PRODUCT. PATIENT. PHYSICIAN. PARTNER. PROOF.

POISED FOR SUCCESS.

PLC
SYSTEMS INC.

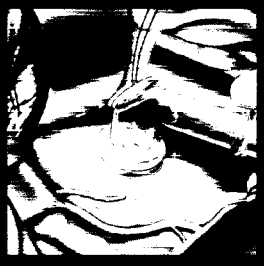
Annual Report 2001

PLC Systems Inc.

is the leading medical device company specializing in the design and manufacturing of carbon dioxide (CO_2) lasers that treat coronary artery disease. In the United States, Edwards Lifesciences (NYSE: EW) markets and distributes PLC's patented CO_2 Heart Laser, which a cardiac surgeon utilizes to perform CO_2 laser revascularization, also referred to as transmyocardial revascularization (TMR). The CO_2 laser revascularization therapy is a surgical procedure that relieves angina or chest pain in severely debilitated heart patients. PLC's CO_2 Heart Laser is the only laser that has reported and published long-term angina relief results. To date, more than 8,000 patients have been treated with a CO_2 Heart Laser.

Procedure

A cardiac surgeon utilizes PLC's CO_2 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 new blood vessels are formed in conjunction with these channels.

Entering 2000

Great Technology:
FDA Approved
Medicare Reimbursed

Appointed Experienced Management Team

During 2000

Formulated Partnership Strategy

Rapidly Advanced the Development of PLC's Next-Generation Heart Laser (HL2)

Presented Long-Term (Five Years) Angina Relief Data

During 2001

Formed Strategic Partnership with Edwards Lifesciences

Received FDA Approval for HL2

Published Long-Term (Five Years) Angina Relief Data

Entering 2002

Dear Shareholders,

I am pleased to report that 2001 was a very successful year for PLC. We started the year on a positive note, worked through the transition of the partnership and finished the year strong with record fourth-quarter laser and disposable kit shipments.

Our success came from implementing our strategic plan, which was to deliver the Product, the Partner and the Proof. The PLC team has put all these pieces together. *We are poised for success.*

During 2001,

PLC introduced the next-generation Heart Laser (HL2)

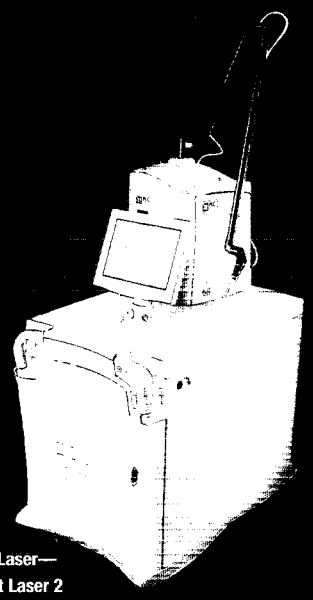
We have the Product

PLC and Edwards launched our strategic partnership

We have the Partner

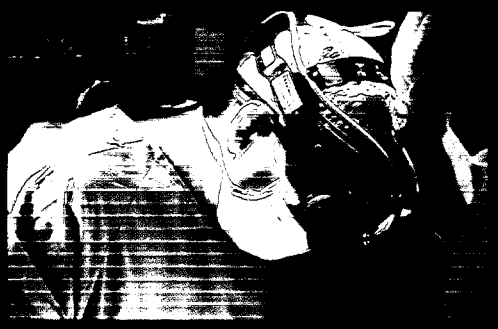
PLC published the long-term benefits of CO_2 TMR

We have the Proof



PLC's Next-Generation Laser—
CO_2 Heart Laser 2

Physician



Anthony Furnary, MD

Heart surgery today involves a different type of patient than we worked on 10 or 20 years ago. Our patient population is older, sicker and has more complex problems. Patients' lives have been extended through the innovative technologies of bypass grafting, angioplasty and stenting. However, the progression of coronary artery disease has not been halted, it does continue. There is a need for additional tools (therapies) to help those patients that suffer from debilitating angina not amenable to traditional therapies. One additional tool we have available today is the PLC CO_2 Heart Laser.

The patient that we see today deserves a total revascularization. With PLC's CO_2 Heart Laser, we now have the opportunity to provide our patients with total revascularization of the entire myocardium. Heart surgeons are often the last resort for these complex patients. Because of this we prefer to use clinically proven, long-lasting therapies. The CO_2 Heart Laser has five years of solid clinical data backing it up. Most importantly, these patients' lives are dramatically improved after receiving the CO_2 laser revascularization therapy—we are able to give them back their quality of life—which is the ultimate goal.

—Anthony Furnary, MD, Senior Cardiothoracic Surgeon, Starr Wood Cardiac Surgery Group P.C., Providence St. Vincent's Medical Center; Assistant Professor, Oregon Health and Sciences University, Portland, Oregon

PLC and Edwards Form Strategic Partnership

In 2001, PLC established a strategic partnership and entered into an exclusive United States distribution agreement with Edwards for PLC's CO_2 laser revascularization technology and patented disposable hand pieces. This agreement greatly enhances the potential for increased market penetration of PLC's CO_2 laser technology.

During 2001, PLC maintained its own sales force, which concentrated on selling and placing CO2 Heart Laser 2 systems in hospitals. Edwards focused its efforts on increasing the utilization of each laser through education and training programs. Edwards provides CO_2 laser revascularization with significant new sales and marketing strength. On January 15, 2002, PLC announced that Edwards had exercised an option to assume U.S. sales and marketing responsibility for PLC's CO_2 laser revascularization therapy.

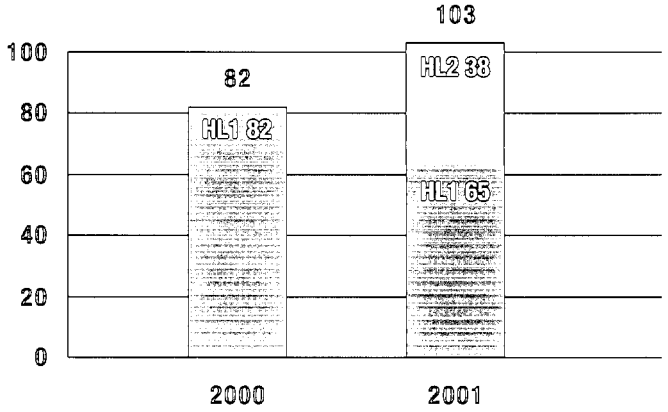
Our Objectives Are Clear

Increase the Laser Base
Increase the Utilization of Each Laser

PLC's "razor/razor blade" business model focuses on driving CO_2 laser revascularization procedures. Each CO_2 laser procedure involves a PLC-patented disposable hand piece, which we call "the kit." It is the number of kits that we ship on an ongoing basis that will be the long-term measure of PLC's success. There are two critical elements necessary to drive the adoption of CO_2 laser revascularization. It is our partnership

PLC U.S. Laser Base

PLC increases U.S. laser base by more than 25 percent



The introduction of the HL2 was a 2001 strategic success for PLC. The smaller, more mobile HL2 can be moved easily from surgical suite to surgical suite, which increases the laser's availability to a greater number of cardiac surgeons in the hospital.

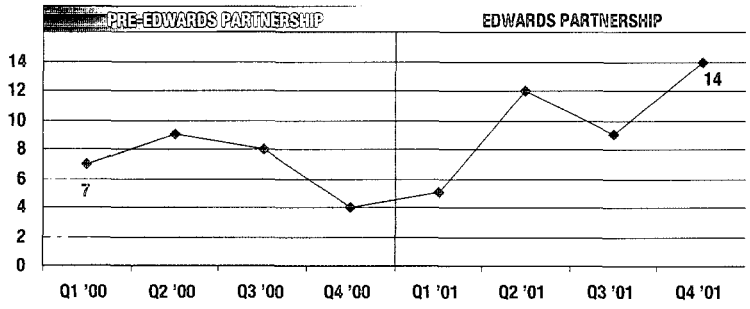
strategy that enables us to address both elements: increasing the installed laser base and providing the education and training necessary to drive procedural adoption. With the Product, the Partner and the Proof all in place we have the ability to increase our installed base and drive procedures.

Delivering Results

Increasing the Laser Base

The hard work of the last year has paid off. During 2001 we shipped 40 CO_2 Heart Lasers to U.S. hospitals, which is more than a 40 percent increase over U.S. laser shipments in 2000. These U.S. laser shipments enabled PLC to significantly increase its U.S. installed base by 25 percent, from 82 lasers at the end of 2000 to 103 lasers at the end of 2001. PLC's 103 U.S. Heart Laser base is comprised of 65 first-generation CO_2 Heart Lasers (HL1) and 38 next-generation CO_2 Heart Lasers (HL2).

