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A Story of Recovery

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PLC Systems Inc.
2002 Annual Report

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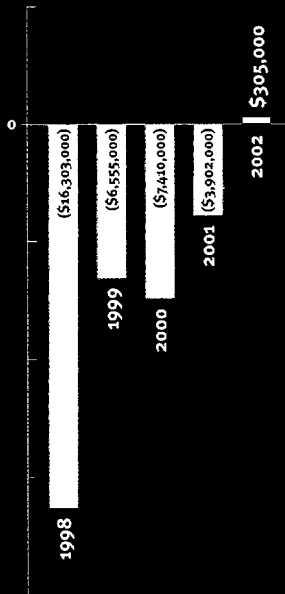
PLC's CO₂ Heart Laser
has treated more than 9,500 angina patients.

The path to profitability

Purpose



PLC Systems Inc.
Net Income (Loss)



*Profitability was
achieved in 2002*

The primary purpose of any business is to create economic value—profit. Along the path to profitability, our business has grown from a novel concept to a proven angina therapy. The journey started in 1988, when company founder—and laser physicist—Dr. Robert Rudko, designed a unique carbon dioxide laser for the treatment of angina in severely debilitated heart patients. This revolutionary therapy is known as Transmyocardial Revascularization (TMR).

Our first angina patient was treated with the CO₂ Heart Laser in 1990. From that early beginning, PLC initiated the clinical trials necessary for U.S. Food & Drug Administration (FDA) approval, which was achieved in 1998. These major accomplishments set the stage for PLC to begin its drive to creating value as a commercial entity.

As TMR has evolved, so has PLC's business model. In 2001, we made the strategic decision to partner our CO₂ Heart Laser technology with Edwards Lifesciences. This alliance has allowed us to concentrate on what we do best—building an unparalleled, high quality product for the global medical market as well as focusing on aspects of the business model that we can best optimize.

PLC's 2002 financial results reflect a significant milestone in our continuing drive to sustained profitability.

Our goals in review

FOCUS

Dear Shareholders,

2002 was a positive year for PLC—in more ways than one. The year started with Edwards Lifesciences exercising their option to assume full sales and marketing responsibility in the United States for our TMR business. In large part because of the savings we realized from this additional commitment to the TMR business by Edwards, we were able to post profitable results for the last three consecutive quarters and the full year of 2002. This year was indeed a positive step forward for TMR and PLC.

As we enter 2003, PLC's management team is completing its third year together. I am very proud of the team's accomplishments. When the new management team came on board, PLC was an undercapitalized company struggling to sell a first generation product that needed improvements. It also was an entity in search of a business model that would enable it to build a sustainable TMR franchise without continuing to lose millions of dollars each year.

From the first day, we focused the company on setting priorities and achieving goals. The first priority was to rapidly finish the development and bring to market our new second-generation CO₂ Heart Laser 2, the HL2. We did this in a remarkably efficient twelve months, which included finishing the pilot development of the product and successfully guiding it through an expedited FDA review.

The next priority was to identify a business model that would reverse the historical pattern previously employed by the company of raising additional capital only to incur ongoing net losses. To succeed in building a profitable business, we felt we needed to focus our efforts on the research, development and manufacturing side of our TMR technology.

This process led us to our next key strategic decision in our early tenure. Although the company's Heart Laser technology is revolutionary, the customer—the cardiac surgeon—was and is a slow adopter of emerging technologies. Faced with this fact, we believed two years ago and still believe today that for TMR to succeed, the therapy needs a strong credible brand and a sustained sales effort in the marketplace. Therefore, we made a pivotal decision to partner our technology with a company who could provide the resources, effort, and well earned reputation to drive the adoption curve of TMR. We searched to find the right partner. Determining the best way to deliver value to our shareholders was the primary element and determining factor in our decision to partner with Edwards.



Mark Tauscher
President and CEO
PLC Systems Inc.

Where we are today
Resolve



As TMR has evolved and gained recognition over the past few years, both the scientific and clinical data have proven that the treatment provides lasting relief to patients suffering from chronic angina. However, TMR is still an emerging therapy and today PLC's financial results are still driven primarily by the number of lasers sold each quarter.

As our installed base of lasers grows, the number of TMR procedures will increase as well, to the point where we believe disposable kit sales will become the dominant revenue contributor to our business in the next few years.

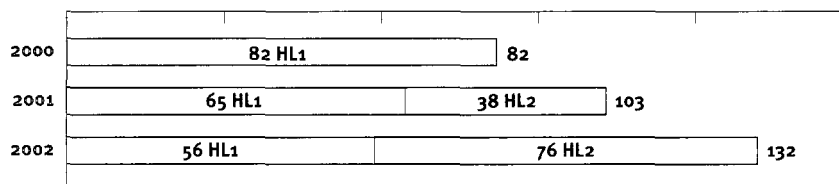
Looking at the past 12 months, we can see progress being made in this regard.

Select highlights from the past year compared to 2001:

- U.S. HL1 and HL2 laser base increased by 28%.
- U.S. HL2 base increased 100%, up to 76 lasers.
- U.S. kit shipments grew 12%, up to 1,407 kits.

We are proud of these accomplishments and believe these increases are a testament to the sales strength that Edwards possesses, as well as an indication of the growing acceptance that TMR has gained in the marketplace.

We also know that more can be done. We need additional growth in both lasers installed and TMR kits shipped. We are focused on achieving these goals with our partner and believe that Edwards provides us and TMR the best chance to succeed.



PLC U.S. LASER BASE

What lies ahead
Initiative

Going forward, we must be vigilant. We will manage our business mindful of sustaining profitability and always thinking about helping our partner drive procedural adoption. That is our primary focus for the future. As TMR adoption rates grow, the business is very well leveraged to allow our high margin disposable kits to positively impact our bottom line and cash flow.

With our TMR partnership established and our business on stable financial ground, we are better positioned to look forward and evaluate new strategic initiatives. We believe we have the opportunity and expertise to start expanding our business into other areas.

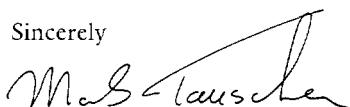
We know that maximizing shareholder value is difficult for a single product, single market company. Therefore it is our intention to look beyond our current product focus in TMR, to other opportunities that would allow us to grow

both our top and bottom line over the next two to five years. We will focus on identifying new products and new technologies that will address new markets for us and enable us to grow our company and its value. It is in this way that we think we can best build shareholder value.

I would like to thank all of our employees for the energy and effort they have put into PLC.

In summary, we believe 2002 marked a significant improvement for PLC, both financially and operationally, and we are looking ahead with great enthusiasm to another successful year in 2003.

Sincerely



Mark Tauscher
President and CEO

With our TMR partnership established and our business on stable financial ground, we are better positioned to look forward and evaluate new strategic initiatives.

Today, in the United States:

50,000,000

people have high blood pressure

12,900,000

suffer from coronary artery disease

7,600,000

have myocardial infarction (acute heart attack)

6,600,000

experience angina (chest pain)

314,000

patients undergo coronary artery bypass surgery annually

The realities of heart disease

Life

The American Heart Association estimates that 100 million Americans have high cholesterol and 60 million Americans suffer from one or more forms of cardiovascular disease.

What causes chest pain?

Angina is the name for chest pain or discomfort that occurs when the heart does not receive enough oxygen-rich blood. This happens when the heart's arteries become partially blocked or narrowed by the accumulation of plaque. The narrowing of these arteries is called coronary artery disease. When angina patients are working hard or just walking, the heart needs more blood. With the narrowing of the coronary artery oxygenated blood has difficulty reaching the heart. At this point, the body signals that there is a problem by producing the chest pain that is called angina. This chest pain may limit an angina patient's ability to participate in simple daily activities, and can substantially reduce a patient's quality of life.

Creating a solution to fight the progression of heart disease

Understanding

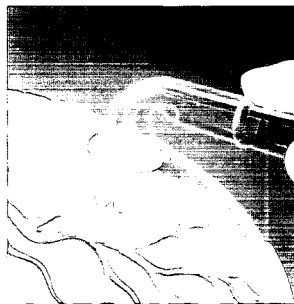
Many advanced heart patients suffering from angina, have undergone a variety of treatments including coronary artery bypass surgery, angioplasty and drug medications.

For those patients who continue to have chest pain, a therapy has emerged—Transmyocardial Laser Revascularization (TMR). During the TMR procedure, a cardiac surgeon utilizes a CO₂ laser to create channels through the wall of the heart (myocardium) to promote increased blood flow into areas of the myocardium. In clinical studies, TMR has demonstrated a reduction in angina and an improvement in quality of life. The CO₂ Heart Laser is the only revascularization laser that has published data showing long-term (five-year) angina relief in severely debilitated heart patients. To date, more than 9,500 patients have been treated with a CO₂ Heart Laser.

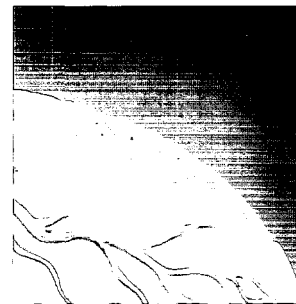
A cardiac surgeon utilizes PLC's CO₂ Heart Laser to create channels to allow oxygen-rich blood to reach previously deprived areas of the patient's heart.



The hand piece is placed on the exterior of the heart.



The laser is synchronized with the heartbeat and 20-40 channels are created.



It is believed the creation of TMR channels promotes angiogenesis, the development of new blood vessels.

**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, 2002

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
(State or other jurisdiction of
incorporation or organization)

04-3153858
(IRS Employer Identification No.)

10 Forge Park, Franklin, Massachusetts
(Address of principal executive offices)

02038
(zip code)

(508) 541-8800

(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on which Registered</u>
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 stock held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2002, was \$9,264,158. As of March 7, 2003, 29,797,548 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 2003 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*

General

PLC Systems Inc. has developed a patented high-powered carbon dioxide, or CO₂, laser system known as The Heart Laser for use in the treatment of severe coronary artery disease, or CAD, in a surgical laser procedure, pioneered by us and our clinical investigators, known as transmyocardial revascularization, or TMR.

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 as a late or last resort 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 arterial bypass grafting (referred to as CABG). 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.

Each TMR procedure requires a sterile, single use TMR kit containing assorted TMR handpieces, drapes and other disposable items. We manufacture The Heart Laser and related disposable TMR kits at our facility in Franklin, Massachusetts and sell them worldwide. In the United States, we sell our products to Edwards Lifesciences LLC, a subsidiary of Edwards Lifesciences Corporation. Edwards has the exclusive right to market and distribute our TMR products to hospitals in the United States at least through January 2006. Outside the United States we sell our products primarily to independent distributors.

Edwards is our largest shareholder, owning approximately 18% of our outstanding common stock as of December 31, 2002. Edwards is also our largest customer, accounting for approximately 87% of our total sales in 2002. As a company, Edwards designs, develops and markets a comprehensive line of products and services to treat late-stage cardiovascular disease.

