

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

(X) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 1998

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD OF \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 1-11388

PLC SYSTEMS INC.  
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

YUKON TERRITORY, CANADA  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

04-3153858  
(I.R.S. EMPLOYER  
IDENTIFICATION NO.)

10 FORGE PARK, FRANKLIN, MASSACHUSETTS  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

02038  
(ZIP CODE)

(508) 541-8800  
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

TITLE OF EACH CLASS	NAME OF EACH EXCHANGE ON WHICH REGISTERED
COMMON STOCK, NO PAR VALUE	AMERICAN STOCK EXCHANGE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

NONE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No  
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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 23, 1999, was \$77,128,690. As of March 23, 1999, 20,230,476 shares of Common Stock, no par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's preliminary proxy statement, which will be issued in connection with the 1999 Annual Meeting of Shareholders (Part III), are incorporated by reference.

FORWARD-LOOKING STATEMENTS

This report (and information incorporated by reference) contains 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. 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 Result 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 risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such 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, risk factors in Item 7, Item 7A, the Company's other SEC reports, and the Company's press releases.

## PART I

### ITEM 1. BUSINESS.

#### GENERAL

PLC Systems Inc. ("PLC" or the "Company") has developed a patented high-powered carbon dioxide ("CO<sub>2</sub>") laser system known as The Heart Laser-TM-System for use in the treatment of coronary artery disease in a surgical laser procedure, pioneered by the Company and its clinical investigators, known as transmyocardial revascularization ("TMR").

TMR is a revolutionary new way of relieving debilitating pain in patients suffering from severe coronary artery disease ("CAD"). The Company's patented high-energy CO<sub>2</sub> 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. The Company's Heart Laser System was developed specifically for TMR and it is believed to be the only TMR system that can create a channel completely through the heart wall with a single laser pulse. In addition, the Company's Heart Laser System uses 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 System 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 performed through a small incision between the patient's ribs while the patient's heart is beating. A patient's recovery is therefore expected to be quicker, less traumatic and less costly than in surgical procedures, such as bypass surgery, which require a heart-lung machine.

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 spasmodic 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. U.S. clinical studies have demonstrated The Heart Laser System to be safe and effective in decreasing angina by two or more classes (angina is measured in classes from one to four, one being the least painful and four being the most) in nearly 75% of the patients studied; in fact, TMR using The Heart Laser System eliminated all angina in one-third of the patients studied.

Over 4,300 patients have been treated with the Company's Heart Laser System in the United States and abroad. As of December 31, 1998, the Company had shipped over 100 Heart Laser Systems worldwide.

#### RECENT DEVELOPMENTS

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

**RECEIPT OF FDA APPROVAL.** On August 20, 1998, the Company received approval from the U.S. FDA to market The Heart Laser System throughout the U.S. for treatment of 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. As part of this approval process, the FDA conducted an inspection of the Company's manufacturing facility in June 1998. The FDA completed its inspection of PLC's manufacturing facility without finding any deficiencies in the Company's manufacturing and quality systems.

**MEDICARE REIMBURSEMENT FOR TMR FORTHCOMING.** In February 1999, the Health Care Financing

Administration (HCFA) announced that Medicare will provide coverage for TMR procedures performed with devices approved by the FDA. The decision rescinds the national noncoverage instruction for TMR implemented by HCFA in May 1997 and sets a new coverage policy to allow payment for TMR consistent with FDA-approved uses of TMR devices. HCFA has not yet determined the effective date of this

policy change.

**FAVORABLE ASSESSMENT OF TMR BY BLUE CROSS/BLUE SHIELD TEC.** 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 as 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 including Kaiser Permanente. TEC assessments are released as reports to TEC program subscribers. Nearly all major payers in the U.S., including governmental payers, private third party payers, and managed care organizations, subscribe to the TEC program and receive TEC assessment reports for use in their own coverage and payment policy decision making.

**PLC ESTABLISHES CENTER OF EXCELLENCE.** In 1998, PLC established a state of the art training program at Rush Presbyterian Medical Center in Chicago to ensure that surgeons and medical staff who will use The Heart Laser System are fully trained in the safe and effective use of the system. This comprehensive program focuses on ensuring the best possible patient outcomes, and includes 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 a laboratory session.

**PLC RECEIVES ISO 9001 CERTIFICATION.** In March 1999, PLC received ISO 9001 certification, allowing the Company to place the CE Mark on its products.

**PLC OBTAINS FAVORABLE SETTLEMENT OF PATENT LITIGATION.** In January 1999, the Company settled its outstanding patent infringement litigation with a competitor, CardioGenesis Corporation. Under the settlement, CardioGenesis agreed that key PLC patents are valid and enforceable. The PLC patents cover the Company's synchronization technology, a critical factor in ensuring the safety of TMR and PMR procedures. As part of the settlement, CardioGenesis must pay:

- a minimum of \$2.5 million to PLC over the next 42 months; and
- license fees and ongoing royalties through at least the year 2009 (so long as the patents remain valid).

**GE CAPITAL SIGNS EXCLUSIVE AGREEMENT WITH PLC.** In September 1998, a unit of GE Capital, a leading vendor financing organization, entered into an exclusive agreement with the Company to provide a broad array of financing alternatives to U.S. hospitals interested in acquiring the PLC Heart Laser System. GE Capital Trans Leasing, a unit of GE Capital's Vendor Financial Services, which specializes in working with equipment manufacturers and dealer/distributors, agreed to work exclusively with PLC to provide financing for laser revascularization systems. These financing alternatives provide PLC with a non-dilutive source of capital to finance placements of The Heart Laser System.

**RENEWAL OF JAPANESE DISTRIBUTION AGREEMENT.** In early 1999, PLC renewed its distribution agreement

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in Japan with Imatron Japan Inc. ("Imatron") to distribute The Heart Laser System in Japan and complete the Japanese regulatory approval process. The agreement includes a commitment by Imatron to purchase a minimum of five Heart Laser Systems during 1999. Along with the United States and Germany, Japan is believed to be one of the three largest markets in the world for products used in the treatment of cardiovascular disease. Between 1995 and 1997, Imatron purchased 12 Heart Laser Systems 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 Heart Laser System in Japan. The companies anticipate approval of their application during the second half of 1999. In early 1999, PLC also hired a direct representative with more than 25 years experience selling cardiovascular products in Japan to support development of the Japanese market.

#### 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 carbon dioxide ("CO(2)") lasers. Dr. Rudko, who holds a Ph.D. in electrical engineering from Cornell University, had spent over twenty-five years designing and developing CO(2) laser systems for Raytheon Company. In the late 1980s, a heart 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, the efficacy of the TMR treatment could not be proven unless the procedure could be performed 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 Heart Laser System, a high-powered laser system capable of creating a channel completely through a human heart wall with a single laser pulse delivered in the fraction of a second between heartbeats.

In November 1990, the Company received a Phase I Investigational Device Exemption ("IDE") for its Heart Laser System from the FDA. In approving the Phase I study, the FDA permitted the use of The Heart Laser System for patients considered not suitable for any other intervention. Phase I trials were performed by Dr. John Crew and were 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 Heart Laser System. 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 was a study comparing 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 its clinical study patients. The long-term TMR analysis included 70 patients at eight hospitals. Each patient had been suffering from severe CAD, including chronic angina, before receiving treatment with The Heart Laser System. The average age of the patients at enrollment was 63. The average preoperative angina class for the group was 3.8. 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 34 months following the TMR procedure, the group's average angina class was significantly improved from 3.8 to 1.5. This was virtually unchanged from the 1.4 average angina class reported at 12 months postoperatively. In fact, three years after TMR with The Heart Laser System, 23% of the patients reported having no angina and 58% were in class 1 or 2.

Since April 1992, the Company has received 14 U.S. patents relating to the underlying laser technology, the use of a laser on a beating heart, The Heart Laser System handpiece, and other laser accessories. The Company also has 12 U.S. patent applications pending that cover various aspects of the technology for The Heart Laser System and the process by which a laser is used to revascularize the

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myocardium, as well as other laser technologies. The Company also holds a number of foreign patents and patent applications.

The Company was incorporated pursuant to the COMPANY ACT of British Columbia, Canada on March 3, 1987. The Company transferred its jurisdiction of incorporation to the Yukon Territory of Canada in March 1999. The Company's principal offices and manufacturing facilities are 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 Ltda, PLC Sistemas Medicos Internacionais GmbH, PLC Medical Systems AG, PLC Medical Systems France, PLC Medical Systems Asia/Pacific Pte Ltd and PLC Medical Systems Australia Pty Ltd.