PLC U.S. CO_2 Heart Laser Shipments 2000-2001

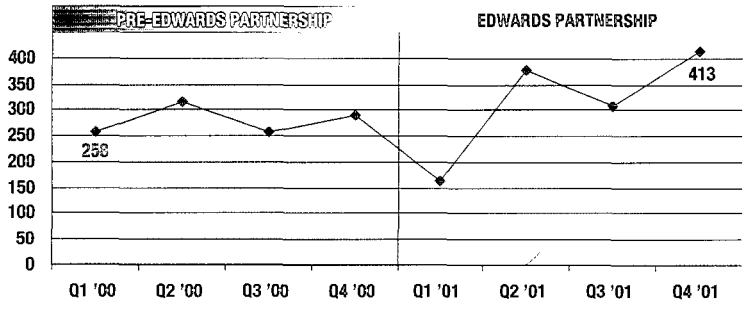


The 14 U.S. lasers shipped in the fourth quarter 2001 is a 250 percent increase over the fourth quarter 2000 laser shipments.

Increasing the Utilization of Each Laser

U.S. kit shipments to hospitals in 2001 were up 12 percent to 1,259 kits. This is a good improvement for the first year of the partnership. During 2001, we invested the right amount of

PLC U.S. Disposable Kit Shipments to Hospitals 2000-2001



The 413 U.S. kits shipped in the fourth quarter 2001 is more than a 40 percent increase over the fourth quarter 2000 kit shipments.

Partner

Edwards Lifesciences

"We believe the CO_2 laser revascularization therapy represents an important advance in the treatment of severe and often debilitating angina or heart pain. With Edwards' clinical and educational capabilities behind PLC's technology, we think it has the potential to become the technology of choice for surgeons and cardiologists who want to achieve a more complete revascularization for their patients."
—Michael A. Mussallem, Chairman and CEO of Edwards Lifesciences

Edwards Lifesciences (NYSE: EW) is a global leader in products and technologies to treat advanced cardiovascular disease and the number-one heart valve company in the world. With a four-decade legacy of working as trusted partners with leading clinicians and scientists, Edwards has some of the most respected brands in cardiovascular care.

The PLC and Edwards relationship capitalizes on each company's strengths, which include Edwards' strong sales and marketing presence in the cardiovascular market and PLC's differentiated CO_2 laser revascularization technology. The combination provides cardiac surgeons with a proven revascularization tool that can relieve heart patients' debilitating angina pain.

Patient

"Today, I am able to do things that truly make me happy."

Luther Hobson

My angina pain was literally killing me. At 73 years old, I had shortness of breath, limited activity and my quality of life was poor. Even two separate coronary artery bypass surgeries—double vessel bypass in December 1997 and double vessel bypass in June 1998—did not ease my significant heart pain. I searched for any relief and I am pleased that my prayers were answered. On February 6, 2001, I received the CO_2 laser revascularization therapy at the Washington Hospital Center.

Since the procedure, I have been feeling much better and more active. Today, I am able to do things that truly make me happy. From playing golf to raising my roses, I now have the part of my life back that is fun.

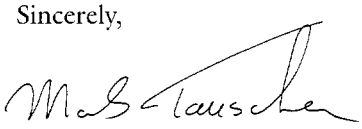
time necessary to launch this partnership correctly, which included training and educational programs. Our expectation is that we should continue to see reasonable and steady kit growth in 2002. In fact, I believe that our fourth-quarter U.S. kit shipments are the beginning of a very positive trend.

Poised for Success

The first year of the Edwards partnership was successful and in January of 2002 Edwards assumed responsibility for the sales and marketing activities of the U.S. CO_2 laser revascularization business. PLC expects to greatly benefit from reduced sales and marketing expenses in 2002 and beyond and we have projected a net savings from the option exercise of $2 million in terms of reduced net loss and cash burn in 2002. We believe the elimination of PLC's U.S. sales and marketing expenses and Edwards' increased commitment to the business will translate into increased market adoption and disposable kit shipments, which will enable PLC to reach quarterly profitability during 2003.

We are focused. We are growing the market. We are building our future. We believe the strategy that we adopted over a year ago of bringing our laser technology to market through a premier strategic partner was the right one. We look forward to reporting on PLC's progress throughout the coming year.

Sincerely,



Mark R. Tauscher
President and Chief Executive Officer
March 25, 2002

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

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

For the fiscal year ended December 31, 2001

OR

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

For the transition period from _____ to _____

Commission file number 1-11388

PLC Systems Inc.

(Exact name of registrant as specified in its charter)

Yukon Territory, Canada	04-3153858
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

10 Forge Park, Franklin, Massachusetts
(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:

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

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

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

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

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 March 15, 2002, was $15,202,796. As of March 15, 2002, 29,611,053 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 2002 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. ("PLC" or the "Company") has developed a patented high-powered carbon dioxide ("CO_2") 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 CO_2 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".

TMR is a laser based treatment for relieving debilitating pain in patients suffering from severe CAD. Each TMR procedure requires a sterile, single use, TMR kit containing assorted TMR handpieces, drapes and other disposable items. The Heart Laser Systems are used by a cardiovascular surgeon to create between 20 and 40 tiny channels in the heart wall of a patient suffering from severe CAD. The Heart Laser Systems were developed specifically for TMR and they are believed to be the only TMR systems that can create a channel completely through the heart wall with a single laser pulse. In addition, the Heart Laser Systems use patented technology to fire this single laser pulse in the fraction of a second between a patient's heartbeats. This patented "synchronization" technology ensures that the Heart Laser Systems will only fire at a relatively safe point in a patient's heartbeat cycle when the heart is relatively still and unresponsive to stimuli. The procedure does not require a heart-lung bypass machine and can be performed through a small incision between the patient's ribs while the patient's heart is beating.

The Company estimates that each year approximately 120,000 patients worldwide are diagnosed with severe CAD, which is not treatable by conventional revascularization techniques. CAD is a form of heart disease caused by the blockage of blood flow into the coronary arteries, which supply oxygen-rich blood to the heart. Typically, severe CAD patients experience excruciating attacks of chest pain, or "angina", and often shortness of breath and fatigue. No longer candidates for traditional surgery, these patients are generally on maximum drug therapy. A U.S. clinical study has demonstrated the HL1 to be safe and effective in decreasing angina by two or more classes after one year (angina is measured in classes from one to four, one being the least painful and four being the most) in 72% of the patients studied; in fact, TMR using the HL1 eliminated all angina in one-third of the patients treated in the study.

More than 8,000 patients have been treated with the Company's Heart Laser Systems in the United States and abroad. As of December 31, 2001, the Company had shipped 181 Heart Laser Systems worldwide. Of these 181 Heart Laser Systems, 103 (38 HL2's and 65 HL1's) are located throughout the U.S. and 78 (2 HL2's and 76 HL1's) are located internationally.

Recent Developments

Transfer of U.S Sales and Marketing Activities To Edwards Lifesciences. On January 15, 2002, PLC announced that Edwards Lifesciences LLC, a subsidiary of Edwards Lifesciences Corporation (hereinafter collectively referred to as "Edwards"), had exercised a pre-existing option to assume full sales and marketing responsibility in the United States for PLC's HL2 and associated TMR procedural kits. Edwards designs, develops and markets a comprehensive line of products and services to treat late-stage cardiovascular disease. Edwards focuses on cardiac surgery, critical care and vascular systems and services, and is the world leader in tissue replacement heart valves and heart valve repair products. Edwards has annual sales of approximately $700,000,000.

Five Year Data on Sustained Angina Relief Published. On September 18, 2001, data from a multi-center, long-term study on the efficacy of CO_2 TMR was published in Circulation, the official journal of the American Heart Association. This study demonstrated that the CO_2 TMR procedure provides significant long-term angina relief.

TMR in Conjunction with Coronary Artery Bypass Surgery Receives Favorable Review. In May 2001, Blue Cross Blue Shield Association's Technology Evaluation Center ("TEC") completed a favorable assessment of TMR as an adjunctive therapy to Coronary Artery Bypass Graft, also known as bypass surgery. TEC concluded that TMR in combination with bypass surgery meets the criteria used to evaluate 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. 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.

New Director Joins PLC Board. In May 2001, Donald E. Bobo, Jr. was appointed to PLC's Board of Directors. Since December 2000, Mr. Bobo has served as Vice President of Corporate Strategy of Edwards. He has over 18 years of experience in the medical products and healthcare industries, where he has served in a variety of senior manager positions. Mr. Bobo received a B.S. degree in Mathematics from Bob Jones University and a M.S. degree in Engineering from the University of Southern California.

