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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549  
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FORM 10-K

<TABLE>  
<C> <S>  
/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
</TABLE>

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000  
OR

<TABLE>  
<C> <S>  
/ / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
</TABLE>

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 1-11388  
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PLC SYSTEMS INC.

(Exact name of registrant as specified in its charter)

<TABLE>  
<S> <C>  
YUKON TERRITORY, CANADA 04-3153858  
(State or other jurisdiction of (IRS Employer  
incorporation or organization Identification No.)  
</TABLE>

10 FORGE PARK, FRANKLIN, MASSACHUSETTS  
(Address of principal executive offices)

02038  
(Zip Code)  
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(508) 541-8800  
(Registrant's telephone number, including area code)  
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SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

<TABLE>  
<S> <C>  
TITLE OF EACH CLASS NAME OF EACH EXCHANGE  
ON WHICH REGISTERED  
COMMON STOCK, NO PAR VALUE AMERICAN STOCK EXCHANGE  
</TABLE>

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SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE  
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Indicate by check mark whether the registrant: (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days.

Yes /X/ No / /

Indicate by check mark if disclosure of delinquent filers pursuant to Item  
405 of Regulation S-K is not contained herein, and will not be contained, to the  
best of 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 16, 2001 was \$18,214,328. As of March 16, 2001, 29,298,667 shares of Common Stock, no par value per share, were outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement, which will be issued in connection with the 2001 Annual Meeting of Shareholders, are incorporated by reference in Part III of its 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. These forward-looking statements include statements in Item 1. "Business"; Item 3. "Legal Proceedings"; Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations"; and Item 7A. "Quantitative and Qualitative Disclosures about Market Risk". 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 successful ability to secure any required financing; the ability to convince health care professionals and third party payers of the medical and economic benefits of the Company's products; the absence of reimbursement for health care providers who use the Company's products, or the risk that reimbursement, if provided, will be inadequate; restrictions imposed by regulatory agencies such as the U.S. Food and Drug Administration; competitive developments; business conditions, growth in certain market segments, and the general economy; uncertainty that any patent protection will exclude competitors or that the Company's products do not infringe any intellectual property rights of others; and the risk factors set forth in Item 7, Item 7A, and the Company's other SEC reports.

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 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".

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 is typically 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.

Over 6,500 patients have been treated with the Company's HL1 in the United States and abroad. As of December 31, 2000, the Company had shipped 156 HL1 systems worldwide.

#### RECENT DEVELOPMENTS

Since the Company's last annual report on Form 10-K, the following significant events have occurred:

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

**STRATEGIC PARTNERSHIP WITH EDWARDS LIFESCIENCES.** On January 9, 2001, PLC announced a strategic marketing alliance and exclusive distributorship agreement with Edwards Lifesciences LLC, a subsidiary

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of Edwards Lifesciences Corporation (collectively referred to as "Edwards"). Edwards is a focused cardiovascular company with market leadership positions in areas such as artificial heart valves, hemodynamic monitoring and peripheral vascular disease. Edwards has annual sales of approximately \$800,000,000.

Under an exclusive, multi-year agreement, Edwards will market and distribute the HL2, as well as all disposable TMR kits and accessories, to customers in the United States. PLC intends to maintain its capital (laser) equipment sales force, at least through 2001, to assist Edwards in marketing the HL2 in the United States. PLC will sell the HL2 and TMR kits to Edwards at a discount to list price and Edwards will remarket the HL2 and TMR kits to hospitals. Edwards' Research Medical Incorporated sales force will be principally responsible for driving increased TMR procedures and kit utilization, as well as providing the PLC capital sales force with HL2 sales leads.

In conjunction with this transaction, Edwards purchased 5,333,333 newly issued shares of PLC common stock for \$4,000,000 and PLC issued to Edwards warrants to purchase an additional 3,000,000 shares of common stock at exercise prices ranging from \$1.50 to \$3.50. The warrants expire over a three to five year period.

**SETTLEMENT OF FEDERAL SECURITIES CLASS ACTION LAWSUIT.** On February 9, 2001, the United States District Court for the District of Massachusetts issued final approval of the settlement of the federal securities class action litigation against PLC. Under the terms of the settlement agreement PLC made no admission or concession of any liability or wrongdoing, or lack of merit in its defenses. Furthermore, PLC's insurance carriers paid the entire settlement amount to the plaintiffs in the case.

**CPT CODING ESTABLISHED FOR CERTAIN TMR PROCEDURES.** On January 1, 2001, a physician reimbursement ("CPT") code was assigned for the TMR procedure when performed as an adjunct to coronary artery bypass grafting. Establishment of a CPT 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.

**FIVE YEAR DATA ON SUSTAINED ANGINA RELIEF RELEASED.** On November 15, 2000, the first long term study on the efficacy of TMR with the HL1 was presented at the American Heart Association meeting. This study has demonstrated that the CO(2) TMR procedure provides significant long-term angina relief.

**NEW DIRECTOR JOINS PLC BOARD.** In May 2000, Mr. Benjamin Holmes was appointed to PLC's Board of Directors. Since December 1994, Mr. Holmes has served as President of the Holmes, Co., a consulting firm that specializes in healthcare with a focus on the medical device industry. From 1985 to 1994, he served as General Manager and Vice President of Hewlett-Packard Medical Products Group. Currently, Mr. Holmes serves as Director of Haemonetics Corporation, Project Hope, the UCLA Foundation and The Wood River Medical Center Foundation.

#### BACKGROUND

In 1981, the Company's former Chairman, Dr. Robert I. Rudko, formed Laser Engineering, Inc. ("LEI"), 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 LEI 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

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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 expanded to eventually include 201 patients at eight clinical sites. In 1995, the FDA approved three new IDEs for studies of TMR using the HL1. The first was a 100 patient randomized study (Phase III) comparing TMR patients to patients receiving medical management. The study was later expanded to 200 patients. The second study was a 400 patient randomized trial comparing TMR patients to patients receiving a second bypass surgery. The third study compared patients receiving TMR in conjunction with bypass surgery to patients receiving only bypass surgery.

The Company recently 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. Angina is measured in classes ranging from one to four, with one being the least painful and four being the most painful. After an average of 55 months following the TMR procedure, the group's average angina class improved from 3.7 to 1.6. This was virtually unchanged from the 1.5 average angina class reported at 12 months postoperatively. In fact, five years after TMR with the HL1, 17% of the patients reported having no angina and 64% were in class 1 or 2.

Since April 1992, the Company has received 24 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.

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.

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 term "Company" means, unless the context requires otherwise, PLC and its subsidiaries, PLC Medical Systems, Inc., PLC Sistemas Medicos Internacionais GmbH and PLC Medical Systems AG.

#### CARDIOVASCULAR DISEASE AND CURRENT THERAPIES

According to the 2001 Heart and Stroke Statistical Update ("2001 HSSU") published by the American Heart Association (the "AHA"), in 1998 an estimated 60.8 million Americans suffered from cardiovascular disease with an estimated 12.4 million Americans suffering from coronary heart disease. Cardiovascular disease is the leading cause of death in the U.S., resulting in approximately 41% (or 950,000) 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 2001 HSSU, an estimated 553,000 coronary artery bypass procedures were performed on 336,000 patients and 539,000 balloon angioplasty procedures were performed on 528,000 patients in the U.S. in 1998. The AHA estimates the cost of cardiovascular disease in the year 2001 at \$298.2 billion, including physician and nursing services, hospital and nursing home 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 diabetics, and others who are 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 including the 1991 Coronary Artery Descriptors and Restenosis Study ("CADRE") and the 1993 Emory Angioplasty vs. Surgery Trial ("EAST") 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. 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 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 (TEE) 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 hand pieces, 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

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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.

**POTENTIALLY QUICKER RECOVERY.** Because TMR using the Heart Laser Systems is less invasive and usually does not involve stopping and starting the heart, the patient may recover more quickly than if conventional bypass techniques were used, with potentially reduced risks of complications.

**NOT DEPENDENT ON PLAQUE TYPE OR LOCATION AND POTENTIALLY LESS RISK OF RESTENOSIS.** Unlike angioplasty, atherectomy devices and stents, which may be

more or less effective, depending on the composition, extent or location of the plaque occluding the artery and which have evidenced high restenosis rates, 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 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 China, South Korea and Taiwan. The Company has 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.

The Company has also developed a procedural kit, which includes single use surgical products to be used with the Heart Laser Systems in performing TMR. The TMR procedure kit contains a set of handpieces, drapes and other TMR surgical accessories.

The Company has developed and implemented a strategy to address the challenges of marketing high cost capital equipment by offering the Heart Laser Systems on a usage basis to hospitals. The Company believes Edwards, as the exclusive distributor for the HL2 in the United States, will continue with this strategy in marketing the HL2 to hospitals.

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The structure of a particular usage based contract, including the length of contract, price billed per procedure and end of term options for purchase, depends primarily on whether the hospital is willing and able to commit to a certain minimum volume of procedures over a defined period of time. If the hospital cannot commit to a sufficient number of procedures, the Heart Laser Systems may be installed with usage fees billed as agreed upon with the hospital. The Company refers to this type of usage arrangement as a retained placement contract. Under a retained placement contract, placement and service fee revenue is recorded over the term of the usage agreement, and the Heart Laser Systems remain the property of the Company and are depreciated over the term of the usage agreement.

If the hospital is willing and able to commit to a sufficient number of procedures at a sufficient procedural fee, such that the substantial risks and benefits of ownership of the Heart Laser Systems have transferred from the Company to the hospital, then the Company classifies the usage agreement as a minimum procedure sales contract (qualifying as a sales-type lease). Under a minimum procedure sales contract, the Company records product revenue at a discounted present value of the guaranteed minimum procedure payments, and records product cost of sale at the time of acceptance of the Heart Laser Systems.

The Company believes retained placement and minimum procedure sales contracts are 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 new technology such as TMR. The Company's financing arrangements with leasing vendors has enabled the Company to monetize future payment streams associated with certain placements. If utilization becomes more predictable, the Company expects a significant number of new accounts to opt for conventional leasing or direct purchase.

The Heart Laser Systems are also sold to customers, and the related sterile handpieces and other disposables are sold separately. These sales are classified as product sales.

Beginning in 2001, under the Edwards distribution arrangement, Edwards will determine the best programs, including sale, lease and rental offerings, which Edwards believes will be most effective in the United States in marketing the HL2 and related TMR kits to hospitals. PLC will sell these products to Edwards at a discount off list price and will generally recognize product sales at the time of shipment to Edwards.

UNITED STATES. The Company has used a direct sales force in the United States to market the HL1. In 2001, the Company plans to continue to employ a direct sales force to assist Edwards in the marketing of the HL2. The sales force is comprised of personnel with a high degree of professionalism and experience in the cardiovascular device business. Initial marketing efforts following FDA approval were directed at cardiothoracic surgeons, whose influence is believed to be critical in a hospital's decision to purchase the Heart Laser Systems. Recent marketing efforts also have emphasized 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. No assurance can be given that such programs will be implemented successfully, or at all.