#### CARDIOVASCULAR DISEASE AND CURRENT THERAPIES

Cardiovascular disease is the leading cause of death in the U.S. with more than 950,000 deaths annually. This represents over 40% of all U.S. deaths. Over 13 million Americans suffer from coronary heart disease with 350,000 new cases every year. Atherosclerosis, 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. Atherosclerosis 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 1998 Heart and Stroke Facts Statistics published by the American Heart Association (the "AHA"), approximately 573,000 coronary bypass operations were performed on 360,000 patients and 434,000 balloon angioplasty procedures were performed in the U.S. on 408,000 patients in 1995. The AHA estimates the cost of cardiovascular disease in 1997 at \$259.1 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, 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 those 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 the use of a heart lung machine.

A less invasive alternative to bypass surgery is balloon angioplasty. The most common form of angioplasty involves inserting into a diseased artery a catheter with a balloon at the tip. 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.

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Management believes that TMR using The Heart Laser System 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 U.S. FDA has approved The Heart Laser System for such patients. TMR is designed to be less invasive and less expensive than traditional bypass surgery, and may avoid the restenosis problem inherent 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 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. Management 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 UTILIZING THE HEART LASER SYSTEM

The main challenge in treating atherosclerosis is to allow adequate blood to flow to the heart muscle without significantly damaging the heart. Conventional and newer techniques described above are used to bypass, reopen or widen blocked or narrowed arteries and could eventually fail due to restenosis or natural disease progression. TMR using The Heart Laser System 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 the 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 the TMR procedure, the patient is given general anesthesia. An incision is made in the patient's side between the ribs, exposing the heart. The 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 System is capable of drilling a transmural channel in less than 0.05 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 System provides a number of benefits, although no assurance can be given that any of the mentioned benefits will

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be received by patients and no assurance can be given that the FDA will approve additional indications for use of The Heart Laser System. These current anticipated benefits include:

**THERAPY FOR PATIENTS NOT SUITABLE FOR CORONARY BYPASS.** The U.S. FDA has approved the use of The Heart Laser System for patients who have severe, stable angina and would otherwise not be suitable for coronary bypass surgery, and for whom other surgical or interventional techniques may not be available or advisable to alleviate the effects of atherosclerotic illness.

**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 OPCAB procedure in which coronary artery bypass graft surgery is performed on a beating heart, management believes that with additional clinical research, TMR may be found to be an effective complement to this procedure. TMR can be performed on the anterior, posterior and lateral walls of the heart while the OPCAB procedure usually is only performed on the anterior wall of the heart.

**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 could potentially be found useful for post-transplant patients suffering from chronic rejection atherosclerosis. Presently, the only treatment for this condition is re-transplantation.

**POTENTIALLY LOWER MEDICAL COSTS.** Management believes the medical costs associated with TMR using The Heart Laser System will be less than the costs of traditional bypass surgery which requires a larger surgical team, more supporting equipment and a longer hospital stay. The cost of TMR in some situations may also be less than angioplasty when combinations of additional devices such as atherectomy catheters, stents or intravascular ultrasound are required.

**POTENTIALLY QUICKER RECOVERY.** Because TMR using The Heart Laser System is less invasive and 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.

#### **DEVELOPMENT OF MARKETING STRATEGY**

The Company's strategy is to establish TMR using The Heart Laser System as a standard of care for treating patients suffering from coronary artery disease. Currently, The Heart Laser System is commercially available in the U.S., the European Community (except France), China and certain countries that do not require governmental approval for commercialization. The Company has submitted applications for government approval to sell The Heart Laser System in other countries including Japan, Taiwan and South Korea.

The Company has also developed a number of single use surgical products to be used with The Heart Laser System in performing TMR to address concerns regarding the spread of infections. The Company sells sterile, single use, TMR procedure kits containing a set of handpieces, drapes and other TMR single use items.

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The Company has developed a strategy to address the challenges of marketing high cost capital equipment. In markets with minimal credit risk, economic stability, adequate health reimbursement, and requisite government approvals, the Company has offered The Heart Laser System on a usage basis whereby the hospital obtains The Heart Laser System in exchange for payment of an initial installation fee and usage fees each time a TMR procedure is performed. The use of the machine is typically subject to contractual yearly minimums for a defined period of time with renewal options. The Heart Laser System remains the property of the Company and is depreciated over the term of the placement contract. The Company refers to this approach as a placement contract. Such placement 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 agreement with GE Capital enables the Company to monetize future payment streams associated with certain domestic placements. If utilization becomes more predictable, the Company expects a significant number of new accounts to opt for conventional leasing, or direct purchase.

The Company will also sell The Heart Laser System outright as capital equipment. The disposable sterile kits would be sold for each procedure, along with yearly service contracts after expiration of any applicable warranty period.

The Company has several different marketing strategies to sell or place The Heart Laser System and accessories depending upon the particular circumstances, including direct sales, sales through distributors, placement type sales, rentals, and leasing. Pricing varies depending upon the particular marketing strategy used and the country in which The Heart Laser System is sold. The Company plans to launch a new purchase program in 1999 that combines aggressive pricing, flexible financing arrangements, and trade-in allowances for customers who have purchased other TMR systems. No assurance can be given that such programs will be implemented successfully, or at all.

**UNITED STATES.** The Company is using a direct sales force in the United States to market The Heart Laser System. The sales force is comprised of personnel with a high degree of professionalism and experience in the cardiovascular device business. The Company has invested considerable resources in recruiting and training of the sales force during 1998. Initial marketing efforts following FDA approval were directed at The Heart Laser System user, the

cardiothoracic surgeon, whose influence is critical in the hospital decision to purchase The Heart Laser System. Subsequent marketing efforts are expected to shift to the hospital administration and the referring physician, 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 media advertising, direct mail, trade shows and educational symposia, all focused on disseminating critical information to decision makers and key purchase influencers.

In 1998, PLC established a state of the art training program at Rush Presbyterian Medical Center in Chicago to train new surgeons and medical staff who will use The Heart Laser System in the safe and effective use of the system and facilitate interaction and discussion among experienced users about best clinical practices. This comprehensive program focuses on ensuring the best possible patient outcomes, and includes 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 System overseas both directly and through distributors.

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PLC received the CE Mark for The Heart Laser System in the third quarter of 1995. The CE Mark allows the Company to sell the Heart Laser System commercially in European Community countries (except in France). Despite receiving the CE Mark, 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 itself.

The Company installed a new Managing Director, Vincent Puglisi, for the European region in August 1998 to increase sales and marketing efforts for The Heart Laser System in this region. Mr. Puglisi also assumed responsibility for operations in the Asia Pacific region in late 1998.

In early 1999, the Company renewed its distribution agreement in Japan with Imatron to distribute The Heart Laser System in Japan and complete the Japanese regulatory approval process. The agreement includes a commitment by Imatron to purchase a minimum of five Heart Laser Systems during 1999. 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 Heart Laser Systems 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 Heart Laser System in Japan. The joint application is believed to be the first submitted by a laser revascularization company seeking to market its product in Japan. The companies anticipate approval of their application during the second half of 1999. No assurance can be given that Japanese regulatory approval will be granted to The Heart Laser System in this timeframe, or at all. PLC also hired a direct representative, Hiroshi Nikko, to support development of the Japanese market. Mr. Nikko brings to PLC more than 25 years of experience selling cardiovascular products in Japan. Prior to joining PLC, Mr. Nikko worked for Nissho Corporation, which distributes the left ventricle assist systems developed by Thermo Cardiosystems and manufactures a hemodialysis filter.

As of December 31, 1998, the Company had shipped over 70 Heart Laser Systems 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

The Company develops and markets one principal product: The Heart Laser System. Approximately 89.5% of the Company's revenue in the fiscal year ended December 31, 1998 and 93.2% in the fiscal year ended December 31, 1997 was derived from The Heart Laser System. No single customer accounted for more than 10% of the Company's revenues in fiscal 1998. In 1997, the Company's exclusive distributor in Japan accounted for approximately 20% of the Company's revenues.

#### MANUFACTURING

The Company manufactures and tests its products 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.

The Company purchases components for its laser systems and its related disposables from a number of sources and management believes that most components are available from multiple sources. For those components that are purchased from a single source, management has entered into exclusive supplier agreements which provide access to technologies, processes and bills of material to enable the Company to

manufacture the components or to have the components manufactured elsewhere. The Company's manufacturing facilities are subject to periodic inspection by regulatory authorities to ensure compliance with FDA and European Community quality regulations. The Company's business is not subject to seasonal fluctuations.

#### GOVERNMENT REGULATION

The Heart Laser System, 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 FDA regulates design, development, manufacturing, and the 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 Control for Health and Safety Act of 1968 ("Radiation 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 U.S. FDA to market The Heart Laser System throughout the U.S. to treat the estimated 80,000 domestic patients each year who suffer from severe coronary artery disease 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. As part of this approval process, the FDA conducted an inspection of the Company's manufacturing facility in June 1998. The FDA completed its inspection of PLC's manufacturing facility without any adverse findings or observations of deficiencies in the Company's manufacturing and quality systems. FDA imposed certain post-approval requirements as conditions of its August clearance. These requirements include a 600 patient post-market study to further assess mortality, a specific "TMR" surgical informed consent, and certain disclaimers placed on all promotion and advertising materials.