Background

In 1981, the Company's Chief Scientific Officer, Dr. Robert I. Rudko, formed Laser Engineering, Inc., now PLC Medical Systems, Inc., to develop and commercialize sealed-off CO_2 lasers. Dr. Rudko, who holds a Ph.D. in electrical engineering from Cornell University, has spent over thirty years designing and developing CO_2 laser systems. In the late 1980s, a surgeon at the San Francisco Heart Institute, Dr. John Crew, was performing early studies of TMR on hearts that had been stopped and placed on a heart-lung machine. Although these early studies appeared promising, at that time it was felt that the efficacy of the TMR treatment should be proven by performing the procedure on a beating heart. Since no laser existed at that time which could perform such a medical procedure, the San Francisco Heart Institute turned to Dr. Rudko and Laser Engineering to design and develop such a laser. The result of that effort was the HL1, a high-powered laser system capable of creating a channel completely through a human heart wall with a single laser pulse delivered in the fraction of a second between heartbeats.

In November 1990, the Company received a Phase I Investigational Device Exemption ("IDE") for its 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. Crew and completed in October 1991. In April 1992, the Company 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, the FDA approved a 100 patient randomized study (Phase III) comparing TMR patients to patients receiving medical management. The study was later expanded to 200 patients.

The Company undertook an effort to gather long-term (more than 12 months) data on eligible patients from its 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. 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 TMR with the HL1, 17% of the patients reported having no angina and 64% were in angina class 1 or 2.

On August 20, 1998, the Company 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. PLC was the first company to receive FDA approval to commercialize a product to perform TMR.

On January 29, 2001, the Company received approval from the FDA to market the HL2. On February 27, 2001, the Company received approval to place the CE Mark on the HL2, thereby allowing the Company to begin marketing its new laser in the European Union and other countries that base regulatory clearance on the European CE Mark.

Since April 1992, the Company has received 26 U.S. patents relating to the underlying laser technology, the use of a laser on a beating heart, the HL1 handpiece and other laser accessories. The Company also has 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. The Company also holds a number of foreign patents and patent applications.

The Company was incorporated pursuant to the COMPANY ACT of British Columbia, Canada on March 3, 1987. The Company transferred its jurisdiction of incorporation to the Yukon Territory of Canada in March 1999. The Company's principal offices and manufacturing facilities are located at 10 Forge Park, Franklin, Massachusetts 02038. The Company's telephone number is (508) 541-8800. As used herein, the terms "PLC" 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 2002 Heart and Stroke Statistical Update ("2002 HSSU") published by the American Heart Association, in 1999 an estimated 61.8 million Americans suffered from cardiovascular disease with an estimated 12.6 million Americans suffering from coronary heart disease. Cardiovascular disease is the leading cause of death in the U.S., resulting in approximately 40% (or 959,000 in 1999) 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 ("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 2002 HSSU, an estimated 571,000 coronary artery bypass procedures were performed on 355,000 patients and 601,000 balloon angioplasty procedures were performed on 587,000 patients in the U.S. in 1999. The American Heart Association estimates the cost of cardiovascular disease in the year 2002 at $329.2 billion, including physician and nursing services, hospital and home nursing services, the cost of medications and lost productivity resulting from disability.

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 drugs eluding 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.

The Company believes 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. Also, with additional clinical research, TMR may be proven useful in conjunction with angioplasty or bypass surgery to obtain more complete revascularization.

In addition to the more conventional treatments described above, there are a number of newer treatments and therapies including minimally invasive direct coronary artery bypass ("MIDCAB"), "off-pump" coronary artery bypass ("OPCAB") and the use of angiogenic growth factors. Some of these techniques and therapies may offer certain improvements in relation to conventional treatments. The Company believes that with further clinical research, TMR may be found useful in conjunction with these less invasive procedures to more effectively revascularize the heart.

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 where channels are created into 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. A Heart Laser System is computer synchronized with the patient's heartbeat, firing only when the left ventricle is filled with blood and is electrically insensitive. The Company believes 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 owned by the Company. The Heart Laser Systems are capable of drilling 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. Each TMR procedure requires a sterile, single use, TMR kit containing assorted TMR handpieces, drapes and other disposable items.

Potential Benefits of TMR

Based on clinical results to date, the Company believes 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. 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 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.

Potential Use in Conjunction with Both Conventional and Minimally Invasive Coronary Bypass. TMR may allow the surgeon to provide oxygenated blood to areas of the heart muscle that are not accessible by coronary bypass grafts. With the advent of the MIDCAB and OPCAB procedures, in which coronary artery bypass graft surgery is performed on a beating heart, the Company believes that with additional clinical research, TMR may be found to be an effective complement to these procedures. TMR can be performed on the anterior, posterior and lateral walls of the heart while the MIDCAB procedure usually is only performed on the anterior wall of the heart. Further, although the OPCAB procedure can be performed on posterior and lateral walls of the heart, it generally entails great technical difficulty.

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. The Company believes 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, which would concomitantly with the TMR therapy, inject these agents into the myocardium.

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

Development of Marketing Strategy

The Company's strategy is to market its products principally through key distributors throughout the world. In the United States, the Company has partnered with Edwards as its exclusive distributor for the HL2 and related TMR disposable procedure kits. Outside the United States, the Company has established an independent dealer network to market its products, although in some areas, principally Europe, it continues to sell its products directly to hospitals. In all cases, the Company attempts, either directly or through working with its 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. The Company and its distributors have submitted applications for government approval to sell the HL1 in other countries, including Japan, although the Company cannot predict when, if ever, approval will be obtained.

PLC sells its products to Edwards and its international distributors at a discount off list price and generally recognizes product sales at the time of shipment. In connection with and effective upon the January 2002 sales and marketing option exercise (as discussed above under the heading "Business—Recent Developments") Edwards will receive increased gross margins pursuant to the distribution agreement dated January 9, 2001 between PLC and Edwards.

United States. Beginning in 2001, under the Edwards exclusive distribution arrangement, Edwards determines the best programs, including sale, lease, rental and usage based offerings, that Edwards' believes will be most effective in the United States in marketing the HL2 and related TMR kits to hospitals.

The Company believes 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, the Company expects 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 United States 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 originally established by PLC at Rush Presbyterian Medical Center in Chicago and the Texas Heart Institute in Houston. Edwards expanded the Center of Excellence training programs in 2001 to include a program at Providence St. Vincent Hospital and Medical Center in Portland, Oregon. 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.

International. The Company currently markets the Heart Laser Systems overseas either directly or through independent distributors. International sales (by origin) accounted for 14%, 19% and 12% of the Company's total revenue in 2001, 2000 and 1999, respectively. The Company had no sales by origin in Canada, its jurisdiction of incorporation.

PLC 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 the Company to sell the Heart Laser Systems commercially in European Union countries. Despite the Company's 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, PLC received ISO 9001 certification, allowing the Company to self certify and place the CE Mark on its products.

In early 1999, the Company renewed its distribution agreement in Japan with Ktec Corporation ("Ktec", formerly known as Imatron Japan, Inc.), to distribute the HL1 in Japan and complete the Japanese regulatory approval process. Along with the United States 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 HL1's from PLC to conduct clinical studies in Japan. PLC and Ktec submitted data from these studies to the Japanese government in December 1998 in support of their 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, the Company notified Ktec that it was terminating the existing distribution agreement as a result of Ktec's failure to timely obtain approval from the Japanese government to market the HL1 in Japan. The Company continues to work with Ktec to try and obtain approval to market the HL1 in Japan. However, by canceling the existing distribution agreement with Ktec, the Company has 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, 2001, 2 HL2s and 76 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 90% of our revenues in the fiscal years ended December 31, 2001 and 2000 and 89% in

the fiscal year ended December 31, 1999 were derived from the sales and service of our Heart Laser Systems and related disposables.

During 2001, sales to Edwards accounted for 68% of the Company's total revenues. No single customer accounted for more than 10% of the Company's revenues in fiscal 2000 or 1999.

Manufacturing

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

The Company purchases components for its Heart Laser Systems and its related disposables 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, the Company may not be able to meet demand for its products, which could have a material adverse effect on the Company's business and results of operations.

The Company's 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 have been or may be developed by the Company, 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 and clinical testing, installation, servicing, labeling, distribution and promotion of medical devices in the United States. The Company's 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 the Company's products are or may be sold impose additional regulatory requirements.

On August 20, 1998, the Company 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. PLC was 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.

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, the Company received approval to market the HL2 in the United States.

The Company intends to continuously improve its products after market introduction and may therefore submit future Investigational Device Exemption, Pre-Market Approval and Pre-Market Approval 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 the Company's products.