Supporting the direct sales force is a promotional program that consists of electronic media advertising, public relations, direct mail, trade shows and educational symposia, all focused on disseminating critical information to decision makers and key purchase influencers.

In 2000, PLC's Center of Excellence training program was expanded to the Northeast and Northwest regions to facilitate increased TMR surgeon training for potential sales closure, new site initiation and increasing the number of surgeons trained at current TMR sites. This expansion effort is founded on the programs established at Rush Presbyterian Medical Center in Chicago and Texas Heart Institute in Houston. Both institutions have hosted the Company's training program, which is focused on educating prospective surgeons as well as surgeons from new and existing customer sites in the use of the Heart Laser Systems. These comprehensive programs facilitate interaction among experienced

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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 during the laboratory session.

INTERNATIONAL. The Company currently markets the Heart Laser Systems overseas primarily through distributors. International Sales (by origin) accounted for 19%, 12% and 30% of the Company's total revenues in 2000, 1999, and 1998 respectively. The Company had no sales by origin in Canada, its principle business location.

PLC received the CE Mark for the HL1 in the third quarter of 1995 and for the HL2 in March 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 HL1, the French Ministry of Health instituted a commercial moratorium on TMR procedures in France in October 1997 (See "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 Imatron Japan, Inc. ("Imatron") 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. Imatron also distributes medical equipment in Japan for its parent, Imatron, Inc. a U.S. based manufacturer of diagnostic imaging equipment. Between 1995 and 1997, Imatron purchased 12 HL1's from PLC to conduct clinical studies in Japan. PLC and Imatron 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 Imatron that it was terminating the existing distribution agreement as a result of Imatron's failure to timely obtain approval from the Japanese government to market the HL1 in Japan. The Company continues to work with Imatron to try and obtain approval to market the HL1 in Japan. However, by canceling the existing distribution agreement with Imatron the Company provides itself with flexibility to explore other alternatives, if necessary. No assurance can be given that Japanese regulatory approval will ever be granted for the HL1.

As of December 31, 2000, 74 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



Prior to 2001, the Company marketed one principal product: the HL1. Approximately 90% of the Company's revenues in the fiscal year ended December 31, 2000, 89% in the fiscal year ended December 31, 1999 and 90% in the fiscal year ended December 31, 1998 was derived from the sales and service of HL1 and related disposables sales. No single customer accounted for more than 10% of the Company's revenues in fiscal 2000, 1999 or 1998.

#### MANUFACTURING

The Company manufactures and tests its product at its 37,000 square foot facility in Franklin, Massachusetts, approximately 40 miles west of Boston. The Company moved to this facility in September 1996 and believes that its manufacturing capacity will be sufficient to meet market demands anticipated in the coming year.

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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 and are being 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 U.S. 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 the estimated 80,000 domestic patients each year 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. The Company intends to continuously improve its products after market introduction and may therefore submit future Investigational Device Exemption ("IDE"), Pre-Market Approval ("PMA") and PMA supplement applications to the FDA. No assurance can be given that approval of such new IDEs, PMAs or PMA supplements 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. An evaluation of the safety of the HL1 has been under review by a panel of French experts. There can be no assurance that the Company will be successful in having the moratorium 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

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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

Health care 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 all five criteria used to evaluate new medical technologies: (1) final approval from the FDA; (2) scientific evidence of improvement in health outcomes; (3) net benefit in health outcomes; (4) health outcomes at least as beneficial with any established alternative; and (5) 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 US, 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, 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 ("CPT") code was assigned for the TMR procedure when performed as an adjunct to coronary artery bypass grafting. Establishment of a CPT 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 CPT code was assigned for the TMR procedure when performed as a sole therapy.

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.

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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 by customers.

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 health care providers who perform TMR procedures using the Company's products. Further, no assurance can be given that additional payers will reimburse health care 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 health care 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 health care 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 relieve angina, if ever.

#### PRODUCT LIABILITY AND INSURANCE

The Company's business involves the risk of product liability claims. No claims have been made against the Heart Laser Systems to date. The Company maintains product liability insurance with per claim and aggregate coverage limits of \$10 million, subject to a \$50,000 per occurrence and \$250,000 aggregate self-insured deductible. No assurance can be given that product liability claims, if brought, will not exceed such insurance coverage limits, that such claims will not have a material adverse effect on the Company or that such insurance will be available on commercially reasonable terms or at all.

#### 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 24 U.S. patents. These patents have terms which expire from 2009 through 2017 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

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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 of the Company that subsequently merged with Eclipse Surgical Technologies, Inc. ("Eclipse"), 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. A minimum of \$2.5 million will be paid to the Company in connection with this license agreement.

Although the Company believes its patents to be strong, successful litigation against these patents by a competitor 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

As of December 31, 2000, over 6,500 TMR procedures had been performed using the HLI. In addition, the Company believes that the majority of peer reviewed medical journal articles on TMR report results of TMR procedures performed with the HLI.

The Company's two principal competitors, Eclipse and CardioGenesis, merged on March 17, 1999. Both companies have holmium laser systems. In February 1999, Eclipse 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 Eclipse and CardioGenesis may be adaptable to be used to perform not only TMR, but also a "percutaneous" method of performing TMR, known as "PMR".

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PMR procedures are performed via a catheter inserted through an incision in a patient's leg. PMR may 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, the Company is not currently actively pursuing its development. No assurance can be given that the Company will ever successfully pursue, develop or market a PMR product.

The Company believes several other companies, in addition to Eclipse, are developing PMR. The results of a six-month clinical study ("DIRECT"), which utilized a Johnson & Johnson holmium PMR laser, presented at the Transcatheter Therapeutics Conference ("TCT") 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 TCT concluded that the similar outcomes between those in the treatment group and those in the control group was 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 DIRECT study 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 has taken steps to distinguish surgical TMR from PMR, and its CO(2) laser from holmium lasers. However, no assurance can be given that the Company's efforts to make these distinctions between the therapies and lasers used will be successful. If the Company is unable to do so, the Heart Laser Systems may never gain broad commercial acceptance.

In addition to Eclipse, 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 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 2000 it began 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.

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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, 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 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 \$1,680,000, \$2,672,000 and \$4,468,000 for the years ended December 31, 2000, 1999, and 1998, 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. The Company continues to refine the Heart Laser Systems.

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 16, 2001, the Company had 46 full-time domestic employees, including its executive officers. Of these, 9 are employed in general and administrative positions, 15 are involved in sales and marketing, 8 are involved in research and development, 7 are involved in manufacturing, 4 are involved in service and 3 are involved in quality and regulatory affairs. The Company also employs one part-time employee. None of the Company's employees are represented by a union. In addition, the Company has 3 full time employees for its international operations. The Company considers its relationships with its employees to be satisfactory.

#### ITEM 2. PROPERTIES

Since September 1996, the Company has leased its current 37,000 square foot facility in Franklin, Massachusetts where it maintains its principal executive offices and manufacturing operations. In January 2001, the Company renewed its lease for a period of three years through August 2004. The lease provides for another renewal period of three years. The total base rental payments beginning in September 2001 for the term of the lease are expected to be approximately \$422,000 per year plus operating and maintenance costs and real estate taxes.

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### ITEM 3. LEGAL PROCEEDINGS

In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis, who subsequently merged with Eclipse Surgical Technologies, Inc. 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 (at least 10 years unless the patents are all held invalid in future lawsuits). As part of the settlement, CardioGenesis agreed to pay the Company:

- a minimum of \$2.5 million over the next 42 months; and
- license fees and ongoing royalties on sales of all covered products for at least 10 years (unless the patents are all held invalid in future lawsuits).

In July 1997, an FDA advisory panel recommended against approval of the Company's application to market the HL1 in the United States. Following this recommendation, the Company was named as defendant in 21 purported class action lawsuits filed between August 1997 and November 1997 in the United States District Court for the District of Massachusetts. The lawsuits sought an unspecified amount of damages in connection with alleged violations of the federal securities laws based on the Company's failure to obtain a favorable FDA panel recommendation in 1997. Nineteen of these complaints were consolidated by the court into a single action for pretrial purposes (hereafter referred to as the "federal suit"). Two of these suits were voluntarily dismissed. The Company moved to dismiss all claims in the federal suit. On March 26, 1999, the court issued an order dismissing some, but not all, of the claims in the federal suit. The parties filed cross motions for reconsideration and on October 12, 1999, the court dismissed additional, but not all remaining claims in the federal suit. On February 9, 2001, the Court issued an Order approving the settlement of the federal suit and entered a judgment of dismissal. The settlement of the federal suit did not have a material impact on the Company's financial statements.

The Company also was named as a defendant in a lawsuit filed in Massachusetts Superior Court in September 1998 (hereafter referred to as the "state suit") seeking over \$2 million in damages for alleged negligent misrepresentations and fraud arising from the Company's failure to obtain a favorable FDA recommendation in 1997. On April 13, 2000, the parties filed a Stipulation of Dismissal in connection with the settlement of the state suit. The settlement did not have a material impact on the Company's financial statements.

In November 1998, a hospital in France, Centre Medico Chirurgical Foch ("Foch Hospital"), sued the Company's Portuguese subsidiary, PLC Sistemas Medicos Internacionais Lda., and a third party, Johnson & Johnson Leasing GmbH, in Paris, France alleging breach of contract. In October 1997, the French Ministry of Health suspended commercial use of TMR devices in France. Foch Hospital sought reimbursement of lease payments made for the HL1. On April 18, 2000, the Tribunal de Grande Instance de Paris dismissed this suit for lack of jurisdiction. The Company can make no assurance as to whether Foch Hospital will appeal this decision or bring suit in another jurisdiction.

The Company is not involved in any other litigation of a material nature.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

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## 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 16, 2001, the closing sale price of the Company's Common Stock was \$0.80 per share.

For the periods indicated, the following table sets forth the range of high and low sales prices for the Common Stock from January 1, 1999.

<TABLE>  
<CAPTION>

	HIGH	LOW
	-----	-----
<S>	<C>	<C>
1999		
First Quarter.....	\$7.44	\$2.38
Second Quarter.....	\$4.88	\$2.31
Third Quarter.....	\$4.88	\$2.63
Fourth Quarter.....	\$3.19	\$1.81
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

</TABLE>

As of March 16, 2001, there were approximately 741 record holders of the Company's Common Stock. The Company believes that there are approximately 14,754 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.

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#### ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data of the Company for the five years ended December 31, 2000, 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.

##### SELECTED FINANCIAL DATA

<TABLE>  
<CAPTION>

FOR THE YEARS ENDED DECEMBER 31				
2000	1999	1998	1997	1996
-----	-----	-----	-----	-----
(ALL AMOUNTS ARE IN THOUSANDS EXCEPT PER SHARE DATA)				

<S>	<C>	<C>	<C>	<C>	<C>
<b>STATEMENT OF OPERATIONS DATA:</b>					
<b>Revenues:</b>					
Product sales.....	\$ 6,803	\$ 8,400	\$ 3,088	\$ 5,687	\$ 9,082
Placement and service fees.....	3,437	3,236	2,605	3,254	2,790
<b>Total Revenues.....</b>	<b>10,240</b>	<b>11,636</b>	<b>5,693</b>	<b>8,941</b>	<b>11,872</b>
<b>Costs and expenses:</b>					
Cost of product sales.....	3,765	3,615	1,945	2,721	2,911
Cost of placement and service fees.....	3,168	2,061	2,622	2,595	1,155
Selling, general and administrative.....	9,430	10,054	13,718	13,049	7,023
Research and development.....	1,680	2,672	4,468	5,158	2,835
<b>Loss from operations.....</b>	<b>(7,803)</b>	<b>(6,766)</b>	<b>(17,060)</b>	<b>(14,582)</b>	<b>(2,052)</b>
Other income.....	393	211	457	178	512
<b>Net loss.....</b>	<b>\$(7,410)</b>	<b>\$(6,555)</b>	<b>\$(16,603)</b>	<b>\$(14,404)</b>	<b>\$(1,540)</b>
<b>Net loss per share--Basic and diluted.....</b>	<b>\$ (.32)</b>	<b>\$ (.32)</b>	<b>\$ (.86)</b>	<b>\$ (.84)</b>	<b>\$ (.09)</b>
 Shares used to compute net loss per share--Basic and diluted.....	 23,266	 20,675	 19,218	 17,050	 16,376

</TABLE>

<TABLE>  
<CAPTION>

	AS OF DECEMBER 31				
	2000	1999	1998	1997	1996
<S>	<C>	<C>	<C>	<C>	<C>
<b>BALANCE SHEET DATA:</b>					
Working capital.....	\$ 5,010	\$ 5,459	\$ 5,050	\$12,793	\$11,245
Total assets.....	15,078	15,319	16,257	27,017	19,417
Long term obligations.....	--	--	37	121	27
Secured borrowings, long-term.....	3,079	2,082	--	--	--
Stockholders' equity.....	6,216	8,885	10,662	19,009	16,467

</TABLE>

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

The Company offers placement, purchase and leasing alternatives to customers interested in acquiring the Heart Laser Systems. The Company has developed a strategy to address the challenges of marketing high cost capital equipment by offering the Heart Laser Systems on a usage basis to hospitals. The particular structure of a usage based contract, including the length of contract, price billed per procedure and end of term options for purchase, depends primarily on whether the hospital is willing and able to commit to a certain minimum volume of procedures over a defined period of time. If the hospital cannot commit to a sufficient number of procedures, the Heart Laser Systems may be installed with usage fees billed as agreed upon with the hospital. The Company refers to this type of usage arrangement as a retained placement contract. Under a retained placement contract, placement and service fee revenues are recorded over the term of the usage agreement and the Heart Laser Systems remain the property of the Company and are depreciated over the term of the usage agreement.

If the hospital is willing and able to commit to a sufficient number of procedures at a sufficient procedural fee, such that the substantial risks and benefits of ownership of the Heart Laser Systems have transferred to the hospital, then the Company classifies the usage agreement as a minimum procedure sales contract (qualifying as a sales type lease). Under a minimum procedure sales contract, the Company records product revenues, at a discounted present value of the guaranteed minimum procedure payments, and records product cost of sale at the time of acceptance of the Heart Laser Systems.

The Company believes that retained placement and minimum procedure sales contracts are 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 new technology such as TMR. The Company's financing arrangements with leasing vendors has enabled the Company to monetize future payment streams associated with certain agreements. If utilization becomes more predictable, the Company expects a significant number of new accounts to opt for conventional leasing, or direct purchase.

The Heart Laser Systems are also sold directly to customers, and the related



sterile handpieces and other disposables are sold separately. These sales are classified as product sales.

Customers are given the option to purchase service contracts to cover the cost of maintaining the Heart Laser Systems beyond the applicable warranty period. These service revenues are recorded ratably over the service contract and are classified as a component of placement and service fees.

Beginning in 2001, under an exclusive distribution arrangement with Edwards, Edwards will determine the best programs, including sale, lease and rental offerings, which it believes will be most effective in the United States in marketing the HL2 and related TMR kits to hospitals. PLC will sell these products to Edwards at a discount off list price and will generally recognize product sales revenues at the time of shipment to Edwards.

The Company expects that its revenues and gross profit in 2001 will likely be lower than corresponding quarters in 2000 (excluding the impact on gross margin of a non-recurring charge in the fourth quarter of 2000) as a result of the discounted sale price of lasers and TMR procedural kits when sold to Edwards, until such time, if ever, that Edwards' marketing efforts result in substantially increased TMR procedural volumes and corresponding kit sales.

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 (See Item 7A--Quantitative and Qualitative Disclosures about Market Risk).

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#### RESULTS OF OPERATIONS

##### 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. 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 revenues 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 and, in the latter part of the year, redirected focus on launching the next-generation HL2, for which the Company received FDA approval in January 2001.

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 lasers from less active sites to sites which are potentially more productive.

Management of the Company also 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.

Total gross profit decreased to \$3,307,000 or 32% of total revenues for the year ended December 31, 2000 as compared with the gross profit of \$5,960,000 or 51% 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 53% of revenues, slightly up from 51% 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.

Selling, general and administrative expenses of \$9,430,000 for the year ended December 31, 2000 decreased \$624,000 or 6% when compared with expenses of \$10,054,000 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 has 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. The

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transition of the next generation CO(2) laser from research and development to manufacturing contributed to the decrease in expenditures in this area in 2000.

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.

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.

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 writedown the value of its HLI inventory and capital equipment due to the transition to the new HL2 product.

#### YEAR ENDED DECEMBER 31, 1999 COMPARED TO YEAR ENDED DECEMBER 31, 1998

Total revenues of \$11,636,000 for the year ended December 31, 1999 increased \$5,943,000 or 104% when compared to total revenues of \$5,693,000 for the year ended December 31, 1998. For the year ended December 31, 1999, product sales of \$8,400,000 increased \$5,312,000 or 172% when compared to product sales of \$3,088,000 for the year ended December 31, 1998. The major factors in both increases are primarily due to the 1999 periods reflecting increased sales of the HL1 and related disposables due to the Company's receipt of FDA approval to market the HL1 in August 1998, as well as license and royalty fees associated with the CardioGenesis settlement.

Placement and service fees of \$3,236,000 for the year ended December 31, 1999 increased 24% from placement and service fees of \$2,605,000 for the year ended December 31, 1998. In May 1997, the Health Care Financing Administration ("HCFA") instituted a non-coverage policy for TMR procedures performed on Medicare patients in the United States. The HCFA announcement, coupled with delays in the PMA process, caused the Company to examine its contractual requirements during 1997 and amend substantially all of its retained placement contracts, temporarily replacing contractual minimum billings with actual usage billings. Following approval of the PMA by the FDA on August 20, 1998, the Company renegotiated usage agreements with its customers on a case-by-case basis. The 1999 period reflects revenues from these retained placement contracts with the renegotiated usage agreements following FDA approval. The 1998 period reflects revenues primarily from retained placement contracts with actual usage billings.

For the year ended December 31, 1999, the Company shipped 1,136 disposable kits, an increase of 44% over the 788 disposable kits shipped during the year ended December 31, 1998. Management believes the overall increase is primarily due to marketplace awareness of TMR as an approved procedure subsequent to the August 1998 approval by the FDA and the Company's increased base of installed lasers.

Total gross profit increased to \$5,960,000 or 51% of total revenues for the year ended December 31, 1999 as compared with the gross profit of \$1,126,000 or 20% of total revenues for the year ended December 31, 1998. In the 1998 period, the Company did not generate sufficient sales volume to efficiently cover manufacturing costs, resulting in lower gross margins. In 1999, gross margins improved as a result of an increase in sales volumes and manufacturing cost reductions implemented by the Company.

Selling, general and administrative expenses of \$10,054,000 for the year ended December 31, 1999 decreased \$3,664,000 or 27% when compared with expenses of \$13,718,000 for the year ended December 31, 1998. This reduction is primarily

due to a restructuring of the Company's workforce in April 1999. The 1999 periods reflect reduced headcount and compensation and related benefits related to the reduced workforce.

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Research and development expenditures of \$2,672,000 decreased \$1,796,000 or 40% for the year ended December 31, 1999 when compared with expenditures of \$4,468,000 for the year ended December 31, 1998. The decreases in 1999 compared to 1998 reflect the reduced demands for clinical study compilation and data preparation following the FDA approval for the HL1 in August 1998. In addition, in April 1999, the Company reduced its workforce, and the 1999 periods reflect reduced headcount and compensation and related benefits related to the reduced workforce.

Other income of \$211,000 for the year ended December 31, 1999 decreased \$246,000 or 54% when compared to other income of \$457,000 for the year ended December 31, 1998, primarily due to lower interest income as a result of lower average cash balances in 1999 as compared to 1998.

There was no provision for income tax for the years ended December 31, 1999 or 1998 due to the net losses of \$6,555,000 and \$16,603,000, respectively.

The Company incurred a net loss for the year ended December 31, 1999 of \$6,555,000 compared with a net loss of \$16,603,000 for the year ended December 31, 1998. The smaller net loss resulted from higher total revenues and higher gross margin dollars coupled with lower overall operating expenses in 1999 when compared with 1998.

#### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, the Company had cash, cash equivalents and marketable securities of \$6,014,000.

Over the past three years, the Company incurred significant operating losses and utilized significant amounts of cash to fund operations. During 1999 and 2000, the Company implemented a number of programs to reduce its consumption of cash, including operating expense reductions and establishment of third party financing alliances to enable the Company to monetize certain of its minimum procedure sales contracts.

Throughout 2000, the Company has been in a critical stage of its development as it continues to transition from a research and development oriented company to a commercial enterprise with complete sales, marketing and production capabilities. In March 2000, the Company closed an equity financing with two institutional investors. In conjunction with this financing, 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.

Most recently, in January 2001, the Company entered into a strategic marketing alliance and exclusive distribution agreement with Edwards to distribute the new HL2 laser and all disposable TMR kits throughout the United States. In conjunction with this agreement, the Company received a \$4,000,000 equity investment 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.

The Company believes that its existing cash resources, including cash raised in the January 2001 sale of common stock to Edwards, will meet its working capital requirements through December 31, 2001. However, the Company expects that its revenues and gross profit in 2001 will likely be lower than corresponding quarters in 2000 (excluding the impact on gross margin of the non-recurring charge in the fourth quarter of 2000) as a result of the discounted sale price of lasers and TMR procedural kits when sold to Edwards, until such time, if ever, that Edwards' marketing efforts result in substantially increased TMR procedural volumes and corresponding kit sales. 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, the inability to monetize usage agreements 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

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additional financing. No assurance can be given that the Company 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 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.

The Company has seen an increasing trend on the part of its 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 the deferral of both revenues and the receipt of cash. 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 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.

During the year ended December 31, 2000, the Company incurred a net loss of \$7,410,000, which resulted in the use of approximately \$1,965,000 to support operations. Cash used for investing activities was approximately \$1,591,000 and related to the Company's \$1,303,000 cost to manufacture and deploy placement lasers at customer sites and the purchase of \$288,000 of marketable securities. Cash provided by financing activities was approximately \$5,047,000, primarily consisting of the net proceeds of \$5,037,000 obtained from the sale of the Company's common stock.

At December 31, 2000, the Company had U.S. net operating loss carryforwards of approximately \$46 million available to reduce future taxable income, which expire at various dates through 2020, and the Company had foreign net operating loss carryforwards of approximately \$4.7 million. In addition, various other deferred tax assets have been generated related primarily to intercompany profit, depreciation, accruals, and research and development tax credits. Because the Company believes that, as of December 31, 2000, it is more likely than not that all of the deferred tax assets will not be realized, no tax benefit for prior year losses and other deferred items has been provided. These amounts could provide a benefit to the Company in the future in profitable years, if any, subject to the expirations noted.

#### RISK FACTORS

##### 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 have incurred net losses of \$7,410,000 for the year ended December 31, 2000, \$6,555,000 for the year ended December 31, 1999 and \$16,603,000 for the year ended December 31, 1998. As of December 31, 2000, we had an accumulated deficit of \$82,101,000. We have not achieved profitability and expect to continue to incur net losses for at least the foreseeable future. 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

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 fiscal year ended December 31, 2000 and 89% in the fiscal year ended

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December 31, 1999 was derived from the sales and service of our first generation laser and related disposables.

##### OUR COMPANY MAY BE UNABLE TO RAISE NEEDED FUNDS

As of December 31, 2000, we had cash, cash equivalents and marketable securities totaling \$6,014,000. Based on our current operating plan, we anticipate that our existing capital resources, including cash raised in our January 2001 sale of common stock to Edwards, should be sufficient to meet our working capital requirements through December 31, 2001. 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;
- train heart surgeons to perform TMR procedures using the Heart Laser Systems; and
- obtain widespread third party reimbursement for the TMR procedure.

To date, we have trained only a limited number of heart surgeons and will need to expand our marketing and training capabilities.

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 HLI 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 recent six-month clinical study ("DIRECT"), the results of which were released on October 20, 2000 at the Transcatheter Therapeutics Conference. The DIRECT 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 DIRECT 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

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TMR procedure and an interventional laser PMR procedure, the negative publicity resulting from the DIRECT 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 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. They 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 of our competitors have substantially greater financial resources and are in a better financial position to exploit marketing and research and development opportunities. Our competitors' products use different types of lasers than we use in the Heart Laser Systems, including holmium and excimer lasers that may gain more widespread market acceptance than the Heart Laser

Systems. In addition, we believe that several companies are attempting to develop less invasive methods of performing TMR procedures. These new methods may eliminate the need to make an incision in the patient's chest, reducing costs and speeding recovery. These 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.

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**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 March 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. An evaluation of the safety of the HL1 has been currently under review by a panel of French experts. 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.

**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.

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#### 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 with a per claim and yearly aggregate maximum of \$10 million, subject to a \$50,000 per occurrence and \$250,000 aggregate self-insured deductible, 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 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. We have no assurance that we will ever be able to source some or all of our sole sourced components from more than one supplier. Any interruption in supply from these suppliers could prevent us from meeting commercial demands for the Heart Laser Systems, which could have a material adverse effect on our business, financial condition and results of operations.

#### WE HAVE LIMITED MANUFACTURING EXPERIENCE BUILDING THE HL2

We have only recently begun to manufacture the HL2. 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;
- lack of experienced technical personnel;
- production yields; and
- changing processes and controls over the manufacturing procedures employed.

#### 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

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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 will 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, 2000 we have reserved an additional 4,728,742 shares of common stock for future issuance upon exercise of outstanding options and redeemable warrants.

<TABLE>  
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	RANGE OF EXERCISE/ CONVERSION PRICES	WEIGHTED AVERAGE EXERCISE/ CONVERSION PRICE	SHARES RESERVED FOR FUTURE ISSUANCE
<S>	<C>	<C>	<C>
Options.....	\$ .53 - \$8.88	\$ 3.00	4,071,501
Redeemable Warrants.....	\$1.00 - \$27.81	\$11.37	316,190
Employee Stock Purchase Plan.....	\$.43	\$ .43	341,051
Total.....			4,728,742

</TABLE>

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. In January 2001, we issued additional warrants and adjusted the purchase price for certain outstanding warrants.

**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,

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- 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 make cautionary statements in certain sections of this annual report on Form 10-K, including in the risk factors identified above, and in materials incorporated herein by reference. You should read these cautionary statements 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 German Mark. When the U.S. dollar strengthens against the Franc or Mark, the value of nonfunctional currency sales decreases. When the U.S. dollar weakens, the functional currency amount of sales increases. In the past, the Company's support of its foreign operations has benefited from a stronger U.S. dollar, but has been adversely affected by a weaker U.S. dollar relative to major currencies worldwide. 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 most 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.

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 2001 Annual Meeting of Shareholders (the "Definitive Proxy Statement") under the caption "Item No. 1--Election of Directors".

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the Company's Definitive Proxy Statement under the caption "Item No. 1--Election of Directors".

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".

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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.

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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.

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SIGNATURES

PURSUANT TO THE REQUIREMENTS OF SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934, THE REGISTRANT HAS DULY CAUSED THIS REPORT TO BE SIGNED ON ITS BEHALF BY THE UNDERSIGNED, THEREUNTO DULY AUTHORIZED.

<TABLE>  
<S>

<C> <C>  
PLC SYSTEMS INC.

Date: March 29, 2001

By: /s/ MARK R. TAUSCHER

-----  
 Mark R. Tauscher  
 PRESIDENT AND CHIEF EXECUTIVE OFFICER

</TABLE>

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.

<TABLE>  
 <CAPTION>

NAME -----	CAPACITY -----	DATE -----
<C> /s/ MARK R. TAUSCHER ----- Mark R. Tauscher	<S> President and Chief Executive Officer (Principal Executive Officer)	<C> March 29, 2001
/s/ JAMES G. THOMASCH ----- James G. Thomasch	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 29, 2001
/s/ EDWARD H. PENDERGAST ----- Edward H. Pendergast	Chairman of the Board of Directors	March 29, 2001
/s/ KEVIN J. DUNN ----- Kevin J. Dunn	Director	March 29, 2001
/s/ BENJAMIN HOLMES ----- Benjamin Holmes	Director	March 29, 2001
/s/ ALAN H. MAGAZINE ----- Alan H. Magazine	Director	March 29, 2001
/s/ H.B. BRENT NORTON, M.D. ----- H.B. Brent Norton, M.D.	Director	March 29, 2001
/s/ KENNETH J. PULKONIK ----- Kenneth J. Pulkonik	Director	March 29, 2001

</TABLE>

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<TABLE>  
 <CAPTION>

NAME -----	CAPACITY -----	DATE -----
<C> /s/ ROBERT I. RUDKO, PH.D. ----- Robert I. Rudko, Ph.D.	<S> Director	<C> March 29, 2001
/s/ ROBERTS A. SMITH, PH.D. ----- Roberts A. Smith, Ph.D.	Director	March 29, 2001

</TABLE>

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 APPENDIX A  
 PLC SYSTEMS INC.  
 CONSOLIDATED FINANCIAL STATEMENTS  
 FOR THE YEARS ENDED DECEMBER 2000, 1999, 1998  
 PLC SYSTEMS INC.  
 INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 <CAPTION>

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Consolidated Statements of Operations for the years ended	

December 31, 2000, 1999 and 1998.....	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998.....	F-5
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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, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. 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, 2000 and 1999, and the consolidated results of its operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000 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  
Ernst & Young LLP

Boston, Massachusetts  
February 16, 2001

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PLC SYSTEMS INC.

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2000 AND 1999

<TABLE>  
<CAPTION>

	2000	1999
	-----	-----
	(IN THOUSANDS)	
<S>	<C>	<C>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 5,726	\$ 4,467
Marketable securities.....	288	--
Accounts receivable, net.....	1,400	1,894
Lease receivables, net.....	1,680	642
Inventories, net.....	1,440	2,348
Prepaid expenses and other current assets.....	259	460
	-----	-----
Total current assets.....	10,793	9,811
Equipment, furniture and leasehold improvements, net.....	1,049	3,336
Lease receivables, net.....	2,836	1,782
Other assets.....	400	390
	-----	-----
Total assets.....	\$15,078	\$15,319
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable.....	\$ 1,276	\$ 1,338
Accrued clinical costs.....	576	769
Accrued compensation.....	799	653
Accrued other.....	626	630
Deferred revenue.....	531	138
Secured borrowings.....	1,975	824
	-----	-----
Total current liabilities.....	5,783	4,352
Secured borrowings.....	3,079	2,082
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, 23,965 and 21,223 shares issued and outstanding in 2000 and 1999, respectively.....		
	89,417	84,380
Accumulated deficit.....	(82,101)	(74,691)
Accumulated other comprehensive loss.....	(1,100)	(804)
	-----	-----
	6,216	8,885
	-----	-----
Total liabilities and stockholders' equity.....	\$15,078	\$15,319
	=====	=====

</TABLE>

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

F-3  
PLC SYSTEMS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

<TABLE>  
<CAPTION>

	2000	1999	1998
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
	<C>	<C>	<C>
<S>			
Revenues:			
Product sales.....	\$ 6,803	\$ 8,400	\$ 3,088
Placement and service fees.....	3,437	3,236	2,605
	-----	-----	-----
Total revenues.....	10,240	11,636	5,693
Cost of revenues:			
Product sales.....	3,765	3,615	1,945
Placement and service fees.....	3,168	2,061	2,622
	-----	-----	-----
Total cost of revenues.....	6,933	5,676	4,567
Gross profit.....	3,307	5,960	1,126
Operating expenses:			
Selling, general and administrative.....	9,430	10,054	13,718
Research and development.....	1,680	2,672	4,468
	-----	-----	-----
Total operating expenses.....	11,110	12,726	18,186
Loss from operations.....	(7,803)	(6,766)	(17,060)
Other income, net.....	393	211	457
	-----	-----	-----
Net loss.....	\$ (7,410)	\$ (6,555)	\$ (16,603)
	=====	=====	=====
Net loss per share -- Basic and Diluted.....	\$ (.32)	\$ (.32)	\$ (.86)
Shares used to compute net loss per share			
--Basic and Diluted.....	23,266	20,675	19,218

</TABLE>

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

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PLC SYSTEMS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

<TABLE>  
<CAPTION>

	COMMON STOCK		ACCUMULATED DEFICIT	ACCUMULATED OTHER	TOTAL
	SHARES	AMOUNT		COMPREHENSIVE LOSS	
			(IN THOUSANDS)		
<S>	<C>	<C>	<C>	<C>	<C>
Balance, December 31, 1997.....	18,368	\$71,115	\$ (51,533)	\$ (573)	\$19,009
Exercise of stock options.....	142	623	--	--	623
Conversion of 5% debentures due 2002....	577	3,923	--	--	3,923
Conversion of debentures due 2003.....	653	3,810	--	--	3,810
Issuance of warrants.....	--	50	--	--	50
Comprehensive loss:					
Net loss.....	--	--	(16,603)	--	(16,603)
Foreign currency translation.....	--	--	--	(151)	(151)
Total comprehensive loss.....					(16,754)
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

</TABLE>

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

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PLC SYSTEMS INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

<TABLE>  
<CAPTION>

	2000	1999	1998
			(IN THOUSANDS)
<S>	<C>	<C>	<C>
Operating activities:			
Net loss.....	\$ (7,410)	\$ (6,555)	\$ (16,603)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization.....	3,641	2,959	3,170
Compensation on stock options.....	--	84	--
Change in assets and liabilities:			
Accounts receivable.....	488	313	(973)
Inventories.....	908	607	(475)
Prepaid expenses and other assets.....	138	234	89
Accounts payable.....	(63)	342	82
Deferred revenue.....	355	(57)	142
Accrued liabilities.....	(22)	(1,139)	304
Net cash used for operating activities.....	(1,965)	(3,212)	(14,264)
Investing activities:			
Additions to equipment.....	(1,303)	(1,166)	(2,574)
Purchase of marketable securities.....	(288)	--	(1,986)
Maturities of marketable securities.....	--	--	14,831
Net cash provided by (used for) investing activities.....	(1,591)	(1,166)	10,271

<i>Financing activities:</i>			
Net proceeds from sale of common stock.....	5,037	3,803	623
Secured borrowing.....	55	242	240
Principal payments on capital lease obligations.....	(45)	(66)	(79)
Issuance of convertible debentures, net of issuance costs.....	--	--	4,659
	-----	-----	-----
Net cash provided by financing activities.....	5,047	3,979	5,443
Effect of exchange rate changes on cash and cash equivalents.....	(232)	20	(88)
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents.....	1,259	(379)	1,362
Cash and cash equivalents at beginning of year.....	4,467	4,846	3,484
	-----	-----	-----
Cash and cash equivalents at end of year.....	\$ 5,726	\$ 4,467	\$ 4,846
	=====	=====	=====
<i>Non-cash financing activities:</i>			
Conversion of convertible debentures and accrued interest into common stock.....	--	\$ 972	\$ 7,733
Ascribed warrant value.....	--	--	50

</TABLE>

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

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000

1. NATURE OF BUSINESS

PLC Systems Inc. ("PLC" or the "Company") has developed a patented high-powered carbon dioxide laser system known as The Heart Laser ("HL1") for use in the treatment of coronary artery disease ("CAD") in a surgical laser procedure, pioneered by the Company and its clinical investigators, known as transmyocardial revascularization ("TMR"). TMR is a laser based treatment for relieving debilitating pain in patients suffering from severe CAD. The Company's CO(2) laser is used by a cardiovascular surgeon to create between 20 and 40 tiny channels in the heart wall of a patient suffering from severe CAD. Each TMR procedure requires a sterile, single use, TMR kit containing assorted TMR handpieces, drapes and other disposable items.

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 GmbH, and PLC Medical Systems AG. All intercompany accounts and transactions have been eliminated. Certain prior year amounts may 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.

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:

<TABLE>

<S>

<C>

Equipment

3-5 years

Equipment under placement contracts

Life of contract

Office furniture and fixtures	5 years
Equipment under capital lease	5 years
Leasehold improvements	Life of lease

</TABLE>

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.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

2. SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

REVENUE RECOGNITION

The Company sells its principal product, the HL1, and related disposable surgical kits to hospital customers both directly and through distributors. Revenues from the sale of disposable kits are recorded as product sales at the time of shipment. Revenues from the sale or lease of the HL1, which result in substantially all the risks and benefits of ownership of the HL1 being transferred to the customer, are recorded as product sales at the time of ownership transfer. In sales transactions this typically occurs at time of shipment. In lease transactions this typically occurs upon lease commencement, at which time the Company records revenues equal to the present value of the guaranteed minimum lease payments.

The Company also installs the HL1 in hospitals under placement agreements which do 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.

In the fourth quarter, 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.

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 earnings per share is computed based only on the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed using the weighted average number of common shares outstanding during the period, plus the dilutive effect of future issues of common stock relating to stock option programs and convertible debt financing. In calculating diluted earnings per share, the dilutive effect of stock options is computed using the average market price for the period unless 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,

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

2. SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)



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):

<TABLE>  
<CAPTION>

	2000	1999
	-----	-----
<S>	<C>	<C>
Raw materials.....	\$ 946	\$ 1,044
Work in process.....	43	439
Finished goods.....	451	865
	-----	-----
	\$ 1,440	\$ 2,348
	=====	=====

</TABLE>

At December 31, 2000, inventories are stated net of a reserve of \$1,374,000 for potentially obsolete inventory.

4. EQUIPMENT, FURNITURE AND LEASEHOLD IMPROVEMENTS

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

<TABLE>  
<CAPTION>

	2000	1999
	-----	-----
<S>	<C>	<C>
Equipment.....	\$ 2,956	\$ 2,614
Equipment under placement contracts.....	6,434	6,354
Office furniture and fixtures.....	881	881
Equipment under capital lease.....	429	429
Leasehold improvements.....	591	591
	-----	-----
	11,291	10,869
Less accumulated depreciation and amortization.....	10,242	7,533
	-----	-----
	\$ 1,049	\$ 3,336
	=====	=====

</TABLE>

Depreciation expense was \$3,187,000, \$2,340,000 and \$3,116,000, respectively, for the years ended December 31, 2000, 1999 and 1998. Included in 2000 depreciation expense is \$1,265,000 related to the write down of the Company's installed HL1 laser base.

5. LEGAL PROCEEDINGS

CARDIOGENESIS SUIT

In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis, who subsequently merged with Eclipse Surgical Technologies, Inc. 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 (at least 10 years unless the patents are all held invalid in future lawsuits). As part of the settlement, CardioGenesis agreed to pay the Company:

- a minimum of \$2.5 million over the next 42 months; and
- license fees and ongoing royalties on sales of all covered products for at least 10 years (unless the patents are all held invalid in future lawsuits).

#### CLASS ACTION SUITS

In July 1997, a U.S. Food and Drug Administration ("FDA") advisory panel recommended against approval of the Company's application to market the HL1 in the United States. Following this recommendation, the Company was named as defendant in 21 purported class action lawsuits filed between August 1997 and November 1997 in the United States District Court for the District of Massachusetts. The lawsuits sought an unspecified amount of damages in connection with alleged violations of the federal securities laws based on the Company's failure to obtain a favorable FDA panel recommendation in 1997. Nineteen of these complaints were consolidated by the court into a single action for pretrial purposes (hereafter referred to as the "federal suit"). Two of these suits were voluntarily dismissed. The Company moved to dismiss all claims in the federal suit. On March 26, 1999, the court issued an order dismissing some, but not all, of the claims in the federal suit. The parties filed cross motions for reconsideration and on October 12, 1999, the court dismissed additional, but not all, remaining claims in the federal suit. On February 9, 2001, the Court issued an Order approving the settlement of the federal suit and entered a judgment of dismissal. The settlement of the federal suit did not have a material impact on the Company's financial statements.

The Company also was named as a defendant in a lawsuit filed in Massachusetts Superior Court in September 1998 (hereafter referred to as the "state suit") seeking over \$2.0 million in damages for alleged negligent misrepresentations and fraud arising from the Company's failure to obtain a favorable FDA panel recommendation in 1997. The state suit settled on confidential terms, and a Stipulation of Dismissal was filed on April 13, 2000. The settlement of the state suit did not have a material impact on the Company's financial statements.

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PLC SYSTEMS INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000

#### 5. LEGAL PROCEEDINGS (CONTINUED)

##### FOCH HOSPITAL SUIT

In October 1997, the French Ministry of Health suspended commercial use of TMR devices in France. In November 1998, a hospital in France, Centre Medico Chirurgical Foch ("Foch Hospital"), sued the Company's former Portuguese subsidiary, PLC Sistemas Medicos Internacionais Lda., and a third party, Johnson & Johnson Leasing GmbH, in Paris, France alleging breach of contract and seeking reimbursement of lease payments made for the HL1. On April 18, 2000, the Tribunal de Grande Instance de Paris dismissed this suit for lack of jurisdiction. The Company can make no assurance as to whether Foch Hospital will appeal this decision or bring suit in another jurisdiction.

#### 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 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 entered into an exclusive five-year agreement with Edward Lifesciences LLC ("Edwards"). Edwards will distribute the Company's next generation carbon-dioxide ("CO(2)") TMR laser (which was approved on January 9, 2001 by the FDA) and all associated TMR disposable components to hospitals throughout the United States. In conjunction with this agreement, the Company issued 5,333,333 shares of common stock at \$.75 per share resulting in gross proceeds of approximately \$4,000,000. 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.

As of December 31, 2000, 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; and 61,326 shares at \$3.15 per share expiring March 27, 2003. Under the terms of a previous arrangement, the Company also committed to issue an additional warrant to purchase 100,000 shares at \$1.00 per share, which will expire five years from the date of issuance.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

6. STOCKHOLDERS' EQUITY (CONTINUED)

At December 31, 2000, there were 4,728,742 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

During 2000, the Board of Directors, through its Compensation Committee, adopted the following incentive compensation programs:

- a) In May 2000, the Company adopted the 2000 Employee Stock Purchase Plan (the "Purchase Plan") for all eligible employees. Under the 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. During 2000, employees purchased 58,949 shares at a price of \$.43 per share. At December 31, 2000, 341,051 shares were reserved for future issuance.
- b) In May 2000, the Company adopted the 2000 Equity Incentive Plan ("2000 Plan"), which provides for the grant of incentive stock options and non-qualified stock options of up to 500,000 shares of common stock.
- c) In October 2000, the Company adopted the 2000 Non-Qualified Stock Option Plan ("2000 Non-Qualified Plan"), which provides for the grant of non-qualified stock options to substantially all employees of up to 317,672 shares of common stock.
- d) In November 2000, the Company adopted the 2000 Non-Qualified Retention and Performance Equity Plan ("2000 Retention Plan"), which provides for the grant of non-qualified stock options of up to 400,000 shares of common stock.

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 Plan, 2000 Non-Qualified Plan and 2000 Retention Plan (collectively, 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.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

7. STOCK OPTION AND STOCK PURCHASE PLANS (CONTINUED)

Annually, the Company grants 10,000 options to each of its non-employee directors who have fully 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.

During 1998, the Board of Directors, through its Compensation and Executive Committees, adopted the following incentive compensation programs:

- a.) In January 1998, the outstanding options of all employees (except executive officers and directors) having a higher exercise price were repriced to \$8.88 per share. As a result, the exercise price of options to purchase 526,784 shares of common stock was reduced to \$8.88 per share.
- b.) In August, 1998, the outstanding options of all directors and executive employees having a higher exercise price were repriced to \$7.75 per share. As a result, the exercise price of options to purchase 1,373,500 shares of Common Stock was reduced to \$7.75 per share.
- c.) In September 1998, a new Senior Management Investment Program ("SMIP") was adopted to promote investment in the Company's stock by directors and members of the Company's senior management team. Under the SMIP, individuals who purchased additional shares of the Company's stock between September 15, 1998 and December 15, 1998 (the "Participants") received options to purchase an additional 1.5 shares of Common Stock at an exercise price equal to the Participant's share purchase price (the "Share Purchase Price"). In addition, Participants received ten "option credits" for each share of Common Stock purchased between September 15, 1998 and December 15, 1998. Participants could use each "option credit" to: (i) reduce the exercise price of an outstanding option (vested or unvested) to purchase one share of Common Stock to the Participant's Share Purchase Price; or (ii) extend the expiration date of any outstanding option (vested or unvested) for an additional three years; or (iii) acquire new vested options with an exercise price equal to the Participant's Share Purchase Price (at a rate of 6.67 option credits for each new option to purchase one share of Common Stock). Under this program, the Company granted options to purchase an additional 331,575 shares of Common Stock at exercise prices ranging from \$3.875 to \$6.625 per share. Furthermore, prior to December 15, 1998 the Company reduced the exercise prices of options to purchase 1,243,500 shares of Common Stock to new exercise prices ranging from \$4.6875 to \$5.5625.
- d.) In December 1998, the outstanding options held by employees not eligible to participate in the SMIP having a higher exercise price were repriced to \$4.875 per share. As a result, the exercise price of options to purchase 332,316 shares of Common Stock were repriced to \$4.875 per share.

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.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

7. STOCK OPTION AND STOCK PURCHASE PLANS (CONTINUED)

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

<TABLE>

<CAPTION>

	2000	1999	1998
<S>	<C>	<C>	<C>
Outstanding at beginning of year.....	2,706	2,788	2,187
Granted.....	800	1,204	823
Exercised.....	--	(4)	(142)
Canceled.....	(386)	(1,282)	(80)
Outstanding at end of year.....	3,120	2,706	2,788
Exercisable at end of year.....	1,808	1,681	1,711
Available for grant at end of year.....	952	152	71

</TABLE>

<TABLE>

<CAPTION>

	2000	1999	1998
<S>	<C>	<C>	<C>
Weighted-average exercise price:			
Outstanding at beginning of year.....	\$3.84	\$5.16	\$8.75
Granted.....	\$0.86	\$2.53	\$5.39
Canceled.....	\$4.62	\$5.46	\$9.09
Exercised.....	\$ --	\$3.91	\$4.39
Outstanding at end of year.....	\$3.00	\$3.84	\$5.16
Exercisable at end of year.....	\$4.06	\$4.47	\$4.88
Weighted-average fair value of Options granted during the year.....	\$0.40	\$1.44	\$3.33

</TABLE>

<TABLE>

<CAPTION>

RANGE OF EXERCISE PRICES

	\$ .53125 - \$1.99	\$2.00 - 5.00	\$5.01 - \$8.88
<S>	<C>	<C>	<C>
Options Outstanding:			
Number (in thousands).....	755	1,954	411
Weighted-Average Remaining Contractual Life.....	9.73	6.69	6.88
Weighted-Average Exercise Price.....	\$0.79	\$3.27	\$5.81
Options Exercisable:			
Number (in thousands).....	44	1,369	395
Weighted-Average Exercise Price.....	\$1.66	\$3.66	\$5.74

</TABLE>

Pursuant to the requirements of FAS 123, the following are the pro forma net loss and net loss per share for 2000, 1999 and 1998, as if the compensation cost for the option plans had been determined

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

7. STOCK OPTION AND STOCK PURCHASE PLANS (CONTINUED)

based on the fair value at the grant date for grants in 2000, 1999 and 1998, consistent with the provisions of FAS 123.

<TABLE>

<CAPTION>

	2000	1999	1998
<S>	<C>	<C>	<C>
Proforma net loss (in thousands).....	\$ (8,383)	\$ (5,163)	\$ (22,438)
Proforma net loss per share.....	\$ (.36)	\$ (.25)	\$ (1.17)

</TABLE>

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

<TABLE>  
<CAPTION>

	2000	1999	1998
	-----	-----	-----
<S>	<C>	<C>	<C>
Expected life (years).....	2	2	2
Interest rate.....	6.41%	5.87%	5.53%
Volatility.....	.821	1.052	.761

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.

#### 8. LEASE RECEIVABLES

The Company has entered into third-party financing arrangements to provide an array of lease financing alternatives to hospitals interested in acquiring the HL1. The lease financing alternatives available complement the Company's traditional placement and sales strategies.

Under these arrangements, the Company receives payment from the 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 has transferred substantially all of the risks and rewards of ownership to the customer and the customer has accepted the HL1, the Company recognizes revenues, which are reported as a component of product sales. The Company recognizes 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 is 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 2004. The Company has the option to renew the U.S. facilities lease for up to three years. 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.

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PLC SYSTEMS INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

#### 9. LEASE COMMITMENTS (CONTINUED)

As of December 31, 2000, future minimum lease payments are estimated to be as follows (in thousands):

<TABLE>  
<CAPTION>

YEAR	FUTURE MINIMUM LEASE PAYMENTS
-----	-----
<S>	<C>
2001.....	\$ 354
2002.....	433
2003.....	422
2004.....	281
	-----
	\$1,490
	=====

</TABLE>

Total rent expense was \$327,000 in 2000, \$424,000 in 1999 and \$375,000 in 1998.

#### 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):

<TABLE>  
<CAPTION>

	2000	1999
	-----	-----
<S>	<C>	<C>
Net U.S. operating loss carryforwards.....	\$18,383	\$16,279
Net foreign operating loss carryforwards.....	1,865	1,775
Intercompany profit.....	19	189
Accrued expenses and reserves.....	1,342	991
Tax credits.....	838	824
Deferred revenue.....	39	55
Other.....	426	(62)
	-----	-----
Total deferred tax assets.....	22,912	20,051
Valuation allowance.....	(22,912)	(20,051)
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	=====	=====

</TABLE>

The valuation allowance increased by approximately \$2,861,000 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 \$22,912,000.

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

<TABLE>  
<CAPTION>

	2000	1999	1998
	-----	-----	-----
<S>	<C>	<C>	<C>
Domestic.....	\$ (7,029)	\$ (5,027)	\$ (14,137)
Foreign.....	(381)	(1,528)	(2,466)
	-----	-----	-----
	\$ (7,410)	\$ (6,555)	\$ (16,603)
	=====	=====	=====

</TABLE>

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000

10. INCOME TAXES (CONTINUED)

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

<TABLE>  
<CAPTION>

	2000	1999	1998
	-----	-----	-----
<S>	<C>	<C>	<C>
Statutory income tax benefit.....	\$ (2,520)	\$ (2,229)	\$ (5,645)
Utilization of loss carryforwards.....	--	(290)	(85)
Unbenefited U.S. losses.....	2,390	1,709	4,807
Unbenefited foreign losses.....	130	810	923
	-----	-----	-----
Benefit for income taxes.....	\$ --	\$ --	\$ --
	=====	=====	=====

</TABLE>

At December 31, 2000 the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$46 million, which expire at various dates through 2020. In addition, the Company had foreign net operating loss carryforwards of approximately \$4.7 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).

<TABLE>  
<CAPTION>

	NORTH AMERICA	EUROPE	OTHER	ELIMINATIONS	TOTAL
<S>	<C>	<C>	<C>	<C>	<C>
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
1998					
Net sales to unaffiliated customers.....	\$ 3,992	\$1,615	\$ 86	\$ --	\$ 5,693
Long-lived assets.....	\$ 558	\$ --	\$ --	\$ --	\$ 558

</TABLE>

No one customer accounted for more than 10% of the Company's revenues for the year ended December 31, 2000, 1999 or 1998. The Company believes that its exposure to concentrations of credit risk is not significant based on experiences with these customers. In addition, letters of credit or payment in advance are required in credit risk situations. The Company believes its future revenues will be largely dependent on sales of its products to its principal customer, Edwards, beginning in 2001.

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SCHEDULE II

PLC SYSTEMS INC.  
VALUATION AND QUALIFYING ACCOUNTS

<TABLE>  
<CAPTION>

COLUMN A	COLUMN B	COLUMN C	COLUMN D	COLUMN E
DESCRIPTION	BALANCE AT BEGINNING OF PERIOD	CHARGED TO COSTS AND EXPENSES	DEDUCTIONS	BALANCE AT END OF PERIOD
<S>	<C>	<C>	<C>	<C>
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
For the Year Ended December 31, 1998				
Allowance for Doubtful Accounts.....	\$140,000	\$100,000	\$ 12,000	\$228,000

</TABLE>

PLC SYSTEMS INC.  
QUARTERLY DATA (UNAUDITED)

<TABLE>  
<CAPTION>

	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31*	TOTAL
<S>	<C>	<C>	<C>	<C>	<C>
2000					
Total revenue.....	1,742	3,580	2,549	2,369	10,240
Gross profit (loss).....	756	2,056	1,140	(645)	3,307
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)
1999					
Total revenue.....	\$2,846	\$3,492	\$2,542	\$2,756	\$11,636
Gross profit.....	1,484	1,720	1,232	1,524	5,960
Loss from operations.....	(2,206)	(1,830)	(1,443)	(1,287)	(6,766)
Net loss.....	(2,199)	(1,705)	(1,395)	(1,256)	(6,555)
Net loss per share, basic and diluted.....	(.11)	(.08)	(.07)	(.06)	(.32)

</TABLE>

(\* ) 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 its next generation laser, the CO(2) Heart Laser 2.



<TABLE>  
<CAPTION>

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
<C>	<S>
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 (SEC File No. 1-11388), 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 (SEC File No. 1-11388), 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 (SEC File No. 1-11388), 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 (SEC File No. 1-11388), 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 (File No. 1-11388), as

previously filed with the Securities and Exchange Commission.

10.10 Form of Redeemable Warrant, incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1998 (File No. 1-11388), as previously filed with the Securities and Exchange Commission.

</TABLE>

<TABLE>

<CAPTION>

EXHIBIT  
NUMBER

DESCRIPTION OF DOCUMENT

<C>

<S>

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 (File No. 1-11388), as previously filed with the Securities and Exchange Commission.
10.12*	Employment Agreement of James G. Thomasch, dated November 4, 1999.
10.13*	Employment Agreement of Mark R. Tauscher, dated December 22, 1999.
10.14*	2000 Non-qualified Performance and Retention Equity Plan.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP.

</TABLE>

\* Filed with this annual report on Form 10-K for the fiscal year ended December 31, 2000.

[Letterhead]

Exhibit 10.12

November 4, 1999

Mr. James G. Thomasch  
One Rosebud Lane  
Westford, MA 01886

Dear Jim:

It is my pleasure to offer you the opportunity to join the PLC Medical Systems ("PLCM") team. I am pleased to offer you employment on the following terms:

1. **TITLE AND POSITION:** Senior Vice President of Finance and Administration and Chief Financial Officer reporting to the Chief Executive Officer.
2. **BASE SALARY:** \$6,153.85 biweekly or \$160,000 annualized. Salary reviews are performed annually in December with increases January 1st. Your first scheduled review will be in December 2000.
3. **BONUS:** You will be eligible for a bonus targeted at 40 percent based on performance goals to be agreed upon with the Chief Executive Officer. For 1999, your bonus will be pro-rated without performance goals.
4. **FRINGE BENEFITS:** You will be eligible to receive such benefits as are generally provided to other employees in accordance with PLCM policy as then in effect from time to time. PLCM retains the right to change, add or cease a particular benefit. We have agreed that you will receive four (4) weeks paid vacation (to be taken at mutually satisfactory times). In addition, present benefits include medical, dental, long term disability, short term disability and life insurance benefits as well as participation in PLCM's 401(k) plan after completing one full calendar quarter. In addition, you will receive a non-accountable car allowance of \$1,000 per month.
5. **STOCK OPTIONS:** A proposal will be made to the Board of Directors, at a meeting to be held on November 8, 1999, to approve an incentive stock option grant for 125,000 shares of common stock. The exercise price of incentive stock options would be the fair market value of the stock on the date of the grant and the option would vest 20% on hiring and 20% on each anniversary date. Any stock option grant is subject to the approval of the Board of Directors of PLCM and to your execution and compliance with a standard stock option agreement and your compliance with the applicable Stock Option Plan. I will discuss with you and the Board an accelerated vesting schedule based on performance of PLC Stock. Your options will accelerate upon change of control or termination without cause, subject to usual requirements of time to exercise options.

James G. Thomasch  
November 4, 1999  
Page 2

6. **NON-COMPETITION:** In consideration of your employment by PLCM, you agree to enter into the Non-competition, Proprietary Information and Inventions Agreement attached to this letter. By agreeing to these terms, you are, of course, also warranting to PLCM that you are free and able to join us and

are not subject to any prior employment restrictions that would prohibit you from devoting your full energies to PLCM.

7. **SMOKING:** PLC Medical Systems is a smoke free facility.
8. **SEVERANCE BENEFITS:** If your employment with PLCM is terminated (i) by PLCM without "cause" (as defined below) or (ii) by you for "good reason" (as defined below) within 12 months after a "change of control" (as defined below), PLCM shall pay you an amount (the "Severance Amount") equal to one times your highest annualized base salary plus bonus during the three-year period prior to such termination, plus benefit continuation for one year. One-third of the Severance Amount shall be paid within five days of such termination and the remaining two-thirds shall be paid in nine equal installments over a nine month period following such termination.

For purposes of this Paragraph No. 8, "Cause" means (a) a good faith finding by PLCM that (i) you have failed to perform your reasonably assigned duties for PLCM and have failed to remedy such failure within 10 days following written notice from the PLCM to you notifying you of such failure, or (ii) you have engaged in dishonesty, gross negligence or misconduct, or (b) your conviction of, or the entry of a pleading of guilty or nolo contendere by you to, any crime involving moral turpitude or any felony.

For purposes of this Paragraph No. 8, "good reason" means, in summary: (i) a diminution in your position, authority or responsibilities; (ii) a material reduction in your salary or benefits; or (iii) your relocation more than [30] miles from Franklin, Massachusetts.

For purposes of this Paragraph No. 8, "Change in Control" means, in summary: (i) the acquisition by a party or a group of 35% or more of the outstanding stock of PLCM; (ii) a change, without Board of Directors approval, of a majority of the Board of Directors (whether occurring on one date or over time); (iii) the acquisition of PLCM by means of a reorganization, merger, consolidation or asset sale; or (iv) the approval of a liquidation or dissolution of PLCM.

James G. Thomasch  
November 4, 1999  
Page 3

This letter, together with the Non-competition, Proprietary Information and Inventions Agreement, constitutes our entire offer regarding the terms and conditions of your prospective employment by PLCM. It supersedes any prior agreements, or other promises or statements (whether oral or written) regarding the offered terms of employment. The terms of your employment shall be governed by the law of the Commonwealth of Massachusetts.

As discussed, I would like you to start on November 7, 1999, however, this offer will remain open for two weeks.

If these terms are agreeable to you, please sign and return the copy of this letter enclosed for that purpose.

Jim, I look forward to working with you and am excited at the prospect of having you help PLC reach its potential.

Very truly yours,

/s/ Edward H. Pendergast

-----  
Edward H. Pendergast  
Chairman, President and  
Chief Executive Officer

Agreed and Accepted:

*/s/ James G. Thomasch*

-----  
*James G. Thomasch*

[Letterhead]

Exhibit 10-13

December 22, 1999

Mr. Mark R. Tauscher  
22421 NE 140th Way  
Woodinville, WA 98072

Dear Mark:

I am delighted you have accepted our offer of employment to join the PLCM Medical Systems ("PLCM") team as of December 17, 1999 on the following terms:

- 1) **TITLE AND POSITION:** President, Chief Executive Officer and Member of the Board of Directors reporting to the Board of Directors.
- 2) **BASE SALARY:** \$9,615.39 biweekly or \$250,000 annualized. Since you will be on vacation until January 17th, 2000, PLCM will pay you \$1,000 until that date when your compensation will be at the \$250,000 per year salary. Salary reviews are performed annually in December with increases January 1st. Your first scheduled review will be in December 2000.
- 3) **BONUS:** You will be eligible for a bonus targeted at 50% based on performance goals to be agreed upon initially with the Chairman. The bonus will start at 70% achievement level and may exceed 50%. The first year bonus will be calculated on mutually agreed achievable goals.
- 4) **FRINGE BENEFITS:** You will be eligible to receive such benefits as are generally provided to other employees in accordance with PLCM policy as then in effect from time to time. PLCM retains the right to change, or cease a particular benefit. Present benefits include two weeks paid vacation earned on a monthly basis (to be taken at mutually satisfactory times), medical, dental, short and long term disability and life insurance benefits, and participation in PLCM's 401(k) plan after completing one full calendar quarter. In addition, PLCM will pay for your COBRA benefits for 3 to 6 months while your family is in Washington. You will receive an automobile allowance of \$1,000 per month. Your vacation will be four weeks.
- 5) **STOCK OPTIONS:** The Board of Directors has approved a stock option grant for you for 350,000 shares of PLCM common stock, which vest 20% upon onset of employment and 5% per quarter on quarterly anniversary date of the

Mark R. Tauscher  
December 22, 1999  
Page 2

commencement of employment. The exercise price of incentive stock options is the fair market value of the stock on the date of the grant. Any stock option grant is subject to your execution and compliance with the applicable Stock Option Plan and form of stock option agreement in effect at the time of the grant. The options will be allocated to Incentive Stock Options to the extent allowed, with the balance being non-qualified options. The Board will consider annual increases of up to 50,000 shares based on performance.

- 6) **NON-COMPETITION:** In consideration of your employment by PLCM,

you agree to enter into the Non-competition, Proprietary Information and Inventions Agreement ("the Agreement") attached to this letter. By agreeing to these terms, you are, of course, also warranting to PLCM that you are free and able to join us and are not subject to any prior employment restrictions that would prohibit you from devoting your full energies to PLCM. It is understood that the Agreement would not prohibit you from employment with a competitor if you are employed in an area unrelated to our business as defined in the Agreement.

- 7) **SMOKING:** PLC Medical Systems is a smoke free facility.
- 8) **RELOCATION:** PLCM will pay for your reasonable moving expenses, including cost of moving, cost of selling your house in Washington, closing costs of buying a house in Massachusetts, cost of flying family here and a reasonable number of house hunting trips and will include a gross up of non-deductible expenses. We will attempt to utilize a relocation service if it will provide tax benefit to PLCM without impacting your tax situation. If needed, PLCM will arrange a bridge loan for the time between purchase of a home in Massachusetts and sale of your home in Washington [which bridge loan will be secured by a mortgage on your home in Washington].
- 9) **SEVERANCE BENEFITS:** If your employment with PLCM is terminated (i) by PLCM without "Cause" (as defined below) or (ii), for "Good Reason" (as defined below) with [12] months after a Change of Control (as defined below), PLCM shall pay you one-half of the Severance Amount (as defined below) on termination of your employment with PLCM, and the other half of the Severance Amount shall be payable in nine equal installments over a nine month period following such termination.

For purposes of this Paragraph 9, "Cause" means (a) good faith finding by PLCM that (i) you have failed to perform your reasonably assigned duties for PLCM [and have failed to remedy such failure within 10 days following written notice from PLCM to you notifying you of such failure], or (ii) you have

Mark R. Tauscher  
December 22, 1999  
Page 3

engaged in dishonesty, gross negligence or misconduct, or (b) your conviction of, or the entry of as pleading of guilty or nolo contendere by you to, any crime involving moral turpitude or any felony. Under (a) (i) your Severance Amount will be reduced by one-half the amount paid if your employment is terminated without "cause" Under (a) (ii) and (b) you will be paid no Severance Amount.

For purposes of this Paragraph No. 9, the "Severance Amount" means an amount equal to the product of 1.5 and the sum of (a) your highest annualized base salary during the three-year period prior to the termination of your employment with PLCM (the "Applicable Base Salary") and (b) your previous calendar year's bonus (or, if you have been employed by PLCM for less than one year, a bonus equal to 50% of the Applicable Base Salary)

For purposes of this Paragraph No. 9, "Good Reason" means, in summary: (i) a diminution in your position, authority or responsibilities; (ii) a material reduction in your salary or benefits; or (iii) your relocation more than [100] miles from Franklin, Massachusetts.

For purposes of the Paragraph No. 9, "Change of Control" means, in summary: (i) the acquisition by a party or a group

of 35% or more of the outstanding stock of PLCM; (ii) a change, without Board of Directors approval, of a majority of the Board of Directors (whether occurring on one date or over time); (iii) the acquisition of PLCM by means of a reorganization, merger, consolidation or asset sale; or (iv) the approval of a liquidation or dissolution of PLCM.

This letter, together with the Non-Competition, Proprietary Information and Inventions Agreement, constitutes our entire offer regarding the terms and conditions of your employment by PLCM. It supersedes any prior agreements, or other promises or statements (whether oral or written) regarding the offered terms of employment. The terms of your employment shall be governed by the law of the Commonwealth of Massachusetts. By accepting this offer of employment, you agree that any action, demand, claim or counterclaim concerning any aspect of your employment relationship with PLCM shall be governed by the internal laws of the Commonwealth of Massachusetts (excluding the conflicts of law principles thereof).

We agree that your employment with PLCM commence effective as of December 17, 1999. We understand you will be taking a vacation through January 16th and will pay you \$1,000 for that time. We look forward to your return on January 17, 2000.

If these terms are agreeable to you, please sign and return the copy of this letter enclosed for that purpose.

Mark R. Tauscher  
December 22, 1999  
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Mark, I am very enthusiastic about you becoming President and CEO of PLCM and look forward to working with you.

Sincerely,

/s/ Edward H. Pendergast

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Edward H. Pendergast  
President

Enclosures

Agreed:

/s/ Mark R. Tauscher

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Mark R. Tauscher

Date: 12-23-99



## PLC SYSTEMS INC.

## 2000 NON-QUALIFIED PERFORMANCE AND RETENTION EQUITY PLAN

## 1. PURPOSE

The purpose of this 2000 Non-qualified Performance and Retention Equity Plan (the "Plan") of PLC Systems Inc., a Yukon Territory corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and thereby better aligning the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) and 424(f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"), and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a significant interest, as determined by the Board of Directors of the Company (the "Board").

## 2. ELIGIBILITY

All of the Company's employees are eligible to be granted non-statutory stock options (each, an "Option") under the Plan to purchase shares of common stock, no par value per share, of the Company ("Common Stock"). Each person who has been granted an Option under the Plan shall be deemed a "Participant."

## 3. ADMINISTRATION, DELEGATION

(a) ADMINISTRATION BY BOARD OF DIRECTORS. The Plan will be administered by the Board. The Board shall have authority to grant Options and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Option in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Option. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) DELEGATION TO EXECUTIVE OFFICERS. To the extent permitted by applicable law, the Board may delegate to one or more executive officers of the Company the power to grant Options and exercise such other powers under the Plan as the Board may determine, provided

that the Board shall fix the maximum number of shares subject to Options and the maximum number of shares for any one Participant to be made by such executive officers.

(c) APPOINTMENT OF COMMITTEES. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee or the executive officer referred to in Section 3(b) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or executive officer.

## 4. STOCK AVAILABLE FOR OPTIONS

(a) *NUMBER OF SHARES.* Subject to adjustment under Section 6, Options may be made under the Plan for up to 400,000 shares of Common Stock. If any Option expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part or results in any Common Stock not being issued, the unused Common Stock covered by such Option shall again be available for the grant of Options under the Plan. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) *PER-PARTICIPANT LIMIT.* Subject to adjustment under Section 6, the maximum number of shares of Common Stock with respect to which Options may be granted to any Participant under the Plan shall be 100,000 per calendar year.

## 5. STOCK OPTIONS

(a) *GENERAL.* The Board may grant Options and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.

(b) *NON-STATUTORY STOCK OPTIONS.* No Option granted under the Plan is intended to be an "incentive stock option" as defined in Section 422 of the Code.

(c) *EXERCISE PRICE.* The Board shall establish the exercise price at the time each Option is granted and specify it in the applicable option agreement.

(d) *DURATION OF OPTIONS.* Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement, provided, however, that no Option will be granted for a term in excess of 10 years.

(e) *EXERCISE OF OPTION.* Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares for which the Option is exercised.

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(f) *PAYMENT UPON EXERCISE.* Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as the Board may, in its sole discretion, otherwise provide in an option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) by delivery of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board in good faith ("Fair Market Value"), provided (i) such method of payment is then permitted under applicable law and (ii) such Common Stock was owned by the Participant at least six months prior to such delivery;

(4) to the extent permitted by the Board, in its sole discretion, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

## 6. ADJUSTMENTS FOR CHANGES IN COMMON STOCK AND CERTAIN OTHER EVENTS

(a) *CHANGES IN CAPITALIZATION.* In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Common Stock other than a normal cash dividend, (i) the number and class of securities available under this Plan, (ii) the per-Participant limit set forth in Section 4(b), and (iii) the number and class of securities and exercise price per share subject to each outstanding Option shall be appropriately adjusted by the Company (or substituted Options may be granted, if applicable) to the extent the Board shall determine, in good faith, that such an adjustment (or substitution) is necessary and appropriate. If this Section 6(a) applies and Section 6(c) also applies to any event, Section 6(c) shall be applicable to such event, and this Section 6(a) shall not be applicable.

(b) *LIQUIDATION OR DISSOLUTION.* In the event of a proposed liquidation or dissolution of the Company, the Board shall upon written notice to the Participants provide that all then unexercised Options will (i) become exercisable in full as of a specified time at least 10 business days prior to the effective date of such liquidation or dissolution and (ii) terminate effective upon such liquidation or dissolution, except to the extent exercised before such effective date.

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(c) *REORGANIZATION AND ACQUISITION EVENTS.*

(1) *DEFINITIONS.*

(a) A "Reorganization Event" shall mean: (i) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property; or (ii) any exchange of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange transaction.

(b) An "Acquisition Event" shall mean the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, all or substantially all of the individuals and entities who were the beneficial owners of the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") and the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities") immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination.

(2) *EFFECT ON OPTIONS.*

(a) *REORGANIZATION EVENT.* Upon the occurrence of a Reorganization Event that is not also an Acquisition

Event, or the execution by the Company of any agreement with respect to a Reorganization Event that will not also result in an Acquisition Event, the Board shall provide that all outstanding Options shall be assumed, or equivalent options shall be substituted, by the acquiring or

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succeeding corporation (or an affiliate thereof). For purposes hereof, an Option shall be considered to be assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in fair market value to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

Notwithstanding the foregoing, if the acquiring or succeeding corporation (or an affiliate thereof) does not agree to assume, or substitute for, such Options, then the Board shall, upon written notice to the Participants, provide that all then unexercised Options will become exercisable in full as of a specified time prior to the Reorganization Event and will terminate immediately prior to the consummation of such Reorganization Event, except to the extent exercised by the Participants before the consummation of such Reorganization Event; provided, however, in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share of Common Stock surrendered pursuant to such Reorganization Event (the "Acquisition Price"), then the Board may instead provide that all outstanding Options shall terminate upon consummation of such Reorganization Event and that each Participant shall receive, in exchange therefor, a cash payment equal to the amount (if any) by which (A) the Acquisition Price multiplied by the number of shares of Common Stock subject to such outstanding Options (whether or not then exercisable), exceeds (B) the aggregate exercise price of such Options.

- (b) **ACQUISITION EVENT.** In the event of the consummation of an Acquisition Event (regardless of whether such Acquisition Event also constitutes a Reorganization Event), all then-unexercised

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Options will become exercisable in full as of time

specified by the Board prior to the consummation of the Acquisition Event and will terminate immediately prior to the consummation of such Acquisition Event, except to the extent exercised by the Participants before the consummation of such Acquisition Event; provided, however, in the event of an Acquisition Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share of Common Stock surrendered pursuant to such Acquisition Event (the "Acquisition Price"), then the Board may instead provide that all outstanding Options shall terminate upon consummation of such Acquisition Event and that each Participant shall receive, in exchange therefor, a cash payment equal to the amount (if any) by which (A) the Acquisition Price multiplied by the number of shares of Common Stock subject to such outstanding Options (whether or not then exercisable), exceeds (B) the aggregate exercise price of such Options.

7. GENERAL PROVISIONS APPLICABLE TO OPTIONS

(a) TRANSFERABILITY OF OPTIONS. Except as the Board may otherwise determine or provide in an Option, Options shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) DOCUMENTATION. Each Option shall be evidenced by a written instrument in such form as the Board shall determine. Each Option may contain terms and conditions in addition to those set forth in the Plan.

(c) BOARD DISCRETION. Except as otherwise provided by the Plan, each Option may be made alone or in addition or in relation to any other Option. The terms of each Option grant need not be identical, and the Board need not treat Participants uniformly.

(d) TERMINATION OF STATUS. The Board shall determine the effect on an Option of the disability, death, retirement, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary (as defined below) may exercise rights under the Option. If the Participant has died, the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death is referred to as the "Designated Beneficiary."

(e) WITHHOLDING. Each Participant shall pay to the Company, or make provision satisfactory to the Board for payment of, any taxes required by law to be withheld in connection

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with Options to such Participant no later than the date of the event creating the tax liability. Except as the Board may otherwise provide in an Option, Participants may, to the extent then permitted under applicable law, satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Option creating the tax obligation, valued at their Fair Market Value; provided, however, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). The Company may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) AMENDMENT OF OPTION. The Board may amend, modify or terminate any outstanding Option, including but not limited to, substituting therefor another Option of the same or a different type, and changing the date of exercise or

realization provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(g) *CONDITIONS ON DELIVERY OF STOCK.* The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Option have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) *ACCELERATION.* The Board may at any time provide that any Options shall become immediately exercisable in full or in part.

#### 8. MISCELLANEOUS

(a) *NO RIGHT TO EMPLOYMENT OR OTHER STATUS.* No person shall have any claim or right to be granted an Option, and the grant of an Option shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Option.

(b) *NO RIGHTS AS STOCKHOLDER.* Subject to the provisions of the applicable Option, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Option until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to such Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between

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the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(c) *EFFECTIVE DATE AND TERM OF PLAN.* The Plan shall become effective on the date on which it is adopted by the Board. No Options shall be granted under the Plan after the completion of ten years from the date on which the Plan was adopted by the Board but Options previously granted may extend beyond that date.

(d) *AMENDMENT OF PLAN.* The Board may amend, suspend or terminate the Plan or any portion thereof at any time.

(e) *GOVERNING LAW.* The provisions of the Plan and all Options granted hereunder shall be governed by and interpreted in accordance with the laws of the Commonwealth of Massachusetts, without regard to any applicable conflicts of law.

(f) *FOREIGN NATIONALS.* Options may be granted to participants who are foreign nationals or employed outside the United States on such terms and conditions different from those specified in the Plan as the Board considers necessary or advisable to achieve the purposes of the Plan.

Approved by the Board of Directors  
on November 30, 2000

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PLC SYSTEMS INC.

SUBSIDIARIES OF REGISTRANT

- 1.) *PLC Medical Systems, Inc., a Delaware Corporation*
- 2.) *PLC Sistemas Medicos Internacionais GmbH, a German Corporation*
- 3.) *PLC Medical Systems AG, a Swiss Corporation*



CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-68923, 333-80045 and 333-43454 and Form S-8 Nos. 33-95168, 333-51547, 333-37814, 333-48706, 333-51136 and 333-57752) of PLC Systems Inc. of our report dated February 16, 2001 with respect to the consolidated financial statements and schedule of PLC Systems Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2000.

/s/ Ernst & Young LLP

Ernst & Young LLP

Boston, Massachusetts  
March 27, 2001