Recent Developments

New European Clinical Study Launched. In November 2002, we initiated a European, multi-center clinical study with the objective of showing an improvement in angina relief, quality of life and cost effectiveness when CO₂ TMR is performed as an adjunctive therapy to a CABG procedure. The blinded, randomized study will evaluate patients treated with CO₂ TMR in conjunction with CABG to patients treated with CABG alone.

Two New Studies Published that Affirm the Benefits of TMR. On June 15, 2002, data from a clinical study was published in the American Journal of Cardiology that confirmed previous safety and effectiveness results of TMR. On May 15, 2002, a study was published in the Journal of American College of Cardiology that reaffirmed the long-term angina relief data resulting from the CO₂ TMR therapy. The May 15, 2002 study is the second peer-reviewed publication to affirm the successful long-term efficacy of TMR performed with the CO₂ laser.

Background

Our first generation Heart Laser System, or HL1, is a high-powered laser system capable of creating a TMR channel completely through a human heart wall with a single laser pulse delivered in the fraction of a second between heartbeats. In November 1990, we received a Phase I Investigational Device Exemption, or IDE, for the HL1 from the FDA. In approving the Phase I study, the FDA permitted the use of the HL1 for patients considered not suitable for any other intervention. Phase I

trials were performed by Dr. John Crew, a surgeon at the San Francisco Heart Institute, and were completed in October 1991.

In April 1992, we received Phase II clearance from the FDA to perform TMR on 50 patients at four clinical sites. This clearance was eventually expanded to include 201 patients at eight clinical sites. In 1995, we received Phase III clearance from the FDA to perform a 100 patient randomized study comparing TMR patients to patients receiving medical management. Phase III was later expanded to 200 patients.

On August 20, 1998, we received approval from the FDA to market the HL1 throughout the U.S. to treat the estimated 80,000 domestic patients each year who suffer from severe CAD but have regions of the heart that cannot be treated with conventional coronary revascularization techniques, such as bypass surgery or angioplasty. We were the first company to receive FDA approval to commercialize a product to perform TMR.

On January 29, 2001, we received approval from the FDA to market our second generation Heart Laser System, the CO₂ Heart Laser 2, or HL2. The HL2 is less than half the weight and size of the HL1, but delivers the equivalent laser energy, wavelength and beam characteristics. The HL1 and HL2 collectively are referred to throughout this report as the Heart Laser Systems.

On February 27, 2001, we received approval to place the CE Mark on the HL2, thereby allowing us to begin marketing our new laser in the European Union and other countries that base regulatory clearance on the European CE Mark.

We recently undertook an effort to gather long-term (more than 12 months) data on eligible patients from our Phase II and Phase III clinical studies. The long-term TMR analysis included 78 patients at nine hospitals. Each patient had been suffering from chronic angina and from severe 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. This long-term data was published in *Circulation*, the official journal of the American Heart Association, in September 2001.

Since April 1992, we have received 28 U.S. patents relating to the underlying laser technology, the use of a laser on a beating heart, the Heart Laser System handpiece and other laser accessories. We also have patent applications pending that cover various aspects of the technology for the Heart Laser Systems and the process by which a laser is used to revascularize the myocardium, as well as other laser technologies. We also hold a number of foreign patents and patent applications.

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., PLC Sistemas Medicos Internacionais (Deutschland) GmbH and PLC Medical Systems AG.

Cardiovascular Disease and Current Therapies

According to the 2003 Heart and Stroke Statistical Update, or 2003 HSSU, which was published by the American Heart Association, in 2000 an estimated 61.8 million Americans suffered from cardiovascular disease with an estimated 12.9 million suffering from coronary heart disease and

6.6 million suffering from angina pectoris (chest pain). Cardiovascular disease is the leading cause of death in the U.S., resulting in approximately 39% (or 946,000 in 2000) of all deaths in the U.S. annually.

Arteriosclerosis, the principal form of cardiovascular disease and primary cause of heart attacks, is characterized by a progressive accumulation of fatty deposits known as "plaque" in the walls of arteries and the resulting narrowing of the interior of the arteries. Arteriosclerosis reduces blood flow to the muscle wall or the myocardium of the heart, causing ischemia and resulting angina, and can further lead to a complete occlusion of the artery causing a heart attack. According to the 2003 HSSU, an estimated 519,000 coronary artery bypass procedures were performed on 314,000 patients and 561,000 balloon angioplasty procedures were performed in the U.S. in 2000. The American Heart Association estimates the direct and indirect costs of cardiovascular disease in the year 2003 at approximately \$352 billion.

Traditional treatment of atherosclerosis includes drug therapy, surgery and angioplasty. Drug therapy alleviates some of the symptoms of atherosclerosis but is often ineffective in serious cases. 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. Certain patients are not suitable 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.

A less invasive alternative to bypass surgery is balloon angioplasty. 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. Metallic stents were developed to help prevent the sudden closures that sometimes occur after angioplasty and to help reduce restenosis. 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, balloon angioplasty is preferred over bypass surgery when the blockages are not complicated and involve few coronary arteries. While offering certain benefits compared to bypass surgery, certain studies suggest restenosis or reocclusion is a serious problem with traditional angioplasty treatment. While stents have been shown to help reduce restenosis and are used extensively, restenosis continues to occur at a significant rate. 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. Atherectomy, another angioplasty-type treatment, involves the use of a catheter that contains a rotating mechanical device to cut, grind away and remove the plaque.

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 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, like all tissues of the body, 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 computer 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 seconds 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.

Potential Benefits of TMR

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 current anticipated 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 severe, 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 a Third Revascularization Option. In the future, with additional clinical research, TMR may be found to be useful as an alternative to bypass or angioplasty procedures.

Potential Therapy For Heart Transplant Patients. With additional clinical research, TMR potentially could be found useful for post-transplant patients suffering from chronic rejection atherosclerosis. Presently, the only treatment for this condition is re-transplantation.

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.

Not Dependent on Plaque Type or Location and Potentially Less Risk of Restenosis. Unlike angioplasty, atherectomy devices and stents, which have evidenced high restenosis rates depending on the composition, extent or location of the plaque occluding the artery, TMR is not dependent upon plaque type or location.

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 standalone 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.

Marketing Strategy

Our strategy is to market our products principally through key distributors throughout the world. In the U.S., we have partnered with Edwards as our exclusive distributor for the HL2 and related TMR disposable procedure kits. Outside the U.S., we have established an independent distributor network to market our products, although in some areas, principally Europe, we continue to sell our products directly to hospitals. In all cases, we attempt, either directly or through working with our distribution partners, to establish TMR using the Heart Laser Systems as a standard of care for treating patients suffering from severe CAD.

Currently, the Heart Laser Systems are commercially available in the U.S. and the European Union (except France). The HL1 is also commercially available in certain Asian and Latin American countries. We and our distributors have submitted applications for government approval to sell the HL1 in other countries, including Japan, although we cannot predict when, if ever, approval will be obtained.

We sell our products to Edwards and our international distributors at a discount off list price. We generally recognize Heart Laser System sales at the time of shipment to the hospital customer and TMR kit and accessory revenue at the time of shipment to the distributor.

United States. Under the Edwards exclusive distribution arrangement, Edwards determines the programs, including sale, lease, rental and usage based offerings, that it believes will be most effective in the U.S. in marketing the HL2 and related TMR kits to hospitals.

We believe usage based contracts (where the hospital pays a usage fee based on either an agreed upon minimum usage schedule or on an actual usage basis) are particularly appealing to hospitals when capital equipment funds are scarce or unavailable, or when it is difficult to predict early usage as is the case with a new technology such as TMR. If utilization becomes more predictable, we expect a significant number of existing usage based accounts, as well as new accounts, to opt for conventional leasing or purchase of the laser and then order and pay for TMR procedure kits from Edwards on an as needed basis.

Edwards uses a direct sales force in the U.S. to market the HL2 and TMR kits. The sales force is comprised of personnel with a high degree of professionalism and experience in the cardiovascular device business. Edwards' marketing efforts are directed at cardiothoracic surgeons, whose influence is believed to be critical in a hospital's decision to purchase the HL2. In addition, Edwards emphasizes educating hospital administration and referring physicians, with a focus on promoting the economics and viability of TMR as a new hospital technology and driving the growth of TMR procedures. Supporting Edwards' direct sales force is 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.

Edwards also conducts Center of Excellence training programs across the country (i) to facilitate increased TMR surgeon training for potential sales closure, (ii) to facilitate new site initiation, and (iii) to increase the number of surgeons trained at current TMR sites. This training effort is founded on the programs we originally established at Rush Presbyterian Medical Center in Chicago and the Texas Heart Institute in Houston. Edwards expanded the Center of Excellence training programs and recently has conducted programs in 2002 and 2003 at the Cleveland Clinic. These 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 view live, narrated procedures via closed circuit television. Actual hands on training is also provided in the use of the HL2 during the laboratory session.

As of December 31, 2002, 76 HL2s and 56 HL1s had been shipped to hospitals in the U.S.

International. We currently market the Heart Laser Systems overseas either directly or through independent distributors. International sales (by origin) accounted for 5%, 14% and 19% of our total revenue in 2002, 2001 and 2000, respectively. We had no sales by origin in Canada, our jurisdiction of incorporation.

We received the CE Mark for the HL1 in the third quarter of 1995 and for the HL2 in the first quarter of 2001. The CE Mark allows us to sell the Heart Laser Systems commercially in European Union countries. Despite our receipt of the CE Mark for the Heart Laser Systems, the French Ministry of Health instituted a commercial moratorium on TMR procedures in France in October 1997 (as discussed below under the heading "Business—Government Regulation").

In March 1999, we received ISO 9001 certification, allowing us to self certify and place the CE Mark on our products.

In early 1999, we renewed our distribution agreement in Japan with Ktec Corporation (formerly known as Imatron Japan, Inc.) to distribute the HL1 in Japan and attempt to complete the Japanese regulatory approval process. Along with the U.S. and Germany, Japan is believed to be one of the three largest markets in the world for products used in the treatment of cardiovascular disease. Between 1995 and 1997, Ktec purchased 12 HL1s from us to conduct clinical studies in Japan. We, along with Ktec, submitted data from these studies to the Japanese government in December 1998 in support of Ktec's application to market the HL1 in Japan. The joint application is believed to be the first submitted by a laser revascularization company seeking to market its product in Japan.

In early January 2001, we notified Ktec that we were terminating the existing distribution agreement as a result of Ktec's failure to obtain timely approval from the Japanese government to market the HL1 in Japan. We continue to work with Ktec to try and obtain approval to market the HL1 in Japan. However, by canceling the existing distribution agreement with Ktec, we have the flexibility to explore other alternatives, if necessary. No assurance can be given that Japanese regulatory approval will ever be granted for the HL1 or the HL2.

As of December 31, 2002, 2 HL2s and 77 HL1s had been shipped to international markets. Foreign sales may be subject to certain risks, including foreign medical, electrical and safety regulations, export and import restrictions, tariffs and currency fluctuations.

Products and Customers

We manufacture and market one principal product line, which consists of two patented high-powered carbon dioxide laser systems known as the Heart Laser Systems and related disposables. Approximately 92% of our revenues for the fiscal year ended December 31, 2002 and 90% of our revenues for the fiscal years ended December 31, 2001 and 2000 were derived from the sales and service of our Heart Laser Systems and related TMR disposables kits.