As a device manufacturer, the Company is also required to register with the FDA. As such, the Company is subject to inspection on a routine basis for compliance with the FDA's Quality Systems regulations. These regulations require that the Company manufacture its products and maintain its documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, the Company is required to comply with various FDA requirements for reporting. The FDC Act and medical device reporting regulations require that the Company provide information to the FDA on death or serious injuries alleged to have been caused or contributed to by the use of its 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. The Company's 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 the Company, its officers, directors or employees. Failure to comply with regulatory requirements could have a material adverse effect on the Company's 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 ("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 Health Care Finance Administration ("HCFA") 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, HCFA issued an addendum clarifying Medicare coverage for TMR procedures. In response to questions from practicing physicians, HCFA announced that Medicare coverage would be provided in cases where TMR is used as an adjunct to coronary artery bypass grafting.

On January 1, 2001, a physician reimbursement code was assigned for the TMR procedure when performed as an adjunct to coronary artery bypass grafting. 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. In January 2000, a physician reimbursement code was assigned for the TMR procedure when performed as a sole therapy.

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 the Company's 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 the Company believes 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 the Company's products. No assurance can be given, however, that these payers will continue to reimburse healthcare providers who perform TMR procedures using the Company's products. Further, no assurance can be given that additional payers will reimburse healthcare providers who perform TMR procedures using the Company's products or that reimbursement, if provided, will be timely or adequate. In addition, the market for the Company's 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, the Company believes 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, the Company believes that hospitals may delay the implementation of a TMR program until there is documentation of the medical processes by which TMR procedures relive angina, if ever.

Proprietary Processes, Patents, Licenses and Other Rights

It is the Company's policy to file patent applications to protect its technology, inventions and product improvements. The Company also relies on trade secret protection for certain confidential and proprietary information.

Since April 1992, the Company has received 26 U.S. patents. These patents have terms which expire from 2009 through 2018 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. The Company also has U.S. patent applications pending relating to the Heart Laser Systems, handpiece, other technology used in the Heart Laser Systems, and technologies associated with percutaneous myocardial revascularization.

In April 1996, the Company received patents from the European Patent Office and the Japanese Patent Office providing patent protection on its 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. The Company has numerous patents pending related to the Heart Laser Systems and their components in various international patent offices. The Company 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 ("CardioGenesis"), a competitor in the TMR market, agreed to the validity and enforceability of certain of the Company's 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 the Company's proprietary synchronization technology, which the Company believes is a critical factor in increasing the safety of TMR procedures. PLC granted CardioGenesis a non-exclusive worldwide license to the patents in exchange for payment of a license fee and ongoing royalties over of the life of the patents.

Although the Company believes its patents to be strong, successful litigation by a competitor invalidating these patents could have a material adverse effect on the Company's 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 involve complex legal and factual issues and therefore can be highly uncertain.

The Company also relies upon unpatented proprietary technology and trade secrets that it seeks 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 the Company 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 the Company can meaningfully protect its rights in such unpatented technology. In addition, others may hold or receive patents, which contain claims that may cover products developed by the Company.

The Company believes its 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 to and diversion of effort by the Company, may be necessary to enforce patents issued to the Company, to protect trade secrets or know-how owned by the Company, to defend the Company 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 the Company to significant liabilities to third parties, require the Company to seek licenses from third parties and prevent the Company from manufacturing, selling or using its products, any of which could have a material adverse effect on the Company's business, financial condition and results of operations.

Competition

CardioGenesis is the Company's principal competitor in the TMR market. In February 1999, CardioGenesis received FDA approval to market its holmium laser in the U.S. to perform TMR. According to public information, the laser revascularization systems developed by CardioGenesis may

be adaptable to be used to perform not only TMR, but also 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 would provide a less invasive method of creating channels in a human heart if it can be proven safe and effective. Although the Company has a proprietary PMR product design, currently the Company is not actively pursuing its development. No assurance can be given that the Company will ever successfully pursue, develop or market a PMR product.

Presently, there are no FDA approved PMR devices in the marketplace. On July 9, 2001, the FDA Circulatory System Devices Advisory Panel met to consider a Pre-Market Approval Application for CardioGenesis' PMR Laser. CardioGenesis presented the technical aspects of the device along with the results obtained from two clinical studies that were conducted with the CardioGenesis laser. 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 has publicly stated that they intend to continue to seek FDA approval on their PMR device in the future. No assurance can be given on whether such approval will ever be obtained or what the impact of any such approval would be on the Company's business.

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 the Company believes 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 the Company's CO_2 laser TMR approach, poses a significant challenge for the Company in attempting to convince cardiovascular surgeons and referring clinicians of the efficacy of TMR as a procedure. The Company and Edwards have taken steps to distinguish surgical TMR from PMR, and the CO_2 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 the Company or Edwards is 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. The Company believes 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 the Company's synchronized, single pulse CO_2 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 the Company's CO_2 laser. Holmium lasers currently used for TMR are not capable of creating a patent 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. The Company believes that during 2001 it continued to successfully differentiate its CO_2 laser.

Many treatments are available for CAD. The Company believes 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. The Company believes that its competitive success will be based on its 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 its products, attract and retain key personnel, obtain and maintain patent or other protection for its products and successfully differentiate, price, manufacture and market its products either directly or through outside parties.

The Company believes 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. The Company believes 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). Many of the companies manufacturing these products have substantially greater resources and experience than the Company. 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 the Company in manufacturing and marketing their products. No assurance can be given that the Company's competitors or others will not succeed in developing technologies, products or procedures that are more effective than any being developed by the Company or that would render the Company's technology and products obsolete or noncompetitive. Although the Company will continue to work to develop new and improved products, the advent of either new devices or new pharmaceutical agents could hinder the Company's ability to compete effectively and have a material adverse effect on its business, financial condition and results of operations.

Research and Development

Research and development expenses were $904,000, $1,680,000 and $2,672,000 for the years ended December 31, 2001, 2000 and 1999, 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, the

Company has reduced its HL2 research and development program expenses as the product has transitioned into production.

The Company continues to monitor all technologies that may be applicable to TMR to keep it at the forefront of this field. No assurance can be given that the Company's research and development goals will be implemented successfully or that the Company will maintain its position in this market.

Employees

As of March 15, 2002, the Company had 30 full-time domestic employees, including its executive officers. Of these, 9 are in general and administrative positions, 2 are involved in sales, 4 are involved in research and development, 8 are involved in manufacturing, 4 are involved in service and 3 are involved in quality and regulatory affairs. The Company also employs 2 full-time employees for its international operations and one part-time domestic employee. None of the Company's employees are represented by a union. The Company considers its relationships with its employees to be satisfactory.

Item 2. *Properties*

Since September 1996, the Company has leased its current facility in Franklin, Massachusetts where it maintains its principal executive offices and manufacturing and development operations. In June 2001, the Company amended its 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, 2002, 2003, 2004, 2005 and for the eight months ended August 31, 2006 are approximately $281,000, $282,000, $285,000, $286,000 and $191,000, respectively. The Company is also responsible for operating and maintenance costs and real estate taxes.

Item 3. *Legal Proceedings*

In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis. The original CardioGenesis lawsuit, and counterclaim by the Company, dealt with the Company's synchronization patent (U.S. Patent No. 5,125,926). Under the settlement, CardioGenesis agreed that U.S. Patent No. 5,125,926 and related international patents of the Company were valid and enforceable. PLC 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. As part of the settlement, CardioGenesis agreed to pay the Company:

- a minimum of $2.5 million over 42 months ending on June 30, 2002; and
- license fees and ongoing royalties on sales of all covered products until the expiration of all licensed patents.

Should CardioGenesis ever obtain FDA approval to market its PMR laser (which they originally submitted for pre-market approval in July 2001 but were denied approval on), then they would be obligated to pay royalties to the Company on the sales of this product, as long as it was deemed a covered product under the license agreement.

The Company is not involved in any other material litigation.

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, the Company's common stock has traded on the American Stock Exchange ("AMEX") under the symbol "PLC". On March 15, 2002, the closing sale price of the Company's common stock was $0.66 per share.

For the periods indicated, the following table sets forth the range of high and low sales prices for the Company's common stock from January 1, 2000.

	High	Low
2000		
First Quarter	$4.63	$2.06
Second Quarter	$2.50	$1.19
Third Quarter	$1.56	$0.94
Fourth Quarter	$0.94	$0.31
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

As of March 15, 2002, there were approximately 781 record holders of the Company's common stock. The Company believes that there are approximately 12,737 beneficial owners of the Company's common stock.

Dividends

The Company has never paid cash dividends. The Company currently intends to retain all future earnings, if any, for use in its business and does 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 the Company's 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.

Dividends

Under the United States—Canada Income Tax Convention (1980) (the "Convention"), a Canadian withholding tax of 15% generally applies to dividends (including stock dividends) paid or credited to the beneficial owners of the Company's shares:

- who are resident in the United States for the purposes of the Convention, and
- who do not hold the shares in connection with a business carried on through a permanent establishment or a fixed base in Canada.

The Convention provides an exemption from withholding tax on dividends paid or credited to certain tax-exempt organizations that are resident in the United States for purposes of the Convention. Persons who are subject to the United States federal income tax on dividends may be entitled, subject to certain limitations, to either a credit or deduction with respect to Canadian income taxes withheld with respect to dividends paid or credited on the Company's shares.

Item 6. *Selected Financial Data*

The following selected financial data of the Company for the five years ended December 31, 2001, are derived from the audited consolidated financial statements of the Company. The data should be read in conjunction with the consolidated financial statements, related notes and other financial information included elsewhere herein. Certain costs associated with service revenues totaling $330,000, $287,000, $245,000, $220,000 and $258,000 that were previously included in selling, general and administrative expense have been reclassified to cost of placement and service fees for the years ended December 31, 2001, 2000, 1999, 1998 and 1997, respectively.

	For the years ended December 31				
	2001	2000	1999	1998	1997
	(All amounts are in thousands except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales	$ 7,975	$ 6,803	$ 8,400	$ 3,088	$ 5,687
Placement and service fees	1,805	3,437	3,236	2,605	3,254
Total Revenues:	9,780	10,240	11,636	5,693	8,941
Costs and expenses:					
Cost of product sales	4,556	3,765	3,615	1,945	2,721
Cost of placement and service fees	1,035	3,455	2,306	2,842	2,853
Selling, general and administrative	7,438	9,143	9,809	13,498	12,791
Research and development	904	1,680	2,672	4,468	5,158
Loss from operations	(4,153)	(7,803)	(6,766)	(17,060)	(14,582)
Other income	251	393	211	457	178
Net loss	$(3,902)	$(7,410)	$(6,555)	$(16,603)	$(14,404)
Net loss per share—Basic and diluted	$ (.13)	$ (.32)	$ (.32)	$ (.86)	$ (.84)
Shares used to compute net loss per share—Basic and diluted	29,248	23,266	20,675	19,218	17,050

	As of December 31				
	2001	2000	1999	1998	1997
Balance Sheet Data:					
Working capital	$5,785	$5,010	$5,459	$5,050	$12,793
Total assets	12,298	15,078	15,319	16,257	27,017
Long term obligations	—	—	—	37	121
Secured borrowings, long-term	1,446	3,079	2,082	—	—
Stockholders' equity	6,310	6,216	8,885	10,662	19,009

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

Overview

In January 2001, the Company obtained FDA approval to market its next generation laser, the HL2. The HL2 is less than half the weight and size of the Company's 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, the Company 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 United States. In 2001, Edwards' sales force was principally responsible for driving increased TMR procedures and kit utilization, as well as providing the Company's capital sales force with HL2 sales leads. The Company maintained its capital sales force through January 2002 to assist Edwards in marketing the HL2 in the United States.

In January 2002, Edwards exercised a pre-existing option to assume full sales and marketing responsibility in the United States for PLC's HL2 and associated TMR kits. The Company sells the HL2 and TMR kits to Edwards at a discount to list price and Edwards remarkets the HL2 and TMR kits to hospitals. The Company expects to benefit from reduced sales and marketing expenses in 2002 and beyond, and anticipates a reduction in both net loss and cash burn of approximately $2,000,000.

A portion of the Company's operations is conducted outside of the United States. Historically the impact of foreign currency fluctuations on the Company's overall consolidated results of operations has not been material (as discussed below under the heading "Quantitative and Qualitative Disclosures about Market Risk").

Critical Accounting Policies

Revenue Recognition

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

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 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. As of December 31, 2001, the Company had not earned or recorded any such additional shared revenue.

The Company records revenue from the sale of TMR kits and Heart Laser Systems to international dealers 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 which 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, 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. For the year ended December 31, 2001, Heart Laser System revenues, a component of product sales, increased as compared to the year ended December 31, 2000 due to an increase in the number of Heart Laser System transactions, partially offset by a lower average selling price. Lower selling prices are a direct result of the Company's new 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, a component of product sales, increased in 2001 as compared to 2000. Prior to 2001, the Company 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

Placement and service fees of $1,805,000 for the year ended December 31, 2001 decreased 47% from 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. Placement fees declined as a result of (1) various U.S. HL1 customers upgrading to an HL2, which resulted in a laser sale to Edwards and a corresponding shift in recorded disposable kit sales to these new HL2 customers as product sales instead of placement fees, as discussed in product sales above and (2) a decline in international placement contract fees due to decreased kit shipments to international placement contract customers.

Kit Shipments

Management of the Company 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, 2001, the Company 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. Overall, 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.

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 margin in 2000 is primarily due to a non-recurring charge of $2,117,000 which the Company incurred in the fourth quarter to write down the value of its HL1 inventory and capital equipment due to the transition to the new HL2 product. Without this charge, pro forma gross margin would have been 50% of revenues in 2000. The decrease in gross margin in 2001 as compared to the pro forma gross margin in 2000 is a result of lower selling prices of the Company's 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 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. The Company expects 2002 sales and marketing expenditures to significantly decrease as compared to 2001 due to Edwards' exercise of the sales and marketing option in January 2002.

Research and development expenses of $904,000 for the year ended December 31, 2001 decreased $776,000 or 46% when compared with 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. In 2002, research and development expenditures are expected to be comparable with the level of expenditures in 2001.

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. In 2002, other income is expected to decrease due to lower average invested cash balances.

Net Loss

The Company 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 the Company incurred in the fourth quarter of 2000 to write down the value of its 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.

In connection with the January 2002 sales and marketing option exercise by Edwards, Edwards will, pursuant to the terms of the distribution agreement with the Company, retain a greater share of the revenue generated from U.S. TMR kit sales. In addition, royalty revenue is expected to decrease in 2002 because the guaranteed minimum royalties generated from the settlement of the CardioGenesis lawsuit will end on June 30, 2002. Although CardioGenesis is required to pay an ongoing royalty on

sales of covered products after June 30, 2002, the Company expects 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 significantly lower than the guaranteed minimum royalties. As a result, in 2002 the Company expects that its gross profit will likely be lower than the corresponding 2001 period.

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

Total revenues of $10,240,000 for the year ended December 31, 2000 decreased $1,396,000 or 12% when compared to total revenues of $11,636,000 for the year ended December 31, 1999. This decrease of 12% in total revenues was the result of a 19% decrease in product sales offset by a 6% increase in placement and service fees.

Product Sales

For the year ended December 31, 2000, product sales of $6,803,000 decreased $1,597,000 or 19% when compared to product sales of $8,400,000 for the year ended December 31, 1999. Contributing factors to the decrease in product sales are a decline in the number of HL1 sales transactions recognized during the year coupled with a decrease in the average selling price for the HL1 in 2000 and reduced royalties. The Company recorded 18 HL1 sales transactions in 2000 compared to 24 HL1 sales transactions in 1999. The decrease in the number of HL1 sales transactions recognized resulted primarily from the Company's shift from a sale to a placement business model strategy in 2000 and, in the latter part of the year, a redirected focus on launching the next-generation HL2.

Placement and Service Fees

Placement and service fees of $3,437,000 for the year ended December 31, 2000 increased 6% from placement and service fees of $3,236,000 for the year ended December 31, 1999. This increase in placement and service revenues is primarily due to the Company's implementation of its laser redeployment strategy, which focused on moving HL1's from less active sites to sites which are potentially more productive.

Kit Shipments

Management of the Company 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, 2000, the Company shipped 1,606 disposable kits, an increase of 41% over the 1,136 disposable kits shipped during the year ended December 31, 1999. Management believes the overall increase is primarily due to (i) the Company's increased efforts to promote TMR in international markets, (ii) Medicare reimbursement policies, (iii) the Company's increased base of installed lasers, and (iv) increased Company training programs for physicians throughout 2000.

Gross Profit

Total gross profit decreased to $3,020,000 or 29% of total revenues for the year ended December 31, 2000 as compared with the gross profit of $5,715,000 or 49% of total revenues for the year ended December 31, 1999. The decrease in gross margin for the year 2000 is primarily due to a non-recurring charge of $2,117,000 which the Company incurred in the fourth quarter to write down the value of its HL1 inventory and capital equipment due to the transition to the new HL2 product. Without this charge, gross margin in 2000 would have been 50% of revenues, slightly up from 49% of revenues in 1999 as a result of decreased manufacturing overhead expenditures partially offset by lower sales. Of the $2,117,000 charge, $1,265,000 was allocated to placement cost of revenues for the write

down of the Company's installed HL1 placement laser base to its estimated net realizable value and $852,000 was allocated to product cost of revenues for potentially obsolete HL1 inventory at December 31, 2000.

Operating Expenses

Selling, general and administrative expenses of $9,143,000 for the year ended December 31, 2000 decreased $666,000 or 7% when compared with expenses of $9,809,000 for the year ended December 31, 1999. The decrease is primarily attributable to a decrease in compensation related expenditures as a result of a reduced headcount throughout 2000 when compared to 1999. The Company used a portion of the savings from the headcount reduction to increase its sales and marketing initiatives, particularly in the areas of physician training, internet/web expansion, and advertising and marketing literature.

Research and development expenses of $1,680,000 for the year ended December 31, 2000 decreased $992,000 or 37% when compared with expenses of $2,672,000 for the year ended December 31, 1999. This decrease is a result of reduced expenses in monitoring and data collection, project materials and new product development, partially offset by an increase in compensation.

Other Income

Other income of $393,000 for the year ended December 31, 2000 increased $182,000 or 86% when compared to other income of $211,000 for the year ended December 31, 1999. The increase is a result of both higher average invested cash balances and higher rates of interest on invested funds.

Net Loss

The Company incurred a net loss of $7,410,000 for the year ended December 31, 2000 compared with a net loss of $6,555,000 for the year ended December 31, 1999. The higher net loss resulted from lower total revenues and lower gross margins, which is primarily due to a non-recurring charge of $2,117,000, which the Company incurred in the fourth quarter to write down the value of its HL1 inventory and capital equipment due to the transition to the new HL2 product.

There was no provision for income tax for the years ended December 31, 2000 or 1999 due to net losses of $7,410,000 and $6,555,000, respectively.

Liquidity and Capital Resources

At December 31, 2001, the Company had cash, cash equivalents and marketable securities of $4,977,000.

In conjunction with the execution of the Edwards marketing and distribution agreement in January 2001, the Company received net proceeds of approximately $3,898,000 through the sale of 5,333,333 newly issued shares of common stock at $.75 per share and issued warrants to purchase an additional 3,000,000 shares at exercise prices ranging from $1.50 to $3.50. See Note 6 in the accompanying consolidated financial statements.

During the year ended December 31, 2001, the Company incurred a net loss of $3,902,000, which resulted in the use of approximately $4,610,000 to support operations. Cash provided by investing activities was approximately $81,000 and primarily resulted from the maturity of marketable securities offset by the purchase of capital equipment used in the Company's manufacturing operations. Cash provided by financing activities was approximately $3,766,000, primarily consisting of the net proceeds of $4,002,000 obtained from sales of the Company's common stock offset by a reduction in secured borrowings.

The Company believes that its existing cash resources will meet its working capital requirements through December 31, 2002. However, the Company is largely dependent on the success of Edwards' sales and marketing efforts in the U.S. to substantially increase TMR procedural volumes and revenues. Should TMR procedural volume not increase sufficiently to offset the impact of selling lasers and kits to Edwards at a discounted price, the Company's liquidity and capital resources will be negatively impacted. Additionally, other unanticipated decreases in operating revenues or increases in expenses or further delays in third-party reimbursement to healthcare providers using the Company's products may adversely impact the Company's cash position and require further cost reductions or the need to obtain additional financing. No assurance can be given that the Company, working with Edwards and its international distributors, will be successful in achieving broad commercial acceptance of the Heart Laser Systems or that the Company will be able to operate profitably on a consistent basis.

The Company has seen an increasing trend on the part of hospital customers to acquire the Heart Laser Systems on a usage basis rather than as a capital equipment purchase. The Company believes that this trend is the result of limitations many hospitals currently have on acquiring expensive capital equipment as well as competitive pressures in the marketplace. This shift to a usage business model may result in a longer recovery period for Edwards to recoup their investment in lasers they purchase from the Company. This could result in (1) a delay in the Company's ability to receive additional shared revenue, if any, that it otherwise is entitled to receive under the terms of its distribution agreement with Edwards (see "Critical Accounting Policies—Revenue Recognition") and (2) a delay in the purchase of new lasers by Edwards if their installed base of placement lasers under usage contracts are under-performing and they choose to re-deploy these lasers to other new hospital sites in lieu of purchasing a new laser from the Company. The Company's cash position and its 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. No assurance can be given that a usage based sales model will be successful, whether implemented by the Company or Edwards.

The Company may need to raise additional capital to fund operations during the next twelve months. There can be no assurance that, should the Company require additional financing, such financing will be available on terms and conditions acceptable to the Company. Should additional financing not be available on terms and conditions acceptable to the Company, additional actions may be required that could adversely impact the Company's 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.

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. We have 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, $7,410,000 for the year ended December 31, 2000 and $6,555,000 for the year ended December 31, 1999. As of December 31, 2001, we had an accumulated deficit of $86,003,000. We have not achieved profitability and expect to continue to incur net losses for at least the next year. Moreover, although our business is not seasonal in nature, our revenues 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 disposables. Approximately 90% of our revenues in the years ended December 31, 2001 and December 31, 2000 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 United States. As a result of this relationship, Edwards accounted for 68% of our total revenue in the fiscal year ended December 31, 2001, 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, ECG card 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 common stock may be delisted from AMEX

We are currently below certain of AMEX's continued listing guidelines. If we are unable to regain compliance with AMEX's continued listing guidelines, our common stock could be delisted from

AMEX. If our common stock were delisted from AMEX, we could face a number of negative implications, including reduced liquidity in our common stock as a result of the loss of market efficiencies associated with AMEX and the loss of federal preemption of state securities laws, as well as the potential loss of confidence by investors, suppliers, customers and employees, fewer business development opportunities and greater difficulty in obtaining financing.

Our company may be unable to raise needed funds

As of December 31, 2001, we had cash and cash equivalents totaling $4,977,000. 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, 2002. 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

The Heart Laser Systems are designed for use in the treatment of coronary artery disease in a surgical laser procedure we pioneered known as transmyocardial revascularization. Transmyocardial revascularization is commonly referred to in our industry as "TMR." 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 United States.

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 long-term clinical studies may adversely affect our business

Patients have only been treated with the Heart Laser Systems since January 1990, and, as a result, there have been few long-term follow-up studies. If patients suffer harmful, long-term consequences from the Heart Laser Systems, our business, financial condition and results of operations will be materially and adversely affected.

Our business may 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 CO_2 laser TMR approach, makes it more challenging for us to distinguish our surgical TMR from PMR, and our CO_2 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 their PMR laser, which would provide 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

General

The Heart Laser Systems and our manufacturing activities are subject to extensive, rigorous and changing federal and state regulation in the United States and to similar regulatory requirements in other major markets, including the European Union and Japan. To date, we have received regulatory approval in the United States 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 common-law negligent design claims or manufacturing and labeling claims based on state rules. Such claims may absorb significant management time and could degrade the reputation of PLC 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 United States. Establishing 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 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 United States 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.

Antitakeover 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 stockholders 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, 2001, we have reserved an additional 7,487,173 shares of common stock for future issuance upon exercise of outstanding options, warrants and shares purchasable under an employee stock purchase plan.

	Range of Exercise/ Conversion Prices	Weighted Average Exercise/ Conversion Price	Shares Reserved for Future Issuance
Options	$.52–$8.88	$2.47	4,047,710
Warrants	$1.00–$27.81	$3.33	3,327,215
Employee Stock Purchase Plan	$.425–$.51	$ .45	112,248
Total			7,487,173

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 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 the Company's operations consists of sales activities in foreign jurisdictions. The Company manufactures its products exclusively in the United States and sells the products in the United States and abroad. As a result, the Company's 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 the Company distributes its products. The Company's 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 nonfunctional currency 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 the Company's business financial condition and results of operations, although at the present the Company does not believe that its exposure is significant.

The Company's interest income and expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash equivalents and marketable securities.

Item 8. *Financial Statements And Supplementary Data*

All financial statements required to be filed hereunder are filed as Appendix A hereto, are listed under Item 14(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 the Company's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Company's 2002 Annual Meeting of Shareholders (the "Definitive Proxy Statement") under the caption "Item No. 3—Election of Directors".

Item 11. *Executive Compensation*

The information required by this item is incorporated herein by reference to the Company's Definitive Proxy Statement under the caption "Item No. 3—Election of Directors". The information specified in Item 402(k) and (1) of Regulation S-K and set forth in the Company's Definitive Proxy Statement is not incorporated by reference.

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

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

PART IV

Item 14. *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.

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 14(a) above.

SIGNATURES

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

PLC SYSTEMS, INC.

Date: March 28, 2002

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

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

Name	Capacity	Date
/s/ MARK R. TAUSCHER Mark R. Tauscher	President and Chief Executive Officer (Principal Executive Officer)	March 28, 2002
/s/ JAMES G. THOMASCH James G. Thomasch	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 28, 2002
/s/ EDWARD H. PENDERGAST Edward H. Pendergast	Chairman of the Board of Directors	March 28, 2002
/s/ DONALD E. BOBO Donald E. Bobo	Director	March 28, 2002
/s/ KEVIN J. DUNN Kevin J. Dunn	Director	March 28, 2002
/s/ BENJAMIN HOLMES Benjamin Holmes	Director	March 28, 2002
/s/ ALAN H. MAGAZINE Alan H. Magazine	Director	March 28, 2002
/s/ H.B. BRENT NORTON, M.D. H.B. Brent Norton, M.D.	Director	March 28, 2002
/s/ KENNETH J. PULKONIK Kenneth J. Pulkonik	Director	March 28, 2002
/s/ ROBERT I. RUDKO, PH.D. Robert I. Rudko, Ph.D.	Director	March 28, 2002
/s/ ROBERTS A. SMITH, PH.D. Roberts A. Smith, Ph.D.	Director	March 28, 2002

APPENDIX A

PLC SYSTEMS INC.
CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2001, 2000 and 1999

PLC SYSTEMS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Auditors

To 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, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in the Index at Item 14(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, 2001 and 2000, and the consolidated results of its operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States. 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 15, 2002

PLC SYSTEMS INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2001 and 2000

	2001	2000
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,977	$ 5,726
Marketable securities	—	288
Accounts receivable, net	2,544	1,400
Lease receivables, net	1,510	1,680
Inventories, net	1,001	1,440
Prepaid expenses and other current assets	222	259
Total current assets	10,254	10,793
Equipment, furniture and leasehold improvements, net	383	1,049
Lease receivables, net	1,326	2,836
Other assets	335	400
Total assets	$12,298	$ 15,078
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 968	$ 1,276
Accrued clinical costs	56	576
Accrued compensation	444	799
Accrued other	803	626
Deferred revenue	507	531
Secured borrowings	1,691	1,975
Total current liabilities	4,469	5,783
Deferred revenue	73	—
Secured borrowings	1,446	3,079
Total long term liabilities	1,519	3,079
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 29,527 and 23,965 shares issued and outstanding in 2001 and 2000, respectively	93,419	89,417
Accumulated deficit	(86,003)	(82,101)
Accumulated other comprehensive loss	(1,106)	(1,100)
	6,310	6,216
Total liabilities and stockholders' equity	$12,298	$ 15,078

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, 2001, 2000 and 1999

	2001	2000	1999
	(In thousands, except per share data)		
Revenues:			
Product sales	$ 7,975	$ 6,803	$ 8,400
Placement and service fees	1,805	3,437	3,236
Total revenues	9,780	10,240	11,636
Cost of revenues:			
Product sales	4,556	3,765	3,615
Placement and service fees	1,035	3,455	2,306
Total cost of revenues	5,591	7,220	5,921
Gross profit	4,189	3,020	5,715
Operating expenses:			
Selling, general and administrative	7,438	9,143	9,809
Research and development	904	1,680	2,672
Total operating expenses	8,342	10,823	12,481
Loss from operations	(4,153)	(7,803)	(6,766)
Other income, net	251	393	211
Net loss	$(3,902)	$(7,410)	$(6,555)
Net loss per share—Basic and Diluted	$ (.13)	$ (.32)	$ (.32)
Shares used to compute net loss per share—Basic and Diluted	29,248	23,266	20,675

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, 2001, 2000 and 1999

	Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			
			(In thousands)		
Balance, December 31, 1998	19,740	$79,521	$(68,136)	$ (724)	$10,661
Exercise of stock options	4	17	—	—	17
Conversion of debentures due 2003	163	972	—	—	972
Issuance of common stock	1,316	3,786			3,786
Compensation expense	—	84	—	—	84
Comprehensive loss:					
Net loss	—	—	(6,555)	—	(6,555)
Foreign currency translation				(80)	(80)
Total comprehensive loss					(6,635)
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

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, 2001, 2000 and 1999

	2001	2000	1999
	(In thousands)		
Operating activities:			
Net loss	$(3,902)	$(7,410)	$(6,555)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	904	3,641	2,959
Compensation on stock options	—	—	84
Change in assets and liabilities:			
Accounts receivable	(1,150)	488	313
Inventory	439	908	607
Prepaid expenses and other assets	67	138	234
Accounts payable	(310)	(63)	342
Deferred revenue	42	355	(57)
Accrued liabilities	(700)	(22)	(1,139)
Net cash used for operating activities	(4,610)	(1,965)	(3,212)
Investing activities:			
Purchase of equipment	(207)	(1,303)	(1,166)
Purchase of marketable securities	(333)	(288)	—
Maturity of marketable securities	621	—	—
Net cash provided by (used for) investing activities	81	(1,591)	(1,166)
Financing activities:			
Net proceeds from sales of common shares	4,002	5,037	3,803
Secured borrowings	(236)	55	242
Principal payments on capital lease obligations	—	(45)	(66)
Net cash provided by financing activities	3,766	5,047	3,979
Effect of exchange rate changes on cash and cash equivalents	14	(232)	20
Net (decrease) increase in cash and cash equivalents	(749)	1,259	(379)
Cash and cash equivalents at beginning of year	5,726	4,467	4,846
Cash and cash equivalents at end of year	$ 4,977	$ 5,726	$ 4,467
Non-cash financing activities:			
Conversion of convertible debentures and accrued interest into common stock	—	—	$ 972

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

1. Nature of Business

PLC Systems Inc. ("PLC" or the "Company") has developed a patented high-powered carbon dioxide ("CO_2") 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 CO_2 Heart Laser 2 ("HL2"). The HL2 is less than half the weight and size than 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 United States. In January 2002, Edwards exercised a pre-existing option to assume full sales and marketing responsibilities in the United States 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, 2001.

Outside the United States, 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.

Cash and Marketable Securities

Investments with a maturity of three months or less at the date of purchase are considered to be cash equivalents and those with maturities greater than three months are considered to be marketable securities. Marketable securities are stated at cost, which approximates fair value and mature within six months from the purchase date. Cash equivalents and marketable securities, which are classified as available-for-sale securities consist primarily of time deposits.

Inventories

Inventory is stated at the lower of cost or market value.

2. Significant Accounting Policies (Continued)

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.

Revenue Recognition

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

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 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. As of December 31, 2001, the Company had not earned or recorded any such additional shared revenue.

The Company records revenue from the sale of TMR kits and Heart Laser Systems to international dealers 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 which 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.

In the fourth quarter of 2000, the Company adopted Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"), which provides guidance in applying generally accepted accounting principles to certain revenue recognition issues. The adoption of SAB 101 did not have a material impact on the Company's financial position or overall trends in results of operations.

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 in the accompanying statements of operations and are not material.

Net Loss per Share

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.

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 APB 25 *Accounting for Stock Issued to Employees.*

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. The Company has provided a valuation allowance for all deferred tax assets due to the inability to assume the realization of such tax benefits in the foreseeable future.

3. Inventories

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

	2001	2000
Raw materials	$ 618	$ 946
Work in process	107	43
Finished goods	276	451
	$1,001	$1,440

At December 31, 2001 and 2000, inventories are stated net of a reserve of $1,167,000 and $1,374,000, 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):

	2001	2000
Equipment	$2,240	$ 3,385
Equipment under placement contracts	4,036	6,434
Office furniture and fixtures	879	881
Leasehold improvements	346	591
	7,501	11,291
Less accumulated depreciation and amortization	7,118	10,242
	$ 383	$ 1,049

Depreciation expense was $866,000, $3,187,000 and $2,340,000, respectively, for the years ended December 31, 2001, 2000 and 1999. Included in 2000 depreciation expense is $1,265,000 related to the write down of the Company's HL1 installed laser base.

5. Legal Proceedings

In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis.

The original CardioGenesis lawsuit, counterclaimed by the Company, dealt with the Company's synchronization patent (U.S. Patent No. 5,125,926). Under the settlement, CardioGenesis agreed that U.S. Patent No. 5,125,926 and related international patents of the Company were valid and enforceable. PLC 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. As part of the settlement, CardioGenesis agreed to pay the Company:

- a minimum of $2.5 million over 42 months ending on June 30, 2002; and
- license fees and ongoing royalties on sales of all covered products until the expiration of all licensed patents.

6. Stockholders' Equity

In March 1999, the Company obtained a provisional equity financing commitment of up to $8 million from a major institutional investor. In 1999, the Company had sold 649,474 shares of common stock under this commitment, resulting in proceeds to the Company (net of all issuance costs payable upon closing) of approximately $1,900,000. This commitment expired on July 16, 1999. In July 1999, the Company also sold 666,666 shares of common stock to another investor resulting in net proceeds to the Company of approximately $1,900,000.

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

6. Stockholders' Equity (Continued)

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.

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 committed to issue to a financial advisor a warrant to purchase 100,000 shares at $1.00 per share, which will expire on January 9, 2006.

As of December 31, 2001, the Company had the following outstanding warrants to purchase common stock: 69,875 shares at $27.81 per share expiring July 22, 2002; 80,125 shares at $15.78 per share expiring August 14, 2002; 4,864 shares at $19.53 per share expiring April 23, 2003; 72,351 shares at $2.67 per share expiring March 27, 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; and 1,000,000 shares at $3.50 per share expiring January 2006.

At December 31, 2001, there were 7,487,173 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 time of issuance.

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

7. Stock Option and Stock Purchase Plans

The Company's 1992 Stock Option Plan ("1992 Plan"), 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 4,972,672 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.

7. Stock Option and Stock Purchase Plans (Continued)

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

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

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

	2001	2000	1999
Outstanding at beginning of year	3,120	2,706	2,788
Granted	952	800	1,204
Exercised	—	—	(4)
Canceled	(217)	(386)	(1,282)
Outstanding at end of year	3,855	3,120	2,706
Exercisable at end of year	2,363	1,808	1,681
Available for grant at end of year	193	952	152

	2001	2000	1999
Weighted-average exercise price:			
Outstanding at beginning of year	$3.00	$3.84	$5.16
Granted	$0.64	$0.86	$2.53
Canceled	$2.02	$4.62	$5.46
Exercised	$ —	$ —	$3.91
Outstanding at end of year	$2.47	$3.00	$3.84
Exercisable at end of year	$3.41	$4.06	$4.47
Weighted-average fair value of options granted during the year	$0.40	$0.40	$1.44

7. Stock Option and Stock Purchase Plans (Continued)

	Range of Exercise Prices		
	$0.52–$1.99	$2.00–$5.00	$5.01–$8.88
Options Outstanding:			
Number (in thousands)	1,623	1,821	411
Weighted-Average Remaining Contractual Life	9.20	5.58	5.88
Weighted-Average Exercise Price	$ 0.71	$ 3.29	$5.81
Options Exercisable:			
Number (in thousands)	428	1,524	411
Weighted-Average Exercise Price	$ 0.82	$ 3.49	$5.81

Pursuant to the requirements of FAS 123, the following are the pro forma net loss and net loss per share for 2001, 2000 and 1999, as if the compensation cost for the option plans had been determined based on the fair value at the grant date for grants in 2001, 2000 and 1999, consistent with the provisions of FAS 123.

	2001	2000	1999
Proforma net loss (in thousands)	$(4,767)	$(8,383)	$(5,163)
Proforma net loss per share	$ (.16)	$ (.36)	$ (.25)

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

	2001	2000	1999
Expected life (years)	3	2	2
Interest rate	3.68%	6.41%	5.87%
Volatility	1.071	.821	1.052

The effects on pro forma disclosures of applying FAS 123 are not likely to be representative of the effects on pro forma disclosures of future years.

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. Under the Purchase Plan, employees of the Company purchased 228,803 shares of common stock in 2001 and 58,949 shares of common stock in 2000 at average prices of $.45 and $.43 per share, respectively. At December 31, 2001, 112,248 shares were reserved for future issuance under the Purchase Plan.

8. Lease Receivables

Prior to 2001, the Company entered into third-party financing arrangements whereby the Company received payment from a leasing company equal to the present value of guaranteed minimum procedure payments due from the customer after customer acceptance of the HL1. In transactions where the Company had transferred substantially all of the risks and rewards of ownership to the customer and the customer had accepted the HL1, the Company recognized revenues, which were

8. Lease Receivables (Continued)

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.

9. 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 agreement requires payment of the Company's pro-rata share of property taxes and building operating expenses.

As of December 31, 2001, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments
2002	$ 293
2003	282
2004	285
2005	286
2006	191
	$1,337

Total rent expense was $362,000 in 2001, $327,000 in 2000 and $424,000 in 1999.

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

	2001	2000
Net U.S. operating loss carryforwards	$21,268	$18,383
Net foreign operating loss carryforwards	1,855	1,865
Accrued expenses and reserves	917	1,342
Tax credits	815	838
Other	463	484
Total deferred tax assets	25,318	22,912
Valuation allowance	(25,318)	(22,912)
Net deferred tax assets	$ —	$ —

10. Income Taxes (Continued)

The valuation allowance increased by approximately $2,406,000 in 2001 primarily due to additional net operating loss carryforwards. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset of $25,318,000.

Loss before taxes consisted of the following (in thousands):

	2001	2000	1999
Domestic	$(3,674)	$(7,029)	$(5,027)
Foreign	(228)	(381)	(1,528)
	$(3,902)	$(7,410)	$(6,555)

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

	2001	2000	1999
Statutory income tax benefit	$(1,327)	$(2,520)	$(2,229)
Utilization of loss carryforwards	(14)	—	(290)
Unbenefited U.S. losses	1,249	2,390	1,709
Unbenefited foreign losses	92	130	810
Benefit for income taxes	$ —	$ —	$ —

At December 31, 2001, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately $53 million, which expire at various dates through 2021. In addition, the Company had foreign net operating loss carryforwards of approximately $4.6 million.

11. Segment Information

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

	North America	Europe	Other	Eliminations	Total
2001					
Net sales to unaffiliated customers	$ 8,454	$1,326	$—	$—	$ 9,780
Long-lived assets	$ 167	$ —	$—	$—	$ 167
2000					
Net sales to unaffiliated customers	$ 8,319	$1,921	$—	$—	$10,240
Long-lived assets	$ 192	$ —	$—	$—	$ 192
1999					
Net sales to unaffiliated customers	$10,196	$1,440	$—	$—	$11,636
Long-lived assets	$ 391	$ —	$—	$—	$ 391

Edwards accounted for 68% of the Company's revenues for the year ended December 31, 2001. No one customer accounted for more than 10% of the Company's revenues for the year ended December 31, 2000 or 1999. Beginning in 2001 the Company has a concentration of credit risk due to its exclusive distributorship arrangement with Edwards in the United States. At December 31, 2001 the Company had outstanding accounts receivable from Edwards totaling $2,169,000.

Schedule II

PLC SYSTEMS INC.
Valuation and Qualifying Accounts

Column A	Column B	Column C	Column D	Column E
		Additions		
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Balance at End of Period
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
For the Year Ended December 31, 1999				
Allowance for Doubtful Accounts	$228,000	$190,000	$ 0	$418,000

PLC SYSTEMS INC.
QUARTERLY DATA (UNAUDITED)

	March 31	June 30	September 30	December 31*	Total
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	(.04)	(.04)	(.03)	(.02)	(.13)
2000**					
Total revenue	$ 1,742	$ 3,580	$ 2,549	$ 2,369	$10,240
Gross profit (loss)	685	1,988	1,060	(713)	3,020
Loss from operations	(2,280)	(997)	(1,434)	(3,092)	(7,803)
Net loss	(2,183)	(882)	(1,317)	(3,028)	(7,410)
Net loss per share, basic and diluted	(.10)	(.04)	(.06)	(.13)	(.32)

(*) In the fourth quarter ended December 31, 2000, the Company recorded a one-time charge of $2,117,000 related to the estimated costs of writing down inventory and capital equipment as a result of the Company's product transition from the HL1 to the HL2.

(**) Certain costs associated with service revenues that were previously included in selling, general and administrative expense have been reclassified to cost of revenues.

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.

Exhibit Number	Description of Document
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.
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.
10.18*	2000 Equity Incentive Plan.
10.19*	2000 Employee Stock Purchase Plan.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP.

* Filed with this annual report on Form 10-K for the fiscal year ended December 31, 2001.

\+ 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
Senior Managing Director – Investment Banking,
SunTrust Robinson Humphrey

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

Alan H. Magazine
Senior Advisor, Council on Competitiveness
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.

Roberts A. Smith, Ph.D.
Vice Chairman and Founding Director, ICN Pharmaceuticals, Inc.
Former Professor Emeritus, University of California, Los Angeles

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 PLC.

Annual Meeting

The Annual Meeting of PLC Systems Inc. shareholders will be held on Wednesday, May 22, 2002, 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
(818) 502-1404

Investor Inquiries

John Jordan
Director of Investor Relations
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Fax: 508-541-7990

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Annual Report 2001