Once a product obtains market approval, any 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 The Heart Laser System after market introduction and may therefore submit future IDE, 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 use or sale of The Heart Laser System 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 Heart Laser System had been approved for commercial distribution in the European Community since 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 Heart Laser System is currently under review by a panel of French experts. The Company has provided its clinical results to the panel and is actively working to have the moratorium lifted. 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 use of the Company's products.

As a device manufacturer, the Company is also required to register with the FDA. As such, the Company is subject to inspection on a routine basis for compliance with the FDA's Quality Systems

regulations. These regulations require that the Company manufacture its products and maintain its documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, the Company is required to comply with various FDA requirements for reporting. The Medical Device Reporting Act regulations require that the Company provide information to the FDA on death or serious injuries alleged to have been associated with 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 applications. The Company's laser products are subject to periodic inspection under the Radiation 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 or its employees. Failure to comply with regulatory requirements could have a material adverse effect on the Company's business, financial conditions and results of operations.

#### THIRD PARTY REIMBURSEMENT

Health care providers, such as hospitals and physicians, that purchase medical devices such as The Heart Laser System for use on their patients generally rely on third party payers, principally Medicare, Medicaid and private health insurance plans, to reimburse all or part of the costs associated with



the procedures performed with these devices.

In February 1997, the Health Care Financing Administration ("HCFA") published a national non-coverage instruction for TMR based on its belief that scientific evidence substantiating the safety and effectiveness of TMR was not currently available. It is not unusual for HCFA to deny reimbursement for procedures performed using devices that have not yet received FDA approval. The non-coverage instruction applied to procedures performed on or after May 19, 1997 on Medicare beneficiaries.

In February 1999, HCFA rescinded the national non-coverage instruction for TMR implemented in May 1997 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. HCFA has not yet determined the effective date of this policy change.

In January 1999, the Blue Cross and Blue Shield Association 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 U.S. Food and Drug Administration; (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.

Economic data derived from the Company's clinical studies indicates that TMR using The Heart Laser System may result in a significant reduction in the cost of treating patients with severe CAD. Potentially, this could mean that TMR performed with The Heart Laser System is a procedure that offers real economic advantages to the managed care market, in particular, in which over 70% of all privately insured

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Americans are covered at least in part. No assurance can be given that such economic benefits will be realized by customers.

Certain private insurance companies and HMOs currently provide reimbursement for TMR procedures. No assurance can be given, however, that additional payers will reimburse health care providers who perform TMR procedures 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.

#### PRODUCT LIABILITY AND INSURANCE

The Company's business involves the risk of product liability claims. No claims have been made against The Heart Laser System to date. The Company maintains product liability insurance with aggregate coverage limits of \$10 million. No assurance can be given that product liability claims 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

The Company's policy is to file patent applications to protect 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 14 U.S. patents, of which 12 involve The Heart Laser System and its related technologies. The first patent, which was issued in April 1992, provides patent protection until 2009 and relates to the underlying laser technology needed to create a pulsed, fast flow laser system. The second patent, which was issued in June 1992, provides patent protection until 2009 and relates to the use of a laser on a beating heart to revascularize the heart using TMR. The third patent, which was also issued in June 1992, provides patent protection until 2009 and relates to the system used to time the heart's contractions to synchronize the laser firing at the correct time. The fourth patent, which was issued in April 1993, provides patent protection until 2010 and relates to The Heart Laser System handpiece, which is used to deliver the laser energy to the heart. The fifth patent, which was issued in June 1993, provides patent protection until 2010 and relates to a specialized laser beam manipulator used for conventional laser surgery. The sixth patent, which was issued in October 1993, provides patent protection until 2010 and relates to a self-aligning coupler for a laser endoscope. The seventh patent, which was issued in August 1994, provides patent protection until 2011 and relates to the synchronization of a surgical smoke evacuator to a laser system or other medical device. The eighth patent, which was issued in April 1996, provides patent protection until 2013 and relates to the use of an ECG monitor. The ninth patent, which was issued in September 1996, provides patent protection until 2013 and relates to medical laser technology. The tenth

patent, which was issued in January 1997, provides patent protection until 2014 and relates to The Heart Laser System handpiece. The eleventh patent, which was issued in April 1997, provides patent protection until 2014 and relates to the lens cell for The Heart Laser System. The twelfth patent, which was issued in November 1997, provides patent protection until 2014 and relates to a thoracoscopic cannula system. The thirteenth patent which was issued in December 1997, provides patent protection until 2014 and relates to a thoracoscopic TMR handpiece. The fourteenth patent, which was issued in March 1998, provides patent protection until 2015 and relates to ultrasound detection of revascularization. The Company also has twelve U.S. patent applications pending relating to The Heart Laser System handpiece, other technology used in The Heart Laser System, technology associated with minimally invasive surgical techniques and technologies associated with percutaneous TMR.

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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 issued in April 1997 in Canada. Additional Japanese issued patents cover a TMR handpiece, a self-aligning coupler for a laser endoscope, laser beam manipulation and a laser beam status indicator. In December 1996, a patent was issued in Canada covering a self aligning coupler for a laser endoscope. The Company has numerous patents pending related to The Heart Laser System and its components in various international patent offices. The Company expects to 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.

CardioGenesis Corporation ("CardioGenesis"), a competitor of the Company, agreed to the validity and enforceability of certain of the Company's patents in connection with a settlement of all outstanding litigation between the companies. The patents, U.S. Patent No. 5,125,926 and related international patents, cover the Company's proprietary synchronization technology, a critical factor in ensuring the safety of TMR and PMR procedures. 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. A minimum of \$2.5 million will be paid by CardioGenesis to the Company in connection with this license agreement. (See "Item 3. Legal Proceedings").

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, could require the Company to seek licenses from third parties and could 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

The Company believes that the majority of TMR procedures completed worldwide to date have been performed using The Heart Laser System. As of December 31, 1998, over 4,300 TMR procedures had been performed using The Heart Laser System. In addition, the Company believes that the majority of peer reviewed medical journal articles on TMR report results of TMR procedures performed with The Heart Laser System.

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A number of other companies have entered or are attempting to enter the TMR market. These companies are believed to be using other types of lasers such as holmium and excimer lasers. Holmium and excimer lasers have different physical properties and interact differently with human tissue than the Company's carbon dioxide laser. The Company believes that The Heart Laser System is the only TMR product 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 CO2 laser may cause significantly less damage to the heart than a holmium laser used to

perform TMR. 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 there is ample opportunity to successfully differentiate its CO2 laser and plans to implement an appropriate marketing effort accordingly. No assurance can be given that such a marketing effort will be implemented successfully, or at all.

Several of the companies who have entered the TMR market are developing "percutaneous" methods of performing TMR, known as "PMR". PMR procedures are performed via a catheter inserted through an incision in a patient's leg. The Company has a proprietary PMR development program underway. PMR may provide a less invasive method of creating channels in a human heart if it can be proven safe and effective. No assurance can be given that the Company's PMR development program will be successful.

The Company's two principal competitors, Eclipse and CardioGenesis, merged on March 17, 1999. Both companies have holmium laser systems undergoing clinical studies. 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 can be used to perform both TMR and PMR procedures.

Many treatments are available for coronary artery disease. The Company believes that the primary competitive factors in the medical treatment of coronary artery disease 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 required regulatory approvals, obtain third party reimbursement for use of its products, attract and retain scientific personnel, obtain patent or other protection for its products, and manufacture and successfully market its products either directly or through outside parties.

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

The medical care products industry is characterized by extensive research efforts and rapid technological progress. New technologies and developments are expected to continue at a rapid pace in both industry and academia. Competition in the market for surgical lasers and for the treatment of cardiovascular disease is intense and is expected to increase. Management believes that The Heart Laser System must compete not only with TMR and PMR systems, but 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 and represent significant competition for the Company. Such companies may succeed in developing products that are more effective or less costly in treating coronary disease than The Heart Laser System, and may be more successful than the Company in manufacturing and marketing their products. No

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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 \$4,468,000, \$5,158,000, and \$2,835,000 for the years ended December 31, 1998, 1997 and 1996, respectively. Although the initial design of The Heart Laser System is now completed, management plans to continue to refine The Heart Laser System design, to develop new less invasive methods for performing TMR procedures, including endoscopic and percutaneous delivery systems and to fund clinical trials. The Company intends to continue to monitor all technologies that may be applicable to TMR to maintain a leadership position in this market. No assurance can be given that the Company's research and development goals will be implemented successfully or that the Company will maintain its leadership position in this market.

#### EMPLOYEES

As of March 22, 1999, the Company had 68 full-time domestic employees, including its executive officers. Of these, 16 are employed in general and administrative activities, 22 are involved in sales and marketing, 13 are involved in research and development and 17 are involved in manufacturing. The Company also employs one part-time employee. None of the Company's employees are represented by a union. In addition, the Company has 12 full time employees/consultants for its international operations. Management considers its relations with employees to be satisfactory.