During 2002 and 2001, sales to Edwards accounted for 87% and 68%, respectively, of our total revenues. No single customer accounted for more than 10% of our revenues in fiscal 2000.

Manufacturing

We manufacture and test our product at our facility in Franklin, Massachusetts, approximately 40 miles west of Boston. We moved to this facility in September 1996 and in June 2001 amended our lease to reduce the rentable square footage from 37,000 square feet to 24,000 square feet, effective December 1, 2001. We believe that our manufacturing capacity will be sufficient to meet market demands anticipated in the coming year.

We purchase components for our Heart Laser Systems and our related TMR disposable kits from a number of sources, and management believes that most, but not all, components are available from multiple sources. 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 regulations.

Government Regulation

The Heart Laser Systems, as well as other medical devices that we have or may develop, are subject to extensive regulation by the FDA. Pursuant to the Federal Food, Drug and Cosmetic Act, as amended (the "FDC Act"), the FDA regulates the design, development, manufacturing, clinical testing, installation, 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. In addition, various foreign countries in which our products are or may be sold impose additional regulatory requirements.

On August 20, 1998, we received approval from the FDA to market the HL1 throughout the U.S. to treat patients who suffer from severe CAD but cannot be treated with conventional coronary revascularization techniques, such as bypass surgery or angioplasty. We were the first company to receive FDA approval to commercialize a product to perform TMR. The FDA imposed certain post-approval requirements as conditions of its August 1998 clearance. These requirements included a 600 patient post-market study to further assess mortality, a specific TMR surgical informed consent and the placement of certain disclaimers on all promotion and advertising materials. We are still in process of completing the required postmarket study.

Once a product obtains market approval from the FDA, any material modifications to the existing design or manufacturing process as well as any desire to change its labeling (i.e., intended use) must be approved by the FDA. On January 29, 2001, we received approval to market the HL2 in the U.S.

We intend to continuously improve our products after market introduction and may therefore submit future Investigational Device Exemption, Pre-Market Approval, or PMA, and PMA supplement

applications to the FDA. No assurance can be given that approval of such new applications will be received from the FDA on a timely basis, or at all.

The international regulatory approval process varies from country to country and is subject to change in a given country as regulatory requirements change. There is no assurance that foreign regulatory authorities will allow (or will continue to allow) the use or sale of the Heart Laser Systems in a particular country on a timely basis, or at all.

In addition, regulatory authorities can suspend or modify approvals previously granted in certain circumstances. For example, the French Ministry of Health instituted a commercial moratorium on TMR procedures in France in October 1997. The French Ministry of Health deemed the procedure to be "experimental", although the HL1 had been approved for commercial distribution in the European Union in 1995. As a result, TMR can only be performed within the context of a clinical study in France. There can be no assurance that this moratorium will be lifted or that other countries will not impose restrictions on the use or sale of our products.

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 death 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 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. If the FDA believes that a company is not in compliance with the law, proceedings can be instituted to detain or seize products or force notification and correction of hazards or defects (including a recall), enjoin future violations and assess 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.

Third-Party Reimbursement

Healthcare providers, such as hospitals and physicians, that purchase medical devices, such as the Heart Laser Systems, 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.

In January 1999, the Blue Cross and Blue Shield Association Technology Evaluation Center, or TEC, completed a favorable assessment of TMR. The TEC concluded that TMR meets the criteria used to evaluate new medical technologies, which includes scientific evidence of improvement in health outcomes; net benefit in health outcomes; health outcomes at least as beneficial with any established alternative; and improvements achievable outside investigational settings. The TEC's determination that TMR meets its criteria is a significant step in obtaining reimbursement for TMR by major payers. The TEC's conclusion was based upon a review of data showing the safety and effectiveness of TMR by the TEC program staff, and the TEC's assessment was approved by its panel of independent medical advisors. The TEC program is sponsored by the national Blue Cross and Blue Shield Association, whose members include local Blue Cross and Blue Shield plans nationwide, as well as other major managed care organizations. TEC assessments are released as reports to TEC program subscribers. Nearly all major payers in the U.S., including governmental payers, private third-party payers and

managed care organizations, subscribe to the TEC program and receive TEC assessment reports for use in their own coverage and payment policy making.

In February 1999, the Centers for Medicare and Medicaid Services, or CMS, formerly known as Health Care Finance Administration, rescinded a prior national non-coverage instruction to hospitals for the TMR procedure and announced that Medicare will provide coverage for TMR procedures performed with devices approved by the FDA. The decision set a new coverage policy to allow payment for TMR consistent with FDA-approved uses of TMR devices effective July 1, 1999.

In October 1999, CMS issued an addendum clarifying Medicare coverage for TMR procedures. In response to questions from practicing physicians, CMS announced that Medicare coverage would be provided in cases where TMR is used as an adjunct to coronary artery bypass grafting.

In January 2000, a physician reimbursement code was assigned for the TMR procedure when performed as a sole therapy. Establishment of a physician reimbursement code provides surgeons the ability to electronically submit for reimbursement of the procedure and is believed to provide for quicker and more reliable claim processing. On January 1, 2001, a physician reimbursement code was assigned for the TMR procedure when performed as an adjunct to coronary artery bypass grafting.

In May 2001, TEC completed a favorable assessment of TMR as an adjunctive therapy to bypass surgery. TEC's determination that TMR plus bypass surgery meets its criteria is a significant step in obtaining reimbursement for the combined therapy by major payers, although there can be no assurance that such reimbursement will be obtained.

Economic data derived from our clinical studies indicate that TMR using the Heart Laser Systems may result in a significant reduction in the cost of treating patients with severe CAD. Potentially, this could mean that TMR performed with the Heart Laser Systems is a procedure that offers real economic advantages to the managed care market, which we believe covers a substantial number of privately insured Americans. No assurance can be given that such economic benefits will be realized.

Certain private insurance companies and health maintenance organizations currently provide reimbursement for TMR procedures performed with our products. No assurance can be given, however, that these payers will continue to reimburse healthcare providers who perform TMR procedures using our products. Further, no assurance can be given that additional payers will reimburse healthcare providers who perform TMR 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.

Notwithstanding the FDA approval and Medicare coverage for TMR procedures, the historical absence of widespread reimbursement for the TMR procedure by third-party payers, as well as 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. Although Medicare reimbursement began in July 1999, and some private insurance plans have begun reimbursing healthcare providers for TMR procedures using the Heart Laser Systems, we believe that market acceptance of TMR procedures is likely to be limited until such time as third-party payers begin to provide widespread reimbursement to healthcare providers for use of the Heart Laser Systems. In addition, we believe that hospitals may delay the implementation of a TMR program until there is documentation of the medical processes by which TMR procedures relieve angina, if ever.

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 28 U.S. patents. These patents have terms which expire from 2009 through 2019 and cover, among other things, the underlying laser technology needed 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 the Heart Laser Systems, the handpiece, other technology used in the Heart Laser Systems, and technologies associated with percutaneous myocardial revascularization.

In April 1996, we received patents from the European Patent Office and the Japanese Patent Office providing patent protection on our heart synchronization technology. A patent covering this technology was also issued in April 1997 in Canada. Additional Japanese-issued patents cover a TMR handpiece, a self-aligning coupler for a laser endoscope, laser beam manipulation and a laser beam status indicator. In December 1996, a patent was issued in Canada covering a self-aligning coupler for a laser endoscope. We have numerous patents pending related to the Heart Laser Systems and their components in various international patent offices. We may file additional patent applications in the next year, although there can be no assurance that any additional applications will be filed or that any additional patents will be issued.

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 to be strong, successful litigation by a competitor invalidating 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.

We believe our patents 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

The only competitor in the TMR market at this time is CardioGenesis. In February 1999, CardioGenesis received FDA approval to market its holmium laser in the United States 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.

In addition to their TMR system, CardioGenesis has pursued a "percutaneous" method of performing TMR, 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 has received CE Mark approval for its PMR system, which allows CardioGenesis to sell this product commercially in the European Union. CardioGenesis' PMR system has not been approved by the FDA to be marketed in the U.S., and presently there are no other FDA approved PMR devices in the marketplace.

CardioGenesis filed a PMA application for their PMR system with the FDA in December 1999. In July 2001, the FDA Circulatory System Devices Advisory Panel met to consider this PMA application. CardioGenesis presented the technical aspects of its device along with the results obtained from the device. Following a review of the device, results of the two clinical studies and safety and effectiveness data, the panel in a 7-2 vote found the PMA to be "not approvable".

CardioGenesis amended its PMA application by filing a PMA supplement with the FDA in July 2002. On December 31, 2002, CardioGenesis announced that the FDA's Office of Device Evaluation determined that there was not sufficient information to demonstrate reasonable assurance of the safety and effectiveness of its device, and the FDA issued CardioGenesis a not approvable letter.

In February 2003, CardioGenesis announced that it expects to present to the FDA's Medical Devices Dispute Resolution Panel in the second quarter of 2003, as a means to try and resolve its dispute with the FDA on the non-approvable status of its PMA supplement. No assurance can be given on whether CardioGenesis will receive an approval to market their PMR system in the U.S., or what the impact of any such approval would be on our business.

Although we have a proprietary PMR product design, we currently are not actively pursuing its development. No assurance can be given that we will ever successfully pursue, develop or market a PMR product.

In addition to the two clinical trials conducted with the CardioGenesis laser, the results of a clinical study using a Johnson & Johnson holmium PMR laser, presented at the Transcatheter Therapeutics Conference in Washington, D.C. on October 20, 2000, demonstrated no significant differences in the clinical outcomes measured between those receiving the PMR therapy and those in a control group of patients. The principal investigator who presented the results at the Transcatheter Therapeutics Conference concluded that the similar outcomes between those in the treatment group and those in the control group were suggestive of a strong placebo effect, as opposed to any real therapeutic benefit from the PMR laser revascularization procedure.

Although we believe there are distinct clinical differences and therapeutic outcomes between a surgical laser TMR procedure and an interventional laser PMR procedure, the negative publicity resulting from the clinical study using the Johnson & Johnson holmium PMR laser with respect to all laser revascularization procedures, including our CO₂ laser TMR approach, poses a significant challenge for us and Edwards in attempting to convince cardiovascular surgeons and referring clinicians of the efficacy of TMR as a procedure. We, along with Edwards, have taken steps to distinguish surgical TMR from PMR and to distinguish the CO₂ laser from holmium lasers. However, no assurance can be given that these efforts to make these distinctions between the therapies and lasers used will be successful. If we or Edwards are unable to do so, the Heart Laser Systems may never gain broad commercial acceptance.

