousands, except per share data)				
2004					
Total revenue	$1,909	$1,796	$1,606	$2,262	$7,573
Gross profit	1,143	1,049	1,056	1,256	4,504
Income (loss) from operations	(376)	(333)	(446)	200	(955)
Net income (loss)	(350)	(251)	(436)	204	(833)
Earnings (loss) per share, basic and diluted	(0.01)	(0.01)	(0.01)	0.01	(0.03)
2003					
Total revenue	$1,734	$2,011	$2,254	$2,335	$8,334
Gross profit	1,093	1,387	1,247	1,264	4,991
Income (loss) from operations	(4)	192	217	309	714
Net income	15	203	225	74	517
Earnings (loss) per share, basic and diluted	0.00	0.01	0.01	0.00	0.02

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Schedule II

PLC SYSTEMS INC.

Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Additions Charged to Costs and Expenses	Deductions	Balance at End of Period
For the Year Ended December 31, 2004				
Allowance for Doubtful Accounts	$115,000	$ (2,000)	$ 9,000	$104,000
For the Year Ended December 31, 2003				
Allowance for Doubtful Accounts	$192,000	$(14,000)	$63,000	$115,000
For the Year Ended December 31, 2002				
Allowance for Doubtful Accounts	$267,000	$ —	$75,000	$192,000

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EXHIBIT INDEX

Exhibit Number	Description of Document
3.1*	Articles of Continuance, pursuant to the Yukon Business Corporations Act, as amended.
3.2	By-Law No. 1, a By-Law relating generally to the transaction of the business and affairs of PLC Systems Inc., incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 1999, as previously filed with the Securities and Exchange Commission.
4.1	Form of Common Stock Certificate, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-48340) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.1	1993 Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-58258) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.2	1993 Formula Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-58258) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.3	1995 Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-8 (SEC File No. 33-95168), as previously filed with the Securities and Exchange Commission.
10.4	1997 Executive Stock Option Plan, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 1997, as previously filed with the Securities and Exchange Commission.
10.5	2000 Non-qualified Performance and Retention Equity Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
10.6	2000 Non-Statutory Stock Option Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.7	2000 Equity Incentive Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.8	2000 Employee Stock Purchase Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.9	Form of Stock Option Grant Letter to Employees of the Registrant under the Registrant's 1995 Stock Option Plan, 1997 Executive Stock Option Plan, 2000 Equity Incentive Plan and 2000 Non-Qualified Performance and Retention Plan, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004, as previously filed with the Securities and Exchange Commission.
10.10	Form of Stock Option Grant Letter to Non-Employee Directors of the Registrant under the Registrant's 1995 Stock Option Plan, 1997 Executive Stock Option Plan and 2000 Equity Incentive Plan., incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004, as previously filed with the Securities and Exchange Commission.
10.11	Employment Agreement of James G. Thomasch, dated November 4, 1999, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.

Exhibit Number	Description of Document
10.12	Employment Agreement of Mark R. Tauscher, dated December 22, 1999, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
10.13	Terms of Employment dated October 28, 2003 between the Registrant and Dr. Robert I. Rudko, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2003, as previously filed with the Securities and Exchange Commission.
10.14	Amendment dated March 15, 2005 to Terms of Employment between PLC Medical Systems, Inc. and Dr. Robert I. Rudko, incorporated by reference to the Registrant's current report on Form 8-K filed with Securities and Exchange Commission on March 17, 2005.
10.15+	Distribution Agreement, dated January 9, 2001, by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2001, as previously filed with the Securities and Exchange Commission.
10.16	Shareholders Agreement, dated January 9, 2001, by and between the Registrant and Edwards Lifesciences Corporation, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2001, as previously filed with the Securities and Exchange Commission.
10.17	Warrant to Purchase Common Shares dated January 9, 2001, as issued to Edwards Lifesciences Corporation, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2003, as previously filed with the Securities and Exchange Commission.
10.18	Warrant to Purchase Common Shares dated January 9, 2001, as issued to Edwards Lifesciences Corporation, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2003, as previously filed with the Securities and Exchange Commission.
10.19+	Distribution Agreement by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC dated February 24, 2004, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.20+	Contribution, Development and Manufacturing Agreement by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC dated as of February 24, 2004, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.21	First Amendment to Distribution Agreement entered into as of February 24, 2004 by and among Edwards Lifesciences LLC, the Registrant and PLC Medical Systems, Inc., incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.22	First Amendment to Shareholders Agreement entered into as of February 24, 2004 by and between Edwards Lifesciences Corporation and the Registrant, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.23	Common Stock Purchase Warrant dated January 9, 2001, as issued to Prudential Vector Healthcare Group, a unit of Prudential Securities Incorporated, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2003, as previously filed with the Securities and Exchange Commission.
10.24*	Compensatory Arrangements with Executive Officers.
10.25*	Compensatory Arrangements with Non-Employee Directors.
21.1*	Subsidiaries of the Registrant.

Exhibit Number	Description of Document
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed with this annual report on Form 10-K for the year ended December 31, 2004.

+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Shareholder Information

Board of Directors

Edward H. Pendergast
Chairman, PLC Systems Inc.
President, Pendergast & Company

Donald E. Bobo, Jr.
Vice President and General Manager,
Mitral Business Unit, Percutaneous Valve
Intervention Division
Edwards Lifesciences Corporation

Kevin J. Dunn
President and Chief Executive Officer
Adams Harkness, Inc.

Benjamin L. Holmes
President, Holmes & Co.
Former General Manager and
Vice President, Hewlett-Packard
Medical Products Group

Alan H. Magazine
Management Consultant
Former President, Health Industry
Manufacturers Association

H.B. Brent Norton, M.D.
President and Chief Executive Officer,
IMI International Medical
Innovations Inc.

Robert I. Rudko, Ph.D.
Founder and Chief Scientific Officer
PLC Systems Inc.

Mark R. Tauscher
President and Chief Executive Officer
PLC Systems Inc.

Corporate Officers

Mark R. Tauscher
President and Chief Executive Officer

James G. Thomasch
Senior Vice President of
Finance and Administration,
Chief Financial Officer and Treasurer

Michael F. Adams
Vice President, New Ventures

Kenneth J. Luppi
Vice President, Operations

Robert I. Rudko, Ph.D.
Founder and Chief Scientific Officer

Common Stock

The Common Stock of PLC Systems Inc. is traded on the American Stock Exchange under the symbol of PLC.

Annual Meeting

The Annual Meeting of Shareholders of PLC Systems Inc. will be held on Wednesday, May 18, 2005 at 10:00 a.m. at PLC's facility, 10 Forge Park, Franklin, Massachusetts.

Stock Transfer Agent and Registrar

Please contact U.S. Stock Transfer Corporation with inquiries about:

- Address or name changes
- Lost stock certificate
- Stock transfer

U.S. Stock Transfer Corporation
1745 Gardena Avenue
Glendale, CA 91204
(800) 835-8778

Investor Inquiries

John Jordan
Director of Investor Relations
and Corporate Communications
Tel: 508-541-8800, ext. 145
Fax: 508-541-7990

Headquarters

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