ITEM 2. DESCRIPTION OF PROPERTY.

In September 1996, the Company moved into its current 37,000 square foot facility in Franklin, Massachusetts where it maintains its principal executive offices and manufacturing operations. The premises are leased from an independent third party under a lease which expires in August 2001. The lease provides for two renewal periods of three years each. The total base rental payments for the term of the lease are approximately \$296,400 per year plus operating and maintenance costs and real estate taxes.

ITEM 3. LEGAL PROCEEDINGS.

In September 1996, CardioGenesis filed a civil lawsuit in the United States District Court for the Northern District of California asking the court to declare the Company's synchronization patent (U.S. Patent No. 5,125,926) invalid and unenforceable, or, alternatively, to find that CardioGenesis' TMR and PMR lasers do not infringe this patent. The Company filed a counterclaim alleging that all of CardioGenesis' TMR and PMR lasers infringe U.S. Patent No. 5,125,926. In January 1997, CardioGenesis filed an opposition in the European Patent Office to have the Company's German synchronization patent declared invalid. In April 1997, the Company filed an infringement lawsuit against CardioGenesis and one of its distributors in the Munich District Court alleging that CardioGenesis' TMR and PMR lasers infringe the Company's German synchronization patent.

The PLC patents at issue in these lawsuits cover the Company's synchronization technology, a critical factor in ensuring the safety of TMR and PMR procedures. In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis. Under the settlement, CardioGenesis agreed that U.S. Patent No. 5,125,926 and related international patents of the Company are valid and enforceable. PLC granted CardioGenesis a non-exclusive worldwide license to the patents in exchange for

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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 must 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 Heart Laser System 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 seek 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 have been consolidated by the court into a single action for pretrial purposes. Two of these suits have been dismissed. The Company moved to dismiss all of the remaining claims. On March 26, 1999, the court issued an order dismissing some, but not all of the remaining claims. The Company has also been named as a defendant in a lawsuit filed in Massachusetts Superior Court in September 1998. This suit seeks 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. The Company cannot make a meaningful estimate of the amount or range of loss that could result from an unfavorable outcome of these lawsuits, but an unfavorable outcome could have a material adverse affect on the Company's business, financial position and results of operations. The Company believes that it has valid defenses to these litigation matters and it continues to vigorously defend itself in these matters.

In August 1997, the Company received from the United States Securities and Exchange Commission (the "Commission") an informal request for information relating to the decision by the FDA Advisory Panel not to recommend approval of The Heart Laser System in July 1997. The Company has responded and has not received any further communication from the Commission regarding this matter since June 1998.

In February 1996, PLC Medical Systems, Inc. filed suit against Eclipse Surgical Technologies, Inc. ("Eclipse") in the United States District Court for the District of Massachusetts alleging copyright infringement and unfair and deceptive trade practices based on Eclipse's misappropriation and copying of one of PLC's confidential clinical study protocols. The Company is seeking injunctive relief and damages, as well as any profits derived by Eclipse as a result of the misappropriation, attorney's fees, and treble damages.

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 is seeking reimbursement of lease payments made for the Heart Laser System. The Company intends to vigorously defend itself in this matter. This matter is in the earliest stage of litigation and a meaningful estimate of the loss that could result from this matter has not been made.

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.

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". From March 3, 1992 through September 16, 1992, the Company's Common Stock was traded on the over-the-counter market through the National Association of Securities Dealers Automated Quotation System ("NASDAQ"). On March 22, 1999 the closing sale price of the Company's Common Stock as reported by AMEX was \$2.94 per share.

For the periods indicated, the following table sets forth the range of high and low closing prices for the Common Stock as reported by AMEX from January 1, 1997.

<TABLE>  
<CAPTION>

	SALES	
	HIGH	LOW
	----	---
<S>	<C>	<C>
1997		
----		
First Quarter . . . . .	\$27.63	\$16.63
Second Quarter. . . . .	\$22.88	\$12.38
Third Quarter . . . . .	\$26.81	\$10.25
Fourth Quarter. . . . .	\$14.38	\$6.88
1998		
----		
First Quarter . . . . .	\$18.19	\$8.00
Second Quarter. . . . .	\$18.13	\$9.25
Third Quarter . . . . .	\$12.38	\$3.75
Fourth Quarter. . . . .	\$6.63	\$3.06
1999		
----		
First Quarter (through March 22, 1999). . . . .	\$6.81	\$2.94

</TABLE>

As of March 23, 1999, there were approximately 751 record holders of the Company's Common Stock. Management believes that there are approximately 19,000 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.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data with respect to the Company for the five years ended December 31, 1998, are derived from the audited financial statements of the Company. The data should be read in conjunction with the financial statements, related notes and other financial information included herein.

SELECTED FINANCIAL DATA

<TABLE>  
<CAPTION>

	FOR THE YEARS ENDED DECEMBER 31				
	1998	1997	1996	1995	1994
	----	----	----	----	----
<S>	<C>	<C>	<C>	<C>	<C>
	(ALL AMOUNTS ARE IN THOUSANDS EXCEPT PER SHARE DATA)				

STATEMENT OF OPERATIONS DATA:

Revenue:					
Product sales. . . . .	\$ 3,088	\$ 5,687	\$ 9,082	\$11,938	\$ 5,068
Placement and service fees . . . . .	2,605	3,254	2,790	1,407	111
Costs and expenses:					

Cost of product sales . . . . .	1,945	2,721	2,911	4,177	2,851
Cost of placement and service fees . . . . .	2,622	2,595	1,155	386	17
Selling, general and administrative . . . . .	13,718	13,049	7,023	5,035	3,030
Research and development . . . . .	4,468	5,158	2,835	2,246	2,211
	-----	-----	-----	-----	-----
Income (loss) from operations . . . . .	(17,060)	(14,582)	(2,052)	1,501	(2,930)
Other income . . . . .	457	178	512	588	366
	-----	-----	-----	-----	-----
Income (loss) before income taxes . . . . .	(16,603)	(14,404)	(1,540)	2,089	(2,564)
Provision for income taxes . . . . .	--	--	--	85	--
	-----	-----	-----	-----	-----
Net income (loss) . . . . .	\$(16,603)	\$(14,404)	\$(1,540)	\$ 2,004	\$(2,564)
	-----	-----	-----	-----	-----
Net income (loss) per share - Basic . . . . .	\$ (.86)	\$ (.84)	\$ (.09)	\$ .13	\$ (.18)
	-----	-----	-----	-----	-----
Net income (loss) per share - Diluted . . . . .	\$ (.86)	\$ (.84)	\$ (.09)	\$ .12	\$ (.18)
	-----	-----	-----	-----	-----
Shares used to compute net					
income (loss) per share - Basic . . . . .	19,218	17,050	16,376	15,868	14,372
Shares used to compute net					
income (loss) per share - Diluted . . . . .	19,218	17,050	16,376	16,590	14,372

<CAPTION>

AS OF DECEMBER 31

	1998	1997	1996	1995	1994
	----	----	----	----	----
<S>	<C>	<C>	<C>	<C>	<C>
BALANCE SHEET DATA:					
Working capital . . . . .	\$5,050	\$12,793	\$11,245	\$13,541	\$12,431
Total assets . . . . .	16,257	27,017	19,417	18,290	14,337
Long term obligations . . . . .	37	121	27	32	7
Stockholders' equity . . . . .	10,662	19,009	16,467	15,508	13,059

</TABLE>

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 System. In placement transactions, an installation fee is paid when The Heart Laser System is shipped and the Company then receives a procedure fee per use. Typically, customers commit to pay for a minimum number of procedures during the term of a placement agreement. Sterile handpieces and other disposables are included in the procedure fee. Revenues from these contracts are classified as placement fees. The cost of The Heart Laser System, which is owned by the Company, is depreciated over the term of the placement agreement.

The Heart Laser System is also sold to customers, and the related sterile handpieces and other disposables are sold separately for each procedure. The Company sells The Heart Laser System directly and through distributors. These sales are classified as product sales.

In September 1998, the Company entered into an exclusive agreement with GE Capital Trans Leasing ("GE Capital") to provide a broad array of lease financing alternatives to U.S. hospitals interested in acquiring The Heart Laser System. The lease financing alternatives available through GE Capital are expected to complement the Company's traditional placement and sales strategies. In addition, GE Capital agreed to monetize certain prospective domestic placement agreements by providing funding to the Company in an amount equal to the present value of minimum procedure payments contained in such agreements, subject to approval of creditworthiness and other terms. No revenue was recognized on such transactions in 1998. No assurance can be given that the Company will recognize any revenue as a result of its agreement with GE Capital.

Total revenues of \$5,693,000 for the year ended December 31, 1998 decreased \$3,248,000 or 36% when compared to total revenues of \$8,941,000 for the year ended December 31, 1997. For the year ended December 31, 1998, product sales of \$3,088,000 decreased \$2,599,000 or 46% when compared to product sales of \$5,687,000 for the year ended December 31, 1997. The major factor in these decreases is the decline in the number of sales transactions. In 1998, the Company recorded revenue on six sales compared with revenue recognition on ten sales in 1997.

Placement and service fees of \$2,605,000 for the year ended December 31, 1998 decreased 20% from placement and service fees of \$3,254,000 for the year ended December 31, 1997. Although the Company increased the number of its placement contracts in 1998, revenue from these contracts decreased. 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 FDA Pre-Market Approval ("PMA") process, caused the Company to examine its contractual requirements during 1997 and amend substantially all of its placement contracts, temporarily replacing contractual minimal billings with actual usage billings. Following receipt of the PMA from the FDA on August 20, 1998, placement contracts that provide for minimum billings were reinstated, and the Company is renegotiating those placement agreements that do not provide for minimum billings following FDA approval. In February 1999, HCFA announced its intention to provide coverage for TMR but did not specify an effective date for such coverage.

Total gross profit decreased to \$1,126,000 or 20% of total revenues for the year ended December 31, 1998 as compared with \$3,625,000 or 41% of total revenues for the year ended December 31, 1997. This decrease has resulted from three factors. First, the decrease in revenue in 1998 generated fewer gross margin dollars as compared to 1997. Second, the Company produced fewer Heart Laser Systems than planned in

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1998, resulting in unfavorable manufacturing variances. These unfavorable manufacturing variances are expected to continue until production increases to levels which will fully absorb manufacturing overhead. Third, depreciation on Heart Laser Systems shipped pursuant to placement contracts increased at a greater rate than the corresponding revenue generated from placement contracts.

Selling, general and administrative expenses of \$13,718,000 for the year ended December 31, 1998 increased \$669,000 or 5% when compared with \$13,049,000 for the year ended December 31, 1997. The increase in 1998 reflects sales and marketing expenses incurred to initiate rapid commercialization of The Heart Laser System upon receipt of the PMA.

Research and development expenditures of \$4,468,000 decreased \$690,000 or 13% for the year ended December 31, 1998 when compared with \$5,158,000 for the year ended December 31, 1997. The decrease in 1998 compared to 1997 reflects the reduced demands for clinical study compilation and data preparation following the FDA panel recommendation of approval for The Heart Laser System, offset in part by higher costs associated with the development of new products.

Other income of \$457,000 for the year ended December 31, 1998 increased \$279,000 or 157% when compared to \$178,000 for the year ended December 31, 1997, primarily because of gains recorded in connection with foreign currency transactions.

There was no provision for income tax for the years ended December 31, 1998 or 1997 due to the net losses of \$16,603,000 and \$14,404,000, respectively.

The Company incurred a net loss for the year ended December 31, 1998 of \$16,603,000 compared with a net loss of \$14,404,000 for the year ended December 31, 1997. The larger net loss resulted from lower total revenues and lower gross margin dollars in 1998 when compared with 1997.

#### YEAR ENDED DECEMBER 31, 1997 COMPARED TO YEAR ENDED DECEMBER 31, 1996

Total revenues of \$8,941,000 for the year ended December 31, 1997 decreased \$2,931,000 or 25% when compared to total revenues of \$11,872,000 for the year ended December 31, 1996. For the year ended December 31, 1997, product sales of \$5,687,000 decreased \$3,395,000 or 37% when compared to product sales of \$9,082,000 for the year ended December 31, 1996. The major factors in both of these decreases were declines in the number of Heart Laser Systems sold and the customer mix. In 1997, the Company recorded revenue on sales of ten Heart Laser Systems, including two sold directly and eight sold to distributors. In 1996, the Company recorded revenue on thirteen sales, six of which were sold directly and seven of which were sold to distributors. Heart Laser Systems sold directly to customers typically generate higher revenues than those sold to distributors. Placement and service fees of \$3,254,000 for the year ended December 31, 1997 increased 17% over placement and service fees of \$2,790,000 for the year ended December 31, 1996

Gross profit decreased to \$3,625,000 or 41% of total revenues for the year ended December 31, 1997 as compared with \$7,806,000 or 66% of total revenues for the year ended December 31, 1996. The decrease resulted primarily from three factors. First, fixed manufacturing costs increased in 1997 and production levels decreased, resulting in unfavorable manufacturing variances. Second, the Company sold fewer units under its sales strategy in 1997 than in 1996 and the mix was primarily to distributors in 1997 as compared to direct sales in 1996. Heart Laser Systems sold directly to customers typically carry a higher gross profit than those sold to distributors. Third, depreciation on Heart Laser

Systems shipped pursuant to placement contracts increased at a greater rate than the corresponding revenue generated from placement contracts.

Selling, general and administrative expenses of \$13,049,000 for the year ended December 31, 1997 increased \$6,026,000 or 86% when compared with \$7,023,000 for the year ended December 31, 1996. The Company incurred significant expenses to prepare for an FDA panel review of its PMA application for The

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Heart Laser System. In addition, the Company expanded its management team and its sales force.

Research and development expenditures of \$5,158,000 increased \$2,323,000 or 82% for the year ended December 31, 1997 when compared with \$2,835,000 for the year ended December 31, 1996. These expenditures were incurred in connection with the Company's clinical study compilation and data preparation for FDA submissions and an FDA panel review. These activities required additional staffing and consultants.

Other income of \$178,000 for the year ended December 31, 1997 decreased \$334,000 or 65% when compared to \$512,000 for the year ended December 31, 1996 primarily because of an increase in interest expense. In July and August 1997, the Company received \$18.8 million in net proceeds from the issuance of 5% Convertible Debentures.

There was no provision for income tax for the years ended December 31, 1997 and 1996 due to net losses of \$14,404,000 and \$1,540,000, respectively.

The Company incurred a net loss for the year ended December 31, 1997 of \$14,404,000 compared to a net loss of \$1,540,000 for the year ended December 31, 1996. The increased loss resulted from lower total revenues in 1997 compared with 1996, combined with higher overall expenses in 1997 related to preparation for an FDA panel review of The Heart Laser System.

#### LIQUIDITY AND CAPITAL RESOURCES

During 1997 and 1998 the Company incurred significant operating losses and utilized significant amounts of cash to fund operations. The Company is reaching a critical stage in its growth as it transitions from a research and development company to a commercial company with complete sales, marketing and production capabilities. During this time the Company increased its overall operating expenses and overhead to be positioned to further increase its sale and production capabilities in anticipation of possible FDA approval. In order to be adequately positioned to meet these demands, the Company obtained equity financing. The Company continues to seek equity financing as its primary means of funding operations during this transition.

On March 4, 1999, the Company announced that it had obtained a provisional equity financing commitment of \$8 million from a major institutional investor. The commitment contemplates the sale by the Company of up to \$2 million in common stock during consecutive 20 day periods at prices based on the trailing volume weighted average price of the common stock on the American Stock Exchange on each day during such periods, less a seven percent discount. The Company is unable to use the commitment on any trading day to the extent that the volume weighted average price of the Company's common stock is less than \$3.50 per share, unless the Company and the investor mutually agree to a reduction in such price. If the Company is unable to use the commitment on any given trading day, the commitment amount is automatically reduced by \$100,000 on such day.

The use of the commitment is also dependent upon the Company being eligible to sell shares of its common stock under a Form S-3 Registration Statement under the Securities Act of 1933, as amended, which form requires, among other things, that the Company have a market capitalization of at least \$75 million held by non-affiliates of the Company during the immediately preceding 60-day period. As of March 30, 1999, the Company had sold 323,231 shares of common stock under this commitment, resulting in net proceeds to the Company of \$885,000. As of March 31, 1999, the Company is unable to utilize this commitment due to its stock price.

While the Company anticipates being able to utilize this commitment or obtain other sources of equity financing, there can be no assurance that the Company will be able to raise additional equity financing or that the Company will maintain its eligibility to use Form S-3. To the extent that the Company raises

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additional capital by issuing equity or convertible securities, ownership dilution to the stockholders will result.

During the second half of 1998, the Company implemented a number of programs to reduce its consumption of cash, including operating expense reductions and the financing agreement with GE Capital, which enables the Company to obtain an upfront cash payment on certain domestic placement agreements. While the Company is encouraged by the recent developments with respect to FDA approval and the HCFA announcement that Medicare will provide coverage for TMR procedures performed with devices approved by the FDA, the historical absence of widespread reimbursement for the TMR procedure by third party payers, principally Medicare, Medicaid, and private health insurance plans, has limited demand for and use of The Heart Laser System in the United States. Although Medicare reimbursement is expected to begin in 1999 and some



private insurance plans have begun reimbursing health care providers for TMR procedures using The Heart Laser System, the Company believes that operating losses are likely to continue until such time as third party payers begin to provide widespread reimbursement to healthcare providers for use of The Heart Laser System.

Recognizing the deliberate nature that accompanies a highly regulated process such as the above, management of the Company has outlined a plan of appropriate action steps to attempt to ensure that the Company has adequate sources of cash to meet its working capital needs for at least the next twelve months. In March 1999, management of the Company received approval from the Board of Directors to implement this action plan. The key elements of the plan are as follows:

- Further operating expense reductions to eliminate certain expenditures which are not critically essential to achieving critical business objectives at this time (e.g., discretionary spending, further development efforts)
- Strategic realignment of the Company's international sales organization.
- Pursuit of strategic alternatives related to the Company's domestic sales efforts that can help it further penetrate existing markets.
- Pursuit of strategic financing alternatives including the sale of debt securities, bank financing, strategic alliances, joint ventures or by other means.

While the Company has not yet finalized the specific details of its plan, management is committed to developing restructuring alternatives, which, if implemented, would result in a material charge to operations in 1999.

As a result of implementing the above actions, management believes that its existing cash resources and cash from operations will meet working capital requirements over the next twelve months and improve operating results. However, unanticipated decreases in operating revenues, increases in expenses or further delays in the process of third party payers committing to provide reimbursement to healthcare providers, may adversely impact the Company's cash position and require further cost reductions. No assurance can be given that the Company will be successful in achieving broad commercial acceptance of The Heart Laser System or that the Company will be able to operate profitably on a consistent basis.

During the year ended December 31, 1998, the Company incurred a net loss of \$16,603,000, which resulted in the use of approximately \$14,300,000 to support operations. Cash provided by investing activities was approximately \$10,300,000 primarily related to the net maturities of approximately \$12,800,000 of marketable securities, offset by an investment of \$2,600,000 in fixed assets, primarily related to its placement contract activity. Cash provided by financing activities was approximately \$5,400,000, primarily related to the net proceeds of \$4,700,000 obtained through the issuance of convertible debentures and \$600,000 in proceeds from the sale of the Company's common stock, offset by principal payments on capital lease obligations of \$79,000.

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During the year ended December 31, 1997, the Company incurred a loss of \$14,404,000, which resulted in the use of approximately \$10,050,000 to support operations. Cash used in investing activities was approximately \$10,000,000 primarily related to the net purchase of \$7,400,000 of marketable securities and the investment of \$2,600,000 in fixed assets, primarily related to its placement contract activity. Cash provided by financing activities was approximately \$20,800,000, primarily related to the net proceeds of \$18,800,000 through the issuance of convertible debentures and \$2,000,000 from proceeds of the sale of the Company's common stock.

At December 31, 1998, the Company had U.S. net operating loss carryforwards of approximately \$34.5 million available to reduce future taxable income which expire at various dates through 2012, and the Company had foreign net operating loss carryforwards of approximately \$5.7 million. In addition, various other deferred tax assets have been generated related primarily to intercompany profit, accruals, and research and development tax credits. Because the Company believes that, as of December 31, 1998, 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, subject to the expirations noted.

The Company and certain of its officers have been named as defendants in 21 purported class action lawsuits filed between August 1997 and November 1997. See Note 5 in the accompanying consolidated financial statements for further discussion.

#### YEAR 2000

The Year 2000 problem is the result of computer programs that use two digits rather than four to define the applicable year. On January 1, 2000, computer equipment and programs that have time-sensitive software may not be able to distinguish whether "00" means 1900 or 2000. This could cause a major system failure or could create erroneous results. The Company could be unable to process transactions, send invoices, or engage in similar business activities. The Company may also be vulnerable to other companies' Year 2000 issues.

In 1998, the Company formed a task force to determine what if any Year 2000 compliance issues the Company faces. The task force has developed and

implemented a Year 2000 readiness plan that defines compliance and sets critical milestones to identify any deficiencies and correct them. The task force identified three basic operational areas that have been and will continue to be examined:

- Products -- products the Company currently sells, products the Company sold previously, and products of the Company's most significant suppliers;
- Business Systems -- computer hardware and software used to operate the Company's business, including purchasing, manufacturing, sales and finance; and
- Peripherals -- the Company's telephone, e-mail, security and shipping systems.

In 1998, The Heart Laser System was tested and is believed to be Year 2000 compliant in all material respects. In addition, the Company has purchased and implemented new enterprise resource planning system software that the vendor has represented is Year 2000 compliant. This new software system has replaced substantially all of the Company's previous financial software systems. Current estimates of the impact of the Year 2000 problem on the Company's operations and financial results do not include costs and time that may be incurred as a result of vendor or customer failures to become Year 2000 compliant, but no significant costs have been identified to date.

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Despite investigation and testing by the Company and its business partners, the Company's products and systems may contain errors or defects associated with Year 2000 date functions. The Company believes that its new enterprise resource planning software substantially addresses its material Year 2000 risks; however, the Company is continuing to test its secondary systems and investigate third party compliance efforts. In a worst case scenario, known and unknown errors and defects that could affect the operation of our products or systems could result in:

- delay or loss of revenue;
- cancellation of customer contracts;
- increased service and/or warranty costs;
- increased litigation costs;
- diversion of product development and personnel resources; and
- damage to our reputation.

Furthermore, the Company has not developed a Year 2000 contingency plan to address any failure of our Year 2000 compliance review to identify and correct significant Year 2000 risks. Development of contingency plans is in progress and will continue during calendar year 1999. Such plans could include stockpiling inventory parts and raw materials, accelerating replacement of affected equipment or software, using back-up equipment and software, developing temporary manual procedures to compensate for system deficiencies, and identifying alternative Year 2000 capable suppliers. The Company cannot be sure that such contingency plans will adequately address the year 2000 problem. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

#### RISK FACTORS

##### OUR COMPANY HAS A LIMITED OPERATING HISTORY AND A HISTORY OF 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 \$16,603,000 for the year ended December 31, 1998, \$14,404,000 for the year ended December 31, 1997, and \$1,540,000 for the year ended December 31, 1996. As of December 31, 1998, we have an accumulated deficit of \$68,136,000. We have not achieved profitability and expect to continue to incur net losses for at least the next fiscal year. Moreover, although our business is not seasonal in nature, our revenues tend to vary significantly from fiscal quarter to fiscal quarter.

##### OUR COMPANY IS DEPENDENT ON ONE PRINCIPAL PRODUCT

We develop and market one principal product: a patented high-powered carbon dioxide laser system known as The Heart Laser System. Approximately 93.2% of our revenue in the fiscal year ended December 31, 1997 and 89.5% in the fiscal year ended December 31, 1998 was derived from The Heart Laser System.

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

As of December 31, 1998, we had cash and cash equivalents totaling \$4,846,000, a decrease of \$11,483,000 from the balance of \$16,329,000 we had as of December 31, 1997. The lack of widespread reimbursement for use of The Heart Laser System by third party payers such as Medicare, Medicaid and private health insurance plans has limited demand for and use of The Heart Laser System in the United States.

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Although Medicare reimbursement is expected to begin in 1999 and some private insurance plans have begun reimbursing health care providers for TMR procedures using The Heart Laser System, we believe that operating losses are likely to continue until such time as third party payers begin to provide widespread reimbursement to healthcare providers for use of The Heart Laser System. Although we announced an \$8 million equity financing commitment on March 4, 1999, we have been unable to access that commitment in full (see "Liquidity and Capital Resources" above). We have developed an action plan to ensure that the Company has adequate sources of cash to meet its working capital needs for at least the next twelve months. (See "Liquidity and Capital Resources" above). We are currently exploring a number of alternatives to raise additional capital. We may not be able to raise additional capital upon satisfactory terms and our business, financial condition and results of operations could be materially and adversely affected.

#### IN ORDER TO COMPETE EFFECTIVELY, WE NEED TO GAIN COMMERCIAL ACCEPTANCE

The Heart Laser System is 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. We 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 System are effective, relatively safe and cost effective; and
- train heart surgeons to perform TMR procedures using The Heart Laser System.

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

Over 4,000 patients have been treated with TMR procedures using The Heart Laser System in the United States and overseas. As of December 31, 1998, we had shipped over 100 Heart Laser Systems worldwide. Although The Heart Laser System has received FDA approval and the CE Mark, and a number of research studies have reported favorably on The Heart Laser System, we 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 System, our business, financial condition and results of operations will be materially and adversely affected.

#### RESULTS OF LONG-TERM CLINICAL STUDIES MAY ADVERSELY AFFECT OUR BUSINESS

Patients have only been treated with The Heart Laser System 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 System, our business, financial condition and results of operations will be materially and adversely affected.

#### RAPID TECHNOLOGICAL CHANGES IN OUR INDUSTRY COULD MAKE THE HEART LASER SYSTEM 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 System 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 a variety of product enhancements to address the increasingly sophisticated needs of our

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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. Most of our direct competitors are using a different type of laser than ours, including holmium and excimer lasers. Several of the companies that have entered the market are developing 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 methods may erode the potential TMR market.

#### WE MUST RECEIVE AND MAINTAIN GOVERNMENT APPROVAL IN ORDER TO MARKET OUR PRODUCT

##### GENERAL

The Heart Laser System 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 Community and Japan. To date, we have received regulatory approval in the United States and the European Community, but not in Japan. Without regulatory approval, we cannot market The Heart Laser System in Japan. Even if granted, regulations may significantly restrict the use of The Heart Laser System. 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 SYSTEM AND COULD REVERSE ITS APPROVAL AT ANY TIME

In August 1998, we became the first company to receive FDA approval to market a laser system for TMR procedures. However, the FDA:

- has not allowed us to market the Heart Laser System 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 System at any time.

EUROPE -- ALTHOUGH WE HAVE RECEIVED REGULATORY APPROVAL FROM THE EUROPEAN COMMUNITY, THE EUROPEAN COMMUNITY COULD REVERSE ITS APPROVAL AT ANY TIME AND FRANCE HAS PROHIBITED COMMERCIAL USE OF THE HEART LASER SYSTEM

The Heart Laser System received the CE Mark, which is similar to FDA approval, from the European Community in 1995. The CE Mark allows us to market The Heart Laser System in all European Community countries. However:

- The European Community could reverse its ruling and prohibit use of The Heart Laser System at any time;
- We cannot market The Heart Laser System in France; and
- Other European Community countries could prohibit or restrict use of The Heart Laser System.

Despite receiving the CE Mark, 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 Heart Laser System

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is currently under review by a panel of French experts. We have provided our clinical results to the panel and are actively working to have this moratorium lifted. There is no assurance when or if we will be successful.

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 System in Asia. Prior to marketing The Heart Laser System in Japan, we must receive approval from the Japanese Government. This approval requires a clinical study in Japan with at least 60 patients. This study was completed in 1998. We submitted the results of this study to the Japanese Government in December 1998. We do not know whether the clinical study will be sufficient or when, if ever, we will receive approval to sell The Heart Laser System in Japan.

Additional regulatory applications are pending in Taiwan and South Korea. We cannot be sure when, if at all, we will obtain regulatory approval in any particular country.

ASSERTING AND DEFENDING INTELLECTUAL PROPERTY RIGHTS MAY IMPACT RESULTS OF OPERATION REGARDLESS OF SUCCESS

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 System. We may not be successful in defending or asserting our intellectual property rights.

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. A recent United States Supreme Court decision held 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. Although we have product liability insurance with a yearly aggregate maximum of \$10 million, we cannot be sure that our insurance is adequate to cover any product liability law suits. 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 would divert the attention of our key personnel, degrade the reputation and marketability of our technology and products, and could have a material adverse effect on our business, financial condition and results of operations.

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WE HAVE BEEN SUED FOR ALLEGED VIOLATIONS OF SECURITIES LAW

In July 1997, an FDA advisory panel recommended against approval of our application to market The Heart Laser System. Following this recommendation, we were 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 seek an unspecified amount of damages in connection with alleged violations of the federal securities laws based on our failure to obtain a favorable FDA panel recommendation in 1997. Nineteen of these complaints have been consolidated by the court into a

single action for pretrial purposes and two suits have been dismissed. The Company moved to dismiss all of the remaining claims. On March 26, 1999, the court issued an order dismissing some, but not all of the remaining claims. We have also been named as a defendant in a lawsuit filed in Massachusetts Superior Court in September 1998. This suit seeks over \$2 million in damages for alleged negligent misrepresentations and fraud arising from our failure to obtain a favorable FDA recommendation in 1997. We cannot make a meaningful estimate of the amount or range of loss that could result from an unfavorable outcome of these lawsuits, but an unfavorable outcome could have a material adverse affect on our business, financial position and results of operations. We may not be able to pay the amount of any judgment against us. We believe that we have valid defenses to these litigation matters and are conducting a vigorous defense.

**BECAUSE WE ARE INCORPORATED IN CANADA, YOU MAY NOT BE ABLE TO ENFORCE JUDGMENTS AGAINST US AND OUR CANADIAN DIRECTORS**

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

**ANTITAKEOVER PROVISIONS MAY PREVENT YOU FROM REALIZING A PREMIUM RETURN**

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

In addition, our Articles provide for three classes of directors, with 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 your common stock.

**MARKET PRICE OF OUR STOCK MAY FALL IF OTHER STOCKHOLDERS SELL THEIR STOCK**

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Such sales also might make it more difficult for us to sell equity or equity-related securities in the future at a price we deem appropriate.

**THE VALUE OF YOUR COMMON STOCK MAY DECREASE IF OTHER SECURITY HOLDERS EXERCISE THEIR OPTIONS AND WARRANTS OR CONVERT THEIR DEBT INTO COMMON STOCK**

As shown in the table below, we have reserved an additional 3,186,290 shares of common stock for future issuance upon exercise or conversion of outstanding options, redeemable warrants and convertible debt.

<TABLE>  
<CAPTION>

<S>	Range of Exercise/ Conversion Prices <C>	Weighted Average Exercise/ Conversion Price <C>	Shares Reserved for Future Issuance <C>
Options	\$3.69 - \$8.88	\$5.16	2,868,161
Redeemable Warrants	\$15.78 - \$27.81	\$21.33	154,864
Convertible Debt	\$6.125	\$6.125	163,265
Total			3,186,290

</TABLE>

We plan to issue additional options and warrants in the future. If any of these securities are exercised or converted, you may experience significant dilution in the market value and earnings per share of your common stock.

**WE HAVE NO INTENTION TO PAY DIVIDENDS**

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

**THE YEAR 2000 PROBLEM COULD CAUSE US TO EXPERIENCE MANUFACTURING DELAYS**

The Year 2000 problem is the result of computer programs that use two digits rather than four to define the applicable year. On January 1, 2000, computer equipment and programs that have time-sensitive software may not be able to distinguish whether "00" means 1900 or 2000. This could cause a major system failure or could create erroneous results. We could be unable to process transactions, send invoices, or engage in similar business activities. We may also be vulnerable to other companies' Year 2000 issues.

Despite investigation and testing by us and our business partners, our products may contain errors or defects associated with Year 2000 date functions.

We believe that our new enterprise resource planning software substantially addresses our material Year 2000 risks; however, we are continuing to test our secondary systems and continuing to investigate third party compliance efforts. In a worst case scenario, known and unknown errors and defects that affect the operation of our products or software could result in:

- delay or loss of revenue;
- cancellation of customer contracts;
- diversion of product development resources;
- damage to our reputation; and
- increased service, warranty and litigation costs.

Furthermore, we have not developed a Year 2000 contingency plan to address any failure of our Year 2000 compliance review to identify and correct significant Year 2000 risks. Development of contingency plans is in progress and will continue during calendar year 1999. Such plans could include

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stockpiling inventory parts and raw materials, accelerating replacement of affected equipment or software, using back-up equipment and software, developing temporary manual procedures to compensate for system deficiencies, and identifying alternative Year 2000 capable suppliers. We cannot be sure that our contingency plans will adequately address the year 2000 problem. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

**OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN FORWARD-LOOKING STATEMENTS**

This annual report and information incorporated by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements deal with our current plans and expectations and involve known and unknown risks and uncertainties. Statements containing terms such as:

- believes
- does not believe
- plans
- expects
- intends
- estimates
- anticipates

and other phrases of similar meaning are considered to contain uncertainty and are forward-looking statements.

No forward-looking statement is a guarantee of future performance. Our actual results could differ materially from those anticipated in these forward-looking statements. We make cautionary statements in certain sections of this annual report, including in the risk factors identified above, and in materials incorporated 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.

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**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 in the United States and sells the products. 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 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. Overall, the Company is a net receiver of currencies other than the U.S. dollar and, as such, benefits from a weaker dollar, but is adversely affected by a stronger dollar relative to major currencies worldwide. The Company's exposures are not 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 as well as interest paid on its debt.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

See Item 14 below and the Index therein for a listing of the financial statements and supplementary data filed as part of this report.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

This information is incorporated by reference from the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Company's 1999 Annual Meeting of Stockholders.

ITEM 11. COMPENSATION OF OFFICERS AND DIRECTORS

This information is incorporated by reference from the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Company's 1999 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

This information is incorporated by reference from the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Company's 1999 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

This information is incorporated by reference from the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Company's 1999 Annual Meeting of Stockholders.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

(a) (1) FINANCIAL STATEMENTS. The financial statements required to be filed by Item 8 herewith are as follows:

<TABLE>  
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 PLC SYSTEMS INC. Page  
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 <S> <C>  
 Report of Independent Auditors. . . . . F-2  
 Consolidated Balance Sheets as of December 31, 1998 and 1997 . . . . F-3  
 Consolidated Statements of Operations for the years ended  
 December 31, 1998, 1997 and 1996. . . . . F-4  
 Consolidated Statements of Stockholders' Equity for the years ended  
 December 31, 1998, 1997 and 1996. . . . . F-5  
 Consolidated Statements of Cash Flows for the years ended  
 December 31, 1998, 1997 and 1996. . . . . F-6  
 Notes to Consolidated Financial Statements. . . . . F-7  
 </TABLE>

(a) (2) FINANCIAL STATEMENT SCHEDULES. The following financial statement schedules are filed herewith:

Schedule II Valuation and Qualifying Accounts S-1

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

(a) (3) EXHIBITS.

EXHIBIT INDEX

<TABLE>  
 <CAPTION>  
 EXHIBIT  
 NUMBER DESCRIPTION OF DOCUMENT  
 -----  
 <S> <C>  
 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 Definitive Proxy Statement on Schedule 14A dated May 26, 1998, as previously filed with the Securities and Exchange Commission.  
 3.3 Memorandum and Articles (Bylaws), 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.  
 3.4 Amendment to Memorandum and Articles (Bylaws), 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.  
 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

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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 Convertible Debenture 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.
- 10.7 First Amendment to Convertible Debenture 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 Second Amendment to Convertible Debenture 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.
- 10.9 Form of Convertible Debenture, 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.
- 10.10 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.
- 10.11 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.
- 10.12 Form of Key Employment Agreement for William C. Dow, 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.
- 10.13 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.
- 10.14 Convertible Debenture Purchase 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.
- 10.15 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.
- 10.16 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.
- 10.17 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

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No. 1-11388), as previously filed with the Securities and Exchange Commission.

- 10.18 Key Employee Agreement of Robert Svikhart, incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 1998 (File No. 1-11388), as previously filed with the Securities and Exchange Commission.
- 10.19 Form of Common Stock Purchase Agreement, incorporated by reference to the Registrant's Current Report on Form 8-K dated March 12, 1999 (File No. 1-11388), as previously filed with the Securities and Exchange Commission.
- 21.1 \* Subsidiaries of the Registrant.
- 23.1 \* Consent of Ernst & Young LLP.
- 27.1 \* Financial Data Schedule.



\* Filed with this Annual Report on Form 10-K for the fiscal year ended December 31, 1998.

</TABLE>

(b) REPORTS ON FORM 8-K. No reports on Form 8-K were filed during the last quarter of the period covered by this report.

(c) EXHIBITS. The Company hereby files as part of this Form 10-K the exhibits listed in Item 14(a)(3) as set forth above.

(d) FINANCIAL STATEMENT SCHEDULES. See Item 14(a)(2) 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.

PLC SYSTEMS INC.

Date: March 31, 1999

By: /s/ William C. Dow

-----  
William C. Dow  
President and Chief Executive Officer

PURSUANT TO THE REQUIREMENTS OF THE SECURITIES EXCHANGE ACT OF 1934, THIS REPORT HAS BEEN SIGNED BY THE FOLLOWING PERSONS ON BEHALF OF THE REGISTRANT AND IN THE CAPACITIES AND ON THE DATE INDICATED.

<TABLE>

<CAPTION>

Name	Capacity	Date
----	-----	----
<S>	<C>	<C>
/s/ Edward H. Pendergast	Chairman of the Board of Directors	March 31, 1999
-----	(Principal Executive Officer)	
Edward H. Pendergast		
/s/ Robert Svihart	Chief Financial Officer	March 31, 1999
-----	(Principal Financial and Accounting Officer)	
Robert Svihart		
/s/ William C. Dow	President and Chief Executive Officer	March 31, 1999
-----		
William C. Dow		
/s/ Harold P. Capozzi	Director	March 31, 1999
-----		
Harold P. Capozzi		
/s/ H.B. Brent Norton, M.D.	Director	March 31, 1999
-----		
H.B. Brent Norton, M.D.		
/s/ Kenneth J. Pulkonik	Director	March 31, 1999
-----		
Kenneth J. Pulkonik		
/s/ Robert I. Rudko, Ph.D.	Director	March 31, 1999
-----		
Robert I. Rudko, Ph.D.		
/s/ Roberts A. Smith, Ph.D.	Director	March 31, 1999
-----		
Roberts A. Smith, Ph.D.		

</TABLE>

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PLC SYSTEMS INC.  
CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEARS ENDED DECEMBER 1998, 1997, 1996

PLC SYSTEMS INC.  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Balance Sheets as of December 31, 1998 and 1997 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 1998, 1997 and 1996 . . . . .	F-4

Consolidated Statements of Stockholders' Equity for the years ended December 31, 1998, 1997 and 1996 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 1998, 1997 and 1996 . . . . .	F-6
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Financial Statement Schedule:	
Schedule II - Valuation and Qualifying Accounts. . . . .	S-1

REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders  
PLC Systems Inc.

We have audited the accompanying consolidated balance sheets of PLC Systems Inc. as of December 31, 1998 and 1997, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1998. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with generally accepted auditing standards. 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, 1998 and 1997, and the consolidated results of its operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1998 in conformity with generally accepted accounting principles.

Ernst & Young LLP

Boston, Massachusetts  
February 19, 1999 except for Note 11,  
as to which the date is March 4, 1999

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PLC SYSTEMS INC.  
CONSOLIDATED BALANCE SHEETS  
December 31, 1998 and 1997

<TABLE>  
<CAPTION>

	1998	1997
	----	----
	(In thousands)	
<b>ASSETS</b>		
<S>	<C>	<C>
Cash and cash equivalents	\$ 4,846	\$ 3,484
Marketable securities	-	12,845
Accounts receivable, net	2,262	1,337
Inventories, net	2,953	2,512
Prepaid expenses and other current assets	547	502
	-----	-----
Total current assets	10,608	20,680
Equipment, furniture and leasehold improvements, net	5,091	5,636
Other assets	558	701
	-----	-----
Total assets	\$16,257	\$27,017
	-----	-----

<CAPTION>

LIABILITIES AND STOCKHOLDERS' EQUITY

<S>	<C>	<C>
Current liabilities:		
Accounts payable	\$ 986	\$ 917
Accrued clinical costs	1,016	1,292
Accrued compensation	989	570
Accrued expenses	1,127	923
Deferred revenue	195	70
5% Convertible Debentures due 2002	-	3,819

Convertible Debentures due 2003	934	-
Secured borrowings	240	-
Other accrued liabilities	72	296
	-----	-----
Total current liabilities	5,559	7,887
Capital lease obligations	37	121
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 5,000 shares authorized		
Common stock, no par value, 50,000 shares authorized, 19,740 and 18,368 shares issued and outstanding in 1998 and 1997, respectively	79,521	71,115
Accumulated deficit	(68,136)	(51,533)
Accumulated other comprehensive loss	(724)	(573)
	-----	-----
	10,661	19,009
	-----	-----
Total liabilities and stockholders' equity	\$16,257	\$27,017
	-----	-----

</TABLE>

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

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PLC SYSTEMS INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
For The Years Ended December 31, 1998, 1997 and 1996

<TABLE>  
<CAPTION>

	1998	1997	1996
	----	----	----
	(In thousands, except per share data)		
<S>	<C>	<C>	<C>
Revenue:			
Product sales			
Placement and service fees	\$ 3,088	\$ 5,687	\$ 9,082
	2,605	3,254	2,790
	-----	-----	-----
Total revenues	5,693	8,941	11,872
Cost of revenues:			
Product sales	1,945	2,721	2,911
Placement and service fees	2,622	2,595	1,155
	-----	-----	-----
Total cost of revenues	4,567	5,316	4,066
Gross Profit	1,126	3,625	7,806
Operating expenses:			
Selling, general and administrative	13,718	13,049	7,023
Research and development	4,468	5,158	2,835
	-----	-----	-----
Total operating expenses	18,186	18,207	9,858
Loss from operations	(17,060)	(14,582)	(2,052)
Other income, net	457	178	512
	-----	-----	-----
Net loss	\$(16,603)	\$(14,404)	\$(1,540)
	-----	-----	-----
Net loss per share - Basic	\$ (.86)	\$ (.84)	\$ (.09)
Net loss per share - Diluted	\$ (.86)	\$ (.84)	\$ (.09)
Shares used to compute net loss per share			
- Basic	19,218	17,050	16,376
- Diluted	19,218	17,050	16,376

</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, 1998, 1997 and 1996

<TABLE>  
<CAPTION>

	Common Stock		Accumulated Deficit (In Thousands)	Accumulated Other Comprehensive Loss	Total
	Shares	Amount			
<S>	<C>	<C>	<C>	<C>	<C>
Balance, December 31, 1995	15,944	\$51,411	\$ (35,589)	\$ (314)	\$15,508
Exercise of stockholder warrants	351	1,680			1,680
Exercise of stock options	218	820			820
Repayment of stockholder notes	-	119			119
Comprehensive loss:					
Net loss			(1,540)		
Foreign currency translation				(120)	
Total comprehensive