In addition to CardioGenesis, other companies may enter the TMR market and use lasers such as holmium and excimer lasers. We believe that the Heart Laser Systems are the only existing TMR products that can create a channel completely through the heart wall with a single laser pulse. Research

conducted at the Texas Heart Institute in animal models has indicated that our synchronized, single pulse CO₂ laser may cause significantly less damage to the heart than a holmium laser used to perform TMR. Holmium and excimer lasers have different physical properties and interact differently with human tissue than our CO₂ laser. Holmium lasers currently used for TMR are not capable of creating a channel in one pulse, and must therefore use a fiber-optic probe that "drills" its way from the outside of the heart to the blood-filled left ventricle. The presence of the probe within the heart muscle may contribute to an increased risk of arrhythmias. Moreover, since four to seven firings are required to create a channel, channels formed in the heart wall by such holmium systems have been observed to be jagged and segmented. We believe that during 2002 Edwards continued to successfully differentiate our CO₂ laser.

Many treatments are available for CAD. 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 through outside parties.

We believe that the primary competitive factors within the interventional cardiovascular market are the ability to treat safely and effectively various types of coronary disease, physician familiarity with and acceptance of the procedure, third-party reimbursement policies, and to a lesser extent, ease of product use, product reliability and price.

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.

Research and Development

Research and development expenses were \$889,000, \$904,000 and \$1,680,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Since the HL1 received final approval from the FDA in late August 1998, there has been a significant reduction in research and development expenses related to clinical trials. In addition, since the HL2 received FDA approval in January 2001, we have reduced our HL2 research and development program expenses as the product has transitioned into production.

We continue to monitor all technologies that may be applicable to TMR to keep us at the forefront of this field. No assurance can be given that our research and development goals will be implemented successfully or that we will maintain our position in this market.

Employees

As of March 7, 2003, we had 30 full-time domestic employees, including our executive officers. Of these, 9 are in general and administrative positions, 2 are involved in sales, 5 are involved in research and development, 7 are involved in manufacturing, 4 are involved in service and 3 are involved in quality and regulatory affairs. We also employ 2 full-time employees for our international operations and 1 part-time domestic employee. None of our employees are represented by a union. We consider our relationship with our employees to be satisfactory.

Item 2. Properties

Since September 1996, we have leased our current facility in Franklin, Massachusetts where we maintain our principal executive offices and manufacturing and development operations. In June 2001, we amended our lease and reduced its total facility space from 37,000 square feet to 24,000 square feet. The amended lease has a term of five years and expires on August 31, 2006. The total base rental payments for the fiscal years ending December 31, 2003, 2004, 2005 and for the eight months ended August 31, 2006 are approximately \$282,000, \$285,000, \$286,000 and \$191,000, respectively. We are also responsible for 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 and Related Stockholder Matters

Since September 17, 1992, our common stock has traded on the American Stock Exchange ("AMEX") under the symbol "PLC". On March 7, 2003, the closing sale price of our common stock was \$0.47 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, 2001.

	<u>High</u>	<u>Low</u>
2001		
First Quarter	\$2.00	\$0.50
Second Quarter	\$1.20	\$0.56
Third Quarter	\$1.20	\$0.41
Fourth Quarter	\$0.85	\$0.50
2002		
First Quarter	\$0.76	\$0.55
Second Quarter	\$0.67	\$0.38
Third Quarter	\$1.45	\$0.35
Fourth Quarter	\$0.88	\$0.51

As of March 7, 2003, there were 815 record holders of our common stock. We believe that there are 12,400 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

Sales or Other Dispositions of Shares

Gains on sales or other dispositions of our shares by a non-resident of Canada are generally not subject to Canadian income tax, unless the holder realizes the gains in connection with a business carried on in Canada.

Item 6. Selected Financial Data

The following selected financial data for the five years ended December 31, 2002 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,				
	2002	2001	2000	1999	1998
	(All amounts are in thousands except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales	\$ 7,425	\$ 7,975	\$ 6,803	\$ 8,400	\$ 3,088
Placement and service fees	1,413	1,805	3,437	3,236	2,605
Total revenues:	8,838	9,780	10,240	11,636	5,693
Cost of revenues	4,092	5,591	7,220	5,921	4,787
Gross profit	4,746	4,189	3,020	5,715	906
Operating expenses:					
Selling, general and administrative	3,626	7,438	9,143	9,809	13,498
Research and development	889	904	1,680	2,672	4,468
Total operating expenses	4,515	8,342	10,823	12,481	17,966
Income (loss) from operations	231	(4,153)	(7,803)	(6,766)	(17,060)
Other income, net	74	251	393	211	457
Net income (loss)	\$ 305	\$ (3,902)	\$ (7,410)	\$ (6,555)	\$ (16,603)
Basic and diluted earnings (loss) per share	\$.01	\$ (.13)	\$ (.32)	\$ (.32)	\$ (.86)
Average shares outstanding:					
Basic	29,696	29,248	23,266	20,675	19,218
Diluted	29,784	29,248	23,266	20,675	19,218
	As of December 31,				
	2002	2001	2000	1999	1998
Balance Sheet Data:					
Working capital	\$ 6,470	\$ 5,785	\$ 5,010	\$ 5,459	\$ 5,050
Total assets	10,328	12,298	15,078	15,319	16,257
Secured borrowings, long-term	408	1,446	3,079	2,082	—
Stockholders' equity	6,725	6,310	6,216	8,885	10,662

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

Overview

In January 2001, we obtained FDA approval to market our second generation laser, the HL2. The HL2 is less than half the weight and size of our first generation laser, the HL1, but delivers the equivalent laser energy, wavelength and beam characteristics. The HL1 and the HL2 collectively are referred to throughout this report as the "Heart Laser Systems".

In January 2001, we entered into a strategic marketing alliance and exclusive distribution arrangement with Edwards. Under this arrangement, Edwards is marketing and distributing the HL2, as well as all disposable TMR kits and accessories, to customers in the U.S. In 2001, Edwards' sales force was principally responsible for driving increased TMR procedures and kit utilization, as well as providing our capital sales force with HL2 sales leads. We maintained our capital sales force through January 2002 to assist Edwards in marketing the HL2 in the U.S.

In January 2002, Edwards exercised a pre-existing option to assume full sales and marketing responsibility in the U.S. for our HL2 and associated TMR kits. We sell the HL2 and TMR kits to Edwards at a discount to list price and Edwards remarkets the HL2 and TMR kits to hospitals. We benefited from reduced sales and marketing expenses in 2002, and we expect these savings to continue in 2003 and beyond.

Critical Accounting Policies

Our financial statements are based on the application of significant accounting policies, many of which require management to make significant estimates and assumptions (see Note 2 to the Consolidated Financial Statements). We believe that the following are some of the more critical 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 management's best estimate of the net realizable value of inventory on hand.

Allowance for Doubtful Accounts

The allowance for doubtful accounts reflects management's best estimate of probable losses inherent in the account receivable balance. Management determines the allowance based on known troubled accounts, historical experience, and other currently available evidence.

Warranty and Preventative Maintenance Costs

We warrant 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 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.

Management evaluates the estimated future unrecoverable costs of warranty and preventative maintenance services for our installed base of lasers on a quarterly basis and adjusts our warranty reserve accordingly. Management considers all available evidence, including historical experience and information obtained from supplier audits. In 2002, based upon this experience, we determined that the rate of Heart Laser System failure and cost per failure were lower than previously expected. As a

consequence, during the third and fourth quarters of 2002, we reduced our warranty accrual by approximately \$176,000.

Revenue Recognition

We record revenue from the sale of TMR kits to Edwards at the time of shipment. Heart Laser Systems are billed to Edwards in accordance with purchase orders received by us. Invoiced Heart Laser Systems 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 distribution agreement, once Edwards has recovered a prescribed amount of revenue from a hospital for the use or purchase of a 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 Heart Laser Systems to international distributors or hospitals at the time of shipment. We generally require our international customers to secure Heart Laser System sales through cash deposits and letters of credit.

Prior to entering into the Edwards distribution agreement, we installed Heart Laser Systems 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 Heart Laser System transaction are recorded as a component of placement and service fees when the Heart Laser System is installed.

Results of Operations

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Total revenues of \$8,838,000 for the year ended December 31, 2002 decreased \$942,000 or 10% when compared to total revenues of \$9,780,000 for the year ended December 31, 2001. This decrease was the result of a 7% decrease in product sales and a 22% decrease in placement and service fees.

Product Sales

For the year ended December 31, 2002, product sales of \$7,425,000 decreased \$550,000 or 7% when compared to product sales of \$7,975,000 for the year ended December 31, 2001.

Heart Laser System revenues, the largest component of product sales, increased by \$180,000 in 2002 as compared to 2001. This increase is primarily attributable to an \$857,000 increase in domestic Heart Laser System revenues. The \$857,000 increase in domestic Heart Laser System revenues was due to (1) an increase in the number of Heart Laser System sales, (2) a higher average domestic selling price on Heart Laser System sales and (3) increased revenue sharing earned under the distribution agreement with Edwards. The \$857,000 increase in domestic Heart Laser System revenues was partially offset by a \$677,000 decrease in revenue generated from international Heart Laser System sales.

Disposable TMR kit revenues, the second largest component of product sales, decreased by \$453,000 in 2002 as compared to 2001. This decrease is primarily attributable to a decrease in the average domestic sales price of TMR kits sold to Edwards. This decrease in the average sales price of TMR kits sold to Edwards took effect in January 2002 when Edwards exercised a pre-existing option to

assume full sales and marketing responsibility for the HL2 and associated TMR kits in the U.S. In connection with this option exercise by Edwards, Edwards will, pursuant to the terms of the distribution agreement with us, retain a greater share of the revenue generated from U.S. TMR kit sales.

Royalty revenue, a component of product sales, decreased \$249,000 in 2002 as compared to 2001. This decrease is due to a decline in the guaranteed minimum royalties due from CardioGenesis. Minimum royalties were in effect throughout all of 2001, but only the first two quarters of 2002. 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.

Placement and Service Fees

For the year ended December 31, 2002, placement and service fees of \$1,413,000 decreased \$392,000 or 22% when compared to placement and service fees of \$1,805,000 for the year ended December 31, 2001.

Service fees increased \$173,000 in 2002 as compared to 2001 due to more domestic lasers in service throughout 2002, which resulted in increased billings to Edwards for installation, warranty and preventative maintenance services.

Placement fees declined \$565,000 in 2002 as compared to 2001. Approximately \$336,000 of this \$565,000 decline is attributable to a reduction in domestic placement fees. The \$336,000 reduction in domestic placement fees is in part the result of various U.S. HL1 customers upgrading to the newer HL2. Each upgrade resulted in a laser sale to Edwards and a corresponding shift in recorded disposable TMR kit sales to these new HL2 customers as product sales instead of placement fees.

The remaining \$229,000 of the \$565,000 decline was the result of lower international placement contract fees due to decreased kit shipments to international placement contract customers.

Gross Profit

Total gross profit was \$4,746,000 or 54% of total revenues for the year ended December 31, 2002 as compared with gross profit of \$4,189,000 or 43% of total revenues for the year ended December 31, 2001.

The improvement in gross profit in 2002 as compared to 2001 is due to (1) a higher average selling price and additional shared revenue on Heart Laser System transactions, (2) manufacturing cost savings and improved product yields, (3) lower depreciation charges, (4) a reevaluation of estimated future warranty costs related to our installed base of lasers that resulted in \$176,000 of non-recurring income being reflected as an offset to cost of product sales and (5) an increase in service related revenues. These increases were offset in part by lower overall disposable TMR kit revenues, placement contract revenues and royalty revenues.

Operating Expenses

Selling, general and administrative expenses of \$3,626,000 for the year ended December 31, 2002 decreased \$3,812,000 or 51% when compared with selling, general and administrative expenses of \$7,438,000 for the year ended December 31, 2001. The overall decrease is primarily attributable to (1) significantly reduced domestic sales and marketing expenditures as a result of the January 2002 exercise by Edwards of a pre-existing option to assume the U.S. sales and marketing responsibility for the HL2 and associated TMR kits, (2) reduced international sales and marketing expenditures and (3) reduced administrative expenditures. In 2003, selling, general and administrative expenses are expected to remain at levels similar to those in 2002.

Research and development expenses of \$889,000 for the year ended December 31, 2002 decreased \$15,000 or 2% when compared with research and development expenses of \$904,000 for the year ended December 31, 2001. There were no significant changes in any particular research and development expense related accounts. In 2003, research and development expenses are expected to remain at levels similar to those in 2002.

Other Income

Other income of \$74,000 for the year ended December 31, 2002 decreased \$177,000 or 71% when compared to other income of \$251,000 for the year ended December 31, 2001. This decrease is a result of both a lower overall average investable balance and lower interest rates on invested funds. In 2003, other income is expected to remain at levels similar to those in 2002.

Net Income (Loss)

We recorded a net profit of \$305,000 for the year ended December 31, 2002 compared to a net loss of \$3,902,000 for the year ended December 31, 2001. The net profit in 2002 resulted primarily from higher gross margins and reduced operating expenses as compared to 2001, as discussed above.

There was no provision for income tax for the year ended December 31, 2002, despite a recorded net profit of \$305,000, due to U.S. net operating loss carryforwards being available to reduce taxable income. There was no provision for income tax in 2001 due to a net loss of \$3,902,000.

Kit Shipments

Our management monitors disposable kit shipments as an important metric in evaluating its business. Management believes kit shipments, although not a direct measure, are reasonable indicators of the pace of the adoption of TMR as a therapy in the marketplace.

For the year ended December 31, 2002, a total of 1,649 disposable kits were shipped to end users, an increase of 9% over the 1,510 disposable kits shipped to end users during the year ended December 31, 2001.

Domestic kit shipments increased by 12%, from 1,259 in 2001 to 1,407 in 2002. Management believes the increase in domestic kit shipments is due primarily to (1) an increase in the total number of installed lasers in 2002 and (2) lasers installed and available for only a portion of 2001 being available for all of 2002.

International kit shipments declined slightly from 251 in 2001 to 242 in 2002. The international market has had limited resources and programs to drive procedural adoption.

Year Ended December 31, 2001 Compared to Year Ended December 31, 2000

Total revenues of \$9,780,000 for the year ended December 31, 2001 decreased \$460,000 or 4% when compared to total revenues of \$10,240,000 for the year ended December 31, 2000. This decrease was the result of a 47% decrease in placement and service fees, partially offset by a 17% increase in product sales.

Product Sales

For the year ended December 31, 2001, product sales of \$7,975,000 increased \$1,172,000 or 17% when compared to product sales of \$6,803,000 for the year ended December 31, 2000.

Heart Laser System revenues, the largest component of product sales, increased by \$696,000 in 2001 as compared to 2000. This increase was due to an increase in the number of Heart Laser System sales, partially offset by a lower average selling price. Lower selling prices are a direct result of our

distribution arrangement with Edwards, pursuant to which products are sold at a discount to list price to Edwards and then remarketed by Edwards to hospitals.

Disposable TMR kit revenues, the second largest component of product sales, increased by \$576,000 in 2001 as compared to 2000. Prior to 2001, we recorded disposable kit revenues either as product sales (if the disposable kit was shipped to a customer which had either purchased their Heart Laser System or which otherwise qualified for sales type lease treatment) or as placement fees (if the disposable kit was shipped to a customer with a placement contract). In 2001, all domestic disposable kit shipments were accounted for as product sales because all kits were sold directly to Edwards.

Placement and Service Fees

For the year ended December 31, 2001, placement and service fees of \$1,805,000 decreased \$1,632,000 or 47% when compared to placement and service fees of \$3,437,000 for the year ended December 31, 2000. The overall decrease in placement and service fees reflects a 65% decline in placement fees, partially offset by a 51% increase in service fees.

Service fees increased \$265,000 in 2001 as compared to 2000, primarily due to more domestic lasers being placed in service throughout 2001, which resulted in increased billings to Edwards for installation, warranty and preventative maintenance services.

Placement fees declined \$1,897,000 in 2001 as compared to 2000. Approximately \$1,383,000 of this \$1,897,000 decline is attributable to a reduction in domestic placement fees. The \$1,383,000 reduction in domestic placement fees is in part the result of various U.S. HL1 customers upgrading to the newer HL2. This resulted in a laser sale to Edwards and a corresponding shift in recorded disposable TMR kit sales to these new HL2 customers as product sales instead of placement fees.

The remaining \$514,000 of the \$1,897,000 decline was the result of lower international placement contract fees due to decreased kit shipments to international placement contract customers.

Gross Profit

Total gross profit was \$4,189,000 or 43% of total revenues for the year ended December 31, 2001 as compared with gross profit of \$3,020,000 or 29% of total revenues for the year ended December 31, 2000.

The lower gross profit in 2000 is primarily due to a non-recurring charge of \$2,117,000, which we incurred in the fourth quarter of 2000 to write down the value of our HL1 inventory and capital equipment due to the transition to the new HL2 product. Without this charge, our gross profit would have been 50% of revenues in 2000. The decrease in gross profit in 2001 as compared to gross profit in 2000 is a result of lower selling prices of our products as well as lower overall sales partially offset by lower production costs for the HL2.

Operating Expenses

Selling, general and administrative expenses of \$7,438,000 for the year ended December 31, 2001 decreased \$1,705,000 or 19% when compared with selling, general and administrative expenses of \$9,143,000 for the year ended December 31, 2000. The decrease is mainly attributable to decreases in corporate marketing expenditures, both domestically and internationally, and lower general and administrative expenditures, including reductions in directors fees and travel, depreciation and amortization and salaries and related fringe benefit expenses.

Research and development expenses of \$904,000 for the year ended December 31, 2001 decreased \$776,000 or 46% when compared with research and development expenses of \$1,680,000 for the year ended December 31, 2000. The reduction is a result of decreased HL2 engineering related project

expenditures as this product transitioned into production in early 2001 and reductions in clinical study expenses.

Other Income

Other income of \$251,000 for the year ended December 31, 2001 decreased \$142,000 or 36% when compared to other income of \$393,000 for the year ended December 31, 2000. The decrease is a result of lower interest rates on invested funds.

Net Loss

We incurred a net loss of \$3,902,000 for the year ended December 31, 2001 compared with a net loss of \$7,410,000 for the year ended December 31, 2000. The lower net loss resulted from higher gross margins, which is primarily due to a non-recurring charge of \$2,117,000 which we incurred in the fourth quarter of 2000 to write down the value of our HL1 inventory and capital equipment due to the transition to the new HL2 product, as well as reduced operating expenses.

There was no provision for income tax for the years ended December 31, 2001 or 2000 due to net losses of \$3,902,000 and \$7,410,000, respectively.

Kit Shipments

For the year ended December 31, 2001, we shipped a total of 1,510 disposable kits to end users, a decrease of 6% over the 1,606 disposable kits shipped to end users during the year ended December 31, 2000.

Domestic kit shipments increased by 12%, from 1,123 in 2000 to 1,259 in 2001. Management believes the domestic kit shipment improvement is a result of the benefits of the strategic partnership with Edwards and the introduction of the new HL2 in January 2001.

International kit shipments declined from 483 in 2000 to 251 in 2001. This decrease is primarily attributable to a decrease in the number of international Heart Laser System shipments, which typically are accompanied by an initial kit order, as well as a reduction in the number of TMR procedures being performed in various international accounts.

Liquidity and Capital Resources

At December 31, 2002, we had cash and cash equivalents of \$5,932,000.

During the year ended December 31, 2002, we recorded net income of \$305,000 and generated \$937,000 from operating activities. Cash provided by financing activities was approximately \$46,000, primarily consisting of the net proceeds of \$167,000 obtained from sales of our common stock offset by a \$121,000 reduction in secured borrowings. We believe that our existing cash resources will meet our working capital requirements through December 31, 2003.

However, 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 on a consistent basis.

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 may 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—Revenue Recognition") and (2) a delay in the purchase of new lasers by Edwards if its installed base of placement lasers under usage contracts are under-performing and it chooses to re-deploy these lasers to other new 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.

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 facilities in Zug, Switzerland, and Franklin, Massachusetts that expire in September 2003 and August 2006, respectively. Future annual minimum payments under these operating leases are:

Minimum Operating Lease Obligations

<u>Year(s)</u>	<u>Amount</u>
2003	\$ 296,000
2004	285,000
2005	286,000
2006	<u>191,000</u>
Total operating lease obligations	<u>\$1,058,000</u>

In addition to amounts accrued or payable as of December 31, 2002, we have purchase commitments to make payments to suppliers totaling approximately \$792,000 during 2003.

Risk Factors

The risks and uncertainties described below are not the only risks we face. Additional risks and uncertainties not presently known to us or that are 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.

Our company has a history of operating losses

PLC Systems Inc. was founded in 1987. Prior to 2002 when we recorded a net profit, we had incurred operating losses in every year of our existence except 1995. We incurred net losses of \$3,902,000 for the year ended December 31, 2001 and \$7,410,000 for the year ended December 31, 2000. As of December 31, 2002, we had an accumulated deficit of \$85,698,000. We have only just recently achieved profitability, and we cannot provide any assurance that we will continue to be profitable in the future. Moreover, although our business is not seasonal in nature, our revenues may tend to vary significantly from fiscal quarter to fiscal quarter.

Our company is dependent on one principal product line

We develop and market one principal product line, which consists of two patented high-powered carbon dioxide laser systems, known as the Heart Laser Systems, and related TMR disposable kits. Approximately 92% and 90% of our revenues in the years ended December 31, 2002 and December 31, 2001, respectively, were derived from the sales and service of our Heart Laser Systems and related disposables.

Our company is dependent on one principal customer

Pursuant to a distribution agreement with Edwards, Edwards is our exclusive distributor for our HL2 and TMR kits in the U.S. As a result of this relationship, Edwards accounted for 87% of our total revenue in the fiscal year ended December 31, 2002, and we expect Edwards to account for the majority of our revenue in the future. If our relationship with Edwards does not progress or if Edwards' sales and marketing strategies fail to generate sales of our HL2 and TMR kits 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 laser systems, most notably the power supply and certain optics and fabricated parts, 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. 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 the Heart Laser Systems, 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 Heart Laser Systems 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.

We have limited manufacturing experience building the HL2

We only began manufacturing the HL2 in 2001. The HL2 is based on a different design than the HL1. In order to achieve certain manufacturing cost savings, we have taken a more vertically integrated approach to the manufacture of the HL2 than we did with the HL1. As a result, we may experience manufacturing difficulties, including but not limited to:

- shortages in component parts due to supplier manufacturing or procurement delays;
- supplier quality problems;
- lack of experienced technical personnel;

- low production yields; and
- changing processes and controls over the manufacturing procedures employed.

If we are unable to successfully manufacture the HL2 in a timely manner, we may lose customers, and our business, financial condition and results of operations may be seriously harmed.

Our company may be unable to raise needed funds

As of December 31, 2002, we had cash and cash equivalents totaling \$5,932,000. Based on our current operating plan, we anticipate that our existing capital resources should be sufficient to meet our working capital requirements through December 31, 2003. However, if our business does not progress in accordance with our current business plan, we may need to raise additional funds. 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 stockholders will result.

In order to compete effectively, our Heart Laser Systems need to gain commercial acceptance

TMR is a new technology that is only recently becoming known. Our 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 procedures and the Heart Laser Systems are effective, relatively safe and cost effective;
- support third-party efforts to document the medical processes by which TMR procedures relieve angina, if any;
- have more heart surgeons trained to perform TMR procedures using the Heart Laser Systems; and
- obtain widespread third-party reimbursement for the TMR procedure.

To date, only a limited number of heart surgeons have been trained, and we are dependent on Edwards to expand TMR related marketing and training efforts in the U.S.

Although the Heart Laser Systems have received FDA approval and the CE Mark, they have not yet received widespread commercial acceptance. If we are unable to maintain regulatory approvals or to achieve widespread commercial acceptance of the Heart Laser Systems, our business, financial condition and results of operations will be materially and adversely affected.

Results of a recent clinical study may adversely affect our business

Our business may continue to be adversely affected by a clinical study, the results of which were released on October 20, 2000 at the Transcatheter Therapeutics Conference. The clinical study, which used a Johnson & Johnson holmium PMR laser, demonstrated no significant differences in the clinical outcomes measured between patients receiving PMR therapy and patients in the control group. The principal investigator of the clinical study concluded that the similar outcomes in patients in the treatment group and patients in the control group suggests a strong placebo effect, as opposed to any real therapeutic benefit from the PMR laser revascularization procedure. Although we believe that there are distinct clinical differences and therapeutic outcomes between a surgical laser TMR procedure and an interventional laser PMR procedure, the negative publicity resulting from the clinical study with respect to all laser revascularization procedures, including our CO₂ laser TMR approach, makes it more challenging for us to distinguish our surgical TMR from PMR and to distinguish our

CO₂ laser from holmium lasers. If we or Edwards are unable to distinguish these procedures and therapies, the Heart Laser Systems may never gain broad commercial acceptance and, therefore, our business will be materially and adversely affected.

Rapid technological changes in our industry could make the Heart Laser Systems 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 the Heart Laser Systems obsolete. The advent of new devices and procedures and advances in new drugs and genetic engineering are especially threatening. 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 product 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. Our current competitor in the TMR market, CardioGenesis, uses a different type of laser (holmium) than we use in the Heart Laser Systems, and we have no assurance that our laser will be able to gain more widespread market acceptance.

In addition, CardioGenesis is attempting to obtain FDA approval to market its PMR laser, which provides a less invasive method of creating channels in the heart. If PMR 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. PMR and other new technologies and methods may erode the potential TMR market, which could have a material adverse effect on our business, financial condition and results of operations.

We must receive and maintain government approval in order to market our product

The Heart Laser Systems 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 markets, including the European Union and Japan. To date, we have received regulatory approval in the U.S. and have the ability to market the Heart Laser Systems in the European Union (excluding France). We have not received regulatory approval in Japan. Without regulatory approval, we cannot market the Heart Laser Systems in Japan. Even if granted, regulations may significantly restrict the use of the Heart Laser Systems. The process of obtaining and maintaining required regulatory approval is lengthy, expensive and uncertain.

United States—Although we have received FDA approval, the FDA has restricted the use of the Heart Laser Systems and could reverse its approval at any time

We received FDA approval to market the HL1 and HL2 for TMR procedures in August 1998 and January 2001, respectively. However, the FDA:

- has not allowed us to market the Heart Laser Systems to treat patients whose condition is amenable to conventional treatments, such as heart bypass surgery and angioplasty; and
- could reverse its ruling and prohibit use of the Heart Laser Systems at any time.

Europe—Although we have the ability to market our product in the European Union, individual members of the European Union could, and France has, prohibited commercial use of the Heart Laser Systems

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 reverse its ruling and prohibit use of the Heart Laser Systems at any time;
- we cannot market the Heart Laser Systems in France; and
- other European Union countries could prohibit or restrict use of the Heart Laser Systems.

The French Ministry of Health instituted a commercial moratorium on TMR procedures in October 1997. In its opinion, the procedure is considered to be experimental and should only be performed within the context of a clinical study. There can be no assurance that this moratorium will be lifted on a timely basis or at all.

Asia—We cannot market our product in major Asian markets until we receive government approval

We believe that Japan represents the largest potential market for the Heart Laser Systems in Asia. 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.

We could incur substantial costs defending against possible legal claims in the future

We have been sued for alleged securities law violations in the past, and may be subject to similar claims or other claims in the future. Between August 1997 and November 1997, we were named as defendant in 21 class action lawsuits alleging violations of federal securities laws because we failed to obtain a favorable FDA panel recommendation to market the HL1. Nineteen of the claims were consolidated into a single action and some of the claims were dismissed in 1999. All remaining claims were settled in February 2001. The settlement of these claims did not have a material impact on our financial statements. However, any future litigation or claims, whether or not valid, could result in substantial costs and diversion of resources with no assurance of success.

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 the Heart Laser Systems. 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. The United States Supreme Court has stated that compliance with FDA regulations will not shield a company from commonlaw negligent design claims or manufacturing and labeling claims based on state rules. Such claims may absorb significant management time and could degrade our reputation and the marketability of the Heart Laser Systems. 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 exceeded 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 may be 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 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.

Anti-takeover provisions may prevent you from realizing a premium return

Provisions of Canadian law could make it more difficult for a third party to acquire us, even if the acquisition would be beneficial to you. Specifically, Canadian law requires any person who makes a tender offer that would increase the person's stock ownership to more than 20% of our outstanding common stock to make a tender offer for all of our common stock. These provisions could prevent you from realizing the premium return that shareholders may realize in conjunction with corporate takeovers.

In addition, we have three classes of directors, with approximately one-third elected each year for a three-year term. These provisions may have the effect of delaying or preventing a corporate takeover or a change in our management. This could adversely affect the market price of our common stock.

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

Certain current shareholders hold large amounts of our restricted stock, which they may be able to sell in the public market in the near future. 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.

The value of your common stock may decrease if other security holders exercise their options and warrants

As shown in the table below, as of December 31, 2002, we have reserved an additional 7,139,740 shares of common stock for future issuance upon exercise of outstanding options, warrants and shares purchasable under an employee stock purchase plan.

	<u>Range of Exercise/Conversion Prices</u>	<u>Weighted Average Exercise/Conversion Price</u>	<u>Shares Reserved for Future Issuance</u>
Options	\$.53 – \$8.88	\$2.53	3,535,772
Warrants	\$1.00 – \$19.53	\$2.48	3,177,215
Employee Stock Purchase Plan			426,753
Total			<u>7,139,740</u>

Pursuant to an option exchange program we have instituted (see Note 6 to the Consolidated Financial Statements), we are committed to issue options to purchase 999,345 shares of our common stock at the then fair market value during March of 2003. We may issue additional options and warrants in the future. If any of these securities are exercised, you may experience significant dilution in the market value of your common stock.

We may issue additional options and warrants in the future. If any of these securities are exercised, you may experience significant dilution in the market value of your common 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.

Our actual results could differ materially from those anticipated in forward-looking statements

This annual report and information incorporated by reference into this annual report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements deal with our current plans and expectations and involve known and unknown risks and uncertainties. Statements containing terms such as believes, does not believe, plans, expects, intends, estimates, anticipates and other phrases of similar meaning are considered to contain uncertainty and are forward-looking statements.

No forward-looking statement is a guarantee of future performance. Our actual results could differ materially from those anticipated in these forward-looking statements. We have identified a number of important factors, including the risk factors identified above, that could cause our actual results to differ materially from our forward-looking statements. You should read these important factors as being applicable to all related forward-looking statements, wherever they appear in this annual report, in the materials referred to in this annual report, in the materials incorporated by reference into this annual report or in our press releases. You should not place undue reliance on any forward-looking statement.

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 significantly 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 Swiss Franc and the Euro. When the U.S. dollar strengthens against the Franc or 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.

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.

The Company does not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. We do not believe that a 10% change to the applicable exchange 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.

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 2003 Annual Meeting of Shareholders (referred to as our Definitive Proxy Statement) under the caption "Item No. 1—Election of Directors".

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 and Related Stockholder Matters

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "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. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* Based on their evaluation of PLC's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934) as of a date within 90 days of the filing date of this Annual Report on Form 10-K, our chief executive officer and chief financial officer have concluded that PLC's disclosure controls and procedures are designed to ensure that information required to be disclosed by PLC in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.

(b) *Changes in internal controls.* There were no significant changes in PLC's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(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.

	<u>Page</u>
Report of Independent Auditors	F-2
Consolidated Balance Sheets as of December 31, 2002 and 2001	F-3
Consolidated Statements of Operations for the years ended December 31, 2002, 2001 and 2000	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2002, 2001 and 2000	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000	F-6
Notes to Consolidated Financial Statements	F-7
Schedule II Valuation and Qualifying Accounts	S-1

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) *Reports on Form 8-K.*

Not Applicable.

(c) *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.

(d) *Financial Statement Schedules.*

See Item 15(a) above.

CERTIFICATIONS

I, Mark R. Tauscher, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 25, 2003

/s/ MARK R. TAUSCHER

Mark R. Tauscher
Chief Executive Officer

I, James G. Thomasch, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 25, 2003

/s/ JAMES G. THOMASCH

James G. Thomasch
Chief Financial Officer

APPENDIX A

PLC SYSTEMS INC.
CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2002, 2001 and 2000

PLC SYSTEMS INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Auditors

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, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2002. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2002 and 2001, and the consolidated results of its operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2002 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 12, 2003

PLC SYSTEMS INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2002 and 2001

	<u>2002</u>	<u>2001</u>
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,932	\$ 4,977
Accounts receivable, net of allowance of \$192 and \$267 in 2002 and 2001, respectively	1,349	2,544
Lease receivables	848	1,510
Inventories, net	912	1,001
Prepaid expenses and other current assets	<u>371</u>	<u>222</u>
Total current assets	9,412	10,254
Equipment, furniture and leasehold improvements, net	204	383
Lease receivables	408	1,326
Other assets	<u>304</u>	<u>335</u>
Total assets	<u>\$ 10,328</u>	<u>\$ 12,298</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 400	\$ 968
Accrued compensation	446	444
Accrued other	757	859
Deferred revenue	354	507
Secured borrowings	<u>985</u>	<u>1,691</u>
Total current liabilities	2,942	4,469
Deferred revenue	253	73
Secured borrowings	<u>408</u>	<u>1,446</u>
Total long term liabilities	661	1,519
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 29,798 and 29,527 shares issued and outstanding in 2002 and 2001, respectively	93,586	93,419
Accumulated deficit	(85,698)	(86,003)
Accumulated other comprehensive loss	<u>(1,163)</u>	<u>(1,106)</u>
Total stockholders' equity	6,725	6,310
Total liabilities and stockholders' equity	<u>\$ 10,328</u>	<u>\$ 12,298</u>

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, 2002, 2001 and 2000

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands, except per share data)		
Revenues:			
Product sales	\$ 7,425	\$ 7,975	\$ 6,803
Placement and service fees	1,413	1,805	3,437
Total revenues	<u>8,838</u>	<u>9,780</u>	<u>10,240</u>
Cost of revenues:			
Product sales	3,560	4,556	3,765
Placement and service fees	532	1,035	3,455
Total cost of revenues	<u>4,092</u>	<u>5,591</u>	<u>7,220</u>
Gross profit	4,746	4,189	3,020
Operating expenses:			
Selling, general and administrative	3,626	7,438	9,143
Research and development	889	904	1,680
Total operating expenses	<u>4,515</u>	<u>8,342</u>	<u>10,823</u>
Income (loss) from operations	231	(4,153)	(7,803)
Other income, net	74	251	393
Net income (loss)	<u>\$ 305</u>	<u>\$ (3,902)</u>	<u>\$ (7,410)</u>
Basic and diluted earnings (loss) per share	\$ 0.01	\$ (.13)	\$ (.32)
Average shares outstanding:			
Basic	29,696	29,248	23,266
Diluted	29,784	29,248	23,266

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, 2002, 2001 and 2000

	Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			
Balance, December 31, 1999	21,223	\$84,380	\$(74,691)	\$ (804)	\$ 8,885
Issuance of common stock	2,742	5,037	—	—	5,037
Comprehensive loss:					
Net loss	—	—	(7,410)	—	(7,410)
Foreign currency translation	—	—	—	(296)	(296)
Total comprehensive loss					(7,706)
Balance, December 31, 2000	23,965	\$89,417	\$(82,101)	\$(1,100)	\$ 6,216
Issuance of common stock	5,562	4,002	—	—	4,002
Comprehensive loss:					
Net loss	—	—	(3,902)	—	(3,902)
Foreign currency translation	—	—	—	(6)	(6)
Total comprehensive loss					(3,908)
Balance, December 31, 2001	29,527	\$93,419	\$(86,003)	\$(1,106)	\$ 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	<u>29,798</u>	<u>\$93,586</u>	<u>\$(85,698)</u>	<u>\$(1,163)</u>	<u>\$ 6,725</u>

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, 2002, 2001 and 2000

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands)		
Operating activities:			
Net income (loss)	\$ 305	\$(3,902)	\$(7,410)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation and amortization	211	904	3,641
Change in assets and liabilities:			
Accounts receivable	1,197	(1,150)	488
Inventory	89	439	908
Prepaid expenses and other assets	(149)	67	138
Accounts payable	(571)	(310)	(63)
Deferred revenue	36	42	355
Accrued liabilities	(181)	(700)	(22)
Net cash provided by (used for) operating activities	<u>937</u>	<u>(4,610)</u>	<u>(1,965)</u>
Investing activities:			
Purchase of equipment	(2)	(207)	(1,303)
Purchase of marketable securities	—	(333)	(288)
Maturity of marketable securities	—	621	—
Net cash (used for) provided by investing activities	<u>(2)</u>	<u>81</u>	<u>(1,591)</u>
Financing activities:			
Net proceeds from sales of common shares	167	4,002	5,037
Secured borrowings	(121)	(236)	55
Principal payments on capital lease obligations	—	—	(45)
Net cash provided by financing activities	<u>46</u>	<u>3,766</u>	<u>5,047</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(26)</u>	<u>14</u>	<u>(232)</u>
Net increase (decrease) in cash and cash equivalents	955	(749)	1,259
Cash and cash equivalents at beginning of year	<u>4,977</u>	<u>5,726</u>	<u>4,467</u>
Cash and cash equivalents at end of year	<u>\$5,932</u>	<u>\$ 4,977</u>	<u>\$ 5,726</u>

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

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2002

1. Nature of Business

PLC Systems Inc. ("PLC" or the "Company") has developed a patented high-powered carbon dioxide ("CO₂") laser system known as The Heart Laser ("HL1") for use in the treatment of severe coronary artery disease ("CAD") in a surgical laser procedure, pioneered by the Company and its clinical investigators, known as transmyocardial revascularization ("TMR"). In January 2001, the Company obtained U.S. Food and Drug Administration ("FDA") approval to market its second-generation laser, the CO₂ Heart Laser 2 ("HL2"). The HL2 is less than half the weight and size of the HL1, but delivers the equivalent laser energy, wavelength and beam characteristics. The HL1 and HL2 collectively are referred to throughout this report as the "Heart Laser Systems".

In January 2001, the Company entered into a strategic marketing alliance and exclusive distributorship agreement with Edwards Lifesciences LLC, a subsidiary of Edwards Lifesciences Corporation (collectively referred to as "Edwards"). The distributorship agreement is for five years with a five-year renewal option if certain conditions are met. Under the terms of the agreement, Edwards will market and distribute the HL2, as well as all disposable TMR kits and accessories, to hospitals in the U.S. In January 2002, Edwards exercised a pre-existing option to assume full sales and marketing responsibilities in the U.S. for PLC's HL2 and associated TMR kits. Edwards is also the Company's largest shareholder, owning approximately 18% of the Company's outstanding shares as of December 31, 2002.

Outside the U.S., the Company markets and distributes its products primarily through an independent dealer network, although in certain countries it continues to sell its products directly to hospitals.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of PLC and its three wholly owned subsidiaries, PLC Medical Systems, Inc., PLC Sistemas Medicos Internacionais (Deutschland) GmbH, and PLC Medical Systems AG. 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 management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

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, 2002 and 2001 consist of investments in money market funds. These investments are carried at cost, which approximates fair value.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

2. Significant Accounting Policies (Continued)

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 with a high quality institution. At December 31, 2002 and 2001, the majority of the cash and cash equivalents balance was invested in a single fund, the Galaxy Institutional Treasury Money Market Fund, a no-load money market fund.

Beginning in 2001, the Company has had a concentration of credit risk due to its exclusive distributorship arrangement with Edwards in the U.S. Edwards accounted for 87% and 68% of the Company's revenues for the years ended December 31, 2002 and 2001, respectively. Collateral is not required on the sales to Edwards. At December 31, 2002 and December 31, 2001, the Company had outstanding accounts receivable from Edwards totaling \$1,220,000 and \$2,169,000, respectively. No one customer accounted for more than 10% of the Company's revenues for the year ended December 31, 2000.

Allowance for Doubtful Accounts

The allowance for doubtful accounts reflects management's best estimate of probable losses inherent in the account receivable balance. Management determines the allowance based on known troubled accounts, historical experience, and other currently available evidence.

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 management's best estimate of the net realizable value of inventory on hand.

Equipment, Furniture and Leasehold Improvements

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
Office furniture and fixtures	5 years
Leasehold improvements	Life of lease

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

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

2. Significant Accounting Policies (Continued)

Warranty and Preventative Maintenance Costs

The Company warrants 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 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.

Management 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. Management considers all available evidence, including historical experience and information obtained from supplier audits.

At December 31, 2002 and 2001, the balance of accrued warranty was \$100,000 and \$276,000, respectively. During 2002 and 2001, the Company recognized a warranty benefit (expense) of \$176,000 and (\$226,000), respectively.

Revenue Recognition

The Company records revenue from the sale of TMR kits to Edwards at the time of shipment. Heart Laser Systems are billed to Edwards in accordance with purchase orders received by the Company. Invoiced Heart Laser Systems 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.

Under the terms of the Edwards distribution agreement, once Edwards has recovered a prescribed amount of revenue from a hospital for the use or purchase of a 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 Heart Laser Systems to international distributors or hospitals at the time of shipment. The Company generally requires its international customers to secure Heart Laser System sales through cash deposits and letters of credit.

Prior to entering into the Edwards distribution agreement, the Company installed Heart Laser Systems 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 Heart Laser System transaction are recorded as a component of placement and service fees when the Heart Laser System is installed.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

2. Significant Accounting Policies (Continued)

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. 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 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 have been 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 2001 and 2000, 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 issues of common stock related to stock option programs and warrants since their inclusion would be antidilutive.

In calculating diluted earnings per share, the dilutive effect of stock options is computed using the average market price for the respective period. Potential shares related to certain of the Company's outstanding stock options were excluded because they were anti-dilutive, however these shares could be dilutive in the future. The following table sets forth the computation of basic and diluted earnings per share:

	Years Ended December 31,		
	2002	2001	2000
	(In thousands, except per share data)		
Basic:			
Net income (loss)	\$ 305	\$(3,902)	\$(7,410)
Weighted shares outstanding	29,696	29,248	23,266
Earnings (loss) per share	\$ 0.01	\$ (0.13)	\$ (0.32)
Diluted:			
Net income (loss)	\$ 305	\$(3,902)	\$(7,410)
Weighted shares outstanding	29,696	29,248	23,266
Assumed impact of the exercise of outstanding dilutive stock options using the treasury stock method	88	—	—
Weighted average common and common equivalent shares	29,784	29,248	23,266
Earnings (loss) per share	\$ 0.01	\$ (0.13)	\$ (0.32)

Options to purchase 1,163,737 shares of common stock at \$0.65—\$8.88 per share were outstanding during 2002 but were not included in the computation of diluted EPS because the options' exercise prices were greater than the average market price of the common shares.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

2. Significant Accounting Policies (Continued)

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* ("FAS 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*. In addition, the Company has made the appropriate disclosures as required under Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*.

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 FAS 123 to stock-based employee compensation:

	Years Ended December 31,		
	2002	2001	2000
	(In thousands, except per share data)		
Net income (loss) attributable to common stockholders—As reported	\$ 305	\$(3,902)	\$(7,410)
Add (deduct) total stock-based compensation benefit (expense) determined under fair value based method for all stock option awards	206	(865)	(973)
Net income (loss) attributable to common stockholders—Pro forma	\$ 511	\$(4,767)	\$(8,383)
Earnings (loss) per basic share attributable to common stockholders—As reported	\$0.01	\$ (0.13)	\$ (0.32)
Earnings (loss) per basic share attributable to common stockholders—Pro forma	\$0.02	\$ (0.16)	\$ (0.36)

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

	2002	2001	2000
Expected life (years)	3	3	2
Interest rate	3.82%	3.68%	6.41%
Volatility738	1.071	.821

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

3. Inventories

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

	2002	2001
Raw materials	\$663	\$ 618
Work in process	111	107
Finished goods	138	276
	\$912	\$1,001

At December 31, 2002 and 2001, inventories are stated net of a reserve of \$1,019,000 and \$1,167,000, respectively, for potentially obsolete inventory.

4. Equipment, Furniture and Leasehold Improvements

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

	2002	2001
Equipment	\$2,240	\$2,240
Equipment under placement contracts	2,810	4,036
Office furniture and fixtures	886	879
Leasehold improvements	346	346
	6,282	7,501
Less accumulated depreciation and amortization	6,078	7,118
	\$ 204	\$ 383

Depreciation expense was \$180,000, \$866,000 and \$3,187,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Included in 2000 depreciation expense is \$1,265,000 related to the write down of the Company's HL1 installed laser base under placement contracts.

5. Stockholders' Equity

On March 28, 2000, the Company closed an equity financing with two institutional investors. The Company sold 2,683,000 shares of common stock at \$2.00 per share, resulting in proceeds to the Company (net of all issuance costs) of approximately \$5,012,000, and issued the placement agent a three year warrant for 61,326 shares of common stock with an exercise price of \$3.15 per share. Based on certain events defined in the warrant agreement, the Company was obligated to issue warrants to purchase 11,025 additional shares of common stock at an adjusted purchase price of \$2.67 per share and adjusted the original purchase price of the warrant for 61,326 shares to \$2.67 per share in conjunction with the transaction discussed below.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

5. Stockholders' Equity (Continued)

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. 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.

As of December 31, 2002, the Company had the following outstanding warrants to purchase common stock: 72,351 shares at \$2.67 per share expiring March 27, 2003; 4,864 shares at \$19.53 per share expiring April 23, 2003; 1,000,000 shares at \$1.50 per share expiring January 2004; 1,000,000 shares at \$2.50 per share expiring January 2005; 1,000,000 shares at \$3.50 per share expiring January 2006 and 100,000 shares at \$1.00 per share expiring January 2006.

At December 31, 2002, there were 7,139,740 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.

6. Stock Option and Stock Purchase Plans

The Company's 1993 Formula Stock Option Plan (the "Formula Plan"), 1993 Stock Option Plan ("1993 Plan"), 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 "Plans", allow for the granting of options aggregating 4,617,672 shares of common stock. The Company's Formula Plan provides for the grant of non-qualified options to non-employee directors. 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. In 2002, the Company's 1992 Stock Option Plan ("1992 Plan"), which allowed for the granting of options aggregating 350,000 shares of common stock, expired.

Annually, the Company grants 10,000 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 20,000 options. The options vest over one year on a quarterly basis and

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

6. Stock Option and Stock Purchase Plans (Continued)

expire ten years from the date of grant. The exercise price is the fair market value of the Company's common stock.

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 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 will vest on a cumulative basis with one-sixth of the new option vesting on the date the new option is granted and the remaining portion of the new option vesting in five equal installments at the end of each six-month period thereafter.

On August 26, 2002, the Company filed the Exchange Offer as a tender offer with the Securities and Exchange Commission in accordance with Rule 13e-4 of the Securities Exchange Act of 1934, as amended. The Exchange Offer expired on September 25, 2002, and the Company accepted all stock options tendered. The Company expects that it will issue 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 will be granted six months and a day from the cancellation, no compensation expense will result from the grant of the new options.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

6. Stock Option and Stock Purchase Plans (Continued)

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Outstanding at beginning of year	3,855	3,120	2,706
Granted	5	952	800
Exercised	(185)	—	—
Canceled	(1,526)	(217)	(386)
Outstanding at end of year	<u>2,149</u>	<u>3,855</u>	<u>3,120</u>
Exercisable at end of year	1,824	2,363	1,808
Available for grant at end of year	1,387	193	952
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Weighted—average exercise price:			
Outstanding at beginning of year	\$2.47	\$3.00	\$3.84
Granted	\$0.64	\$0.64	\$0.86
Canceled	\$3.02	\$2.02	\$4.62
Exercised	\$0.62	\$ —	\$ —
Outstanding at end of year	\$2.25	\$2.47	\$3.00
Exercisable at end of year	\$2.53	\$3.41	\$4.06
Weighted—average fair value of options granted during the year	\$0.32	\$0.40	\$0.40

	<u>Range of Exercise Prices</u>		
	<u>\$0.53 - \$0.90</u>	<u>\$1.38 - \$3.00</u>	<u>\$3.90 - \$8.88</u>
Options Outstanding:			
Number (in thousands)	1,171	282	696
Weighted-Average Remaining Contractual Life (years)	8.34	6.91	4.33
Weighted-Average Exercise Price	\$0.59	\$2.33	\$4.99
Options Exercisable:			
Number (in thousands)	858	270	696
Weighted-Average Exercise Price	\$0.59	\$2.35	\$4.99

The Company's Purchase Plan is 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 85,495 shares of common stock in 2002, 228,803 shares of common stock in 2001 and 58,949 shares of common stock in 2000 at average prices of \$0.44, \$0.45 and \$0.43 per share, respectively. At December 31, 2002, 426,753 shares were reserved for future issuance under the Purchase Plan.

PLC SYSTEMS INC.
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
 December 31, 2002

7. 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 HLI. 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 HLI, 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.

8. Lease Commitments

The Company occupies its worldwide facilities under operating lease agreements which expire through August 2006. 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.

As of December 31, 2002, future minimum lease payments are estimated to be as follows (in thousands):

<u>Year</u>	<u>Future Minimum Lease Payments</u>
2003	296
2004	285
2005	286
2006	191
	<u>\$1,058</u>

Total rent expense was \$299,000 in 2002, \$362,000 in 2001 and \$327,000 in 2000.

9. Income Taxes

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

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2002

9. Income Taxes (Continued)

purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows (in thousands):

	2002	2001
Net U.S. operating loss carryforwards	\$ 20,705	\$ 21,268
Net foreign operating loss carryforwards	1,903	1,855
Accrued expenses and reserves	171	917
Tax credits	831	815
Other	718	463
Total deferred tax assets	24,328	25,318
Valuation allowance	(24,328)	(25,318)
Net deferred tax assets	\$ —	\$ —

The valuation allowance decreased by approximately \$990,000 in 2002 primarily due to net income and a reduction in temporary differences associated with accrued expenses and reserves in 2002. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset of \$24,328,000.

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

	2002	2001	2000
Domestic	\$ 638	\$(3,674)	\$(7,029)
Foreign	(333)	(228)	(381)
	\$ 305	\$(3,902)	\$(7,410)

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

	2002	2001	2000
Statutory income tax expense (benefit)	\$ 267	\$(1,327)	\$(2,520)
Utilization of loss carryforwards	(267)	(14)	—
Unbenefited U.S. losses	—	1,249	2,390
Unbenefited foreign losses	—	92	130
Benefit for income taxes	\$ —	\$ —	\$ —

At December 31, 2002, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$52 million, which expire at various dates through 2022. In addition, the Company had foreign net operating loss carryforwards of approximately \$4.8 million.

PLC SYSTEMS INC.
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
 December 31, 2002

10. 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):

	<u>North America</u>	<u>Europe</u>	<u>Total</u>
2002			
Net sales	\$8,420	\$ 418	\$ 8,838
Long-lived assets	\$ 134	\$ —	\$ 134
2001			
Net sales	\$8,454	\$1,326	\$ 9,780
Long-lived assets	\$ 167	\$ —	\$ 167
2000			
Net sales	\$8,319	\$1,921	\$10,240
Long-lived assets	\$ 192	\$ —	\$ 192

PLC SYSTEMS INC.
Valuation and Qualifying Accounts

<u>Column A</u>	<u>Column B</u>	<u>Column C</u>	<u>Column D</u>	<u>Column E</u>
<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Additions</u> <u>Charged to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
For the Year Ended December 31, 2002				
Allowance for Doubtful Accounts	\$267,000	\$ —	\$ 75,000	\$192,000
For the Year Ended December 31, 2001				
Allowance for Doubtful Accounts	\$368,000	\$ 14,000	\$115,000	\$267,000
For the Year Ended December 31, 2000				
Allowance for Doubtful Accounts	\$418,000	\$226,000	\$276,000	\$368,000

PLC SYSTEMS INC.
QUARTERLY DATA (UNAUDITED)
(in thousands, except for per share data)

	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>	<u>Total</u>
2002					
Total revenue	\$2,420	\$2,179	\$1,995	\$2,244	\$8,838
Gross profit	994	1,281	1,230	1,241	4,746
Income (loss) from operations	(274)	120	204	181	231
Net income (loss)	(259)	135	219	210	305
Earnings (loss) per share, basic and diluted	(0.01)	0.00	0.01	0.01	0.01
2001					
Total revenue	\$2,341	\$2,581	\$2,357	\$2,501	\$9,780
Gross profit	1,124	1,100	1,006	959	4,189
Loss from operations	(1,277)	(1,207)	(1,044)	(625)	(4,153)
Net loss	(1,176)	(1,140)	(988)	(598)	(3,902)
Net loss per share, basic and diluted	(0.04)	(0.04)	(0.03)	(0.02)	(0.13)

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Certificate of Incorporation, 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.
3.2	Articles of Continuance, pursuant to the Yukon Business Corporations Act, incorporated by reference to the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1999, as previously filed with the Securities and Exchange Commission.
3.3	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 fiscal 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	1992 Stock Option Plan, 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.
10.2	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.
10.3	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.
10.4	Revised Form of Key Employee Agreement for Dr. Robert I. Rudko, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 1994, as previously filed with the Securities and Exchange Commission.
10.5	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.
10.6	Form of Redeemable Warrant, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 1997, as previously filed with the Securities and Exchange Commission.
10.7	Registration Rights Agreement, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 1997, as previously filed with the Securities and Exchange Commission.
10.8	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.
10.9	Form of Convertible Debenture, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the Quarter ended March 31, 1998, as previously filed with the Securities and Exchange Commission.
10.10	Form of Redeemable Warrant, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 1998, as previously filed with the Securities and Exchange Commission.

Exhibit
Number

Description of Document

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- 10.11 Registration Rights Agreement dated as of April 23, 1998 between Southbrook International Investment, Ltd., Brown Simpson Strategic Growth Fund, L.P. and Brown Simpson Strategic Growth Fund, Ltd. and the Registrant, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 1998, as previously filed with the Securities and Exchange Commission.
- 10.12 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 fiscal year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
- 10.13 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 fiscal year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
- 10.14 2000 Non-qualified Performance and Retention Equity Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
- 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 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.
- 10.18 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.
- 10.19 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.
- 21.1* Subsidiaries of the Registrant.
- 23.1* Consent of Ernst & Young LLP.
- 99.1* Certification 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 fiscal year ended December 31, 2002.

+ Confidential treatment has been requested for certain portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act of 1933, as amended, which portions are 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 of Corporate Strategy,
Edwards Lifesciences Corporation*

Kevin J. Dunn
*Managing Director – Mergers & Acquisitions,
Adams, Harkness & Hill*

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.*

Kenneth J. Pulkonik
*Chairman and President,
Rush Electronics, Ltd.*

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, Quality Assurance and Regulatory Affairs

Kenneth J. Luppi
Vice President, Operations and Development

Vincent C. Puglisi
Vice President and Managing Director, International

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 14, 2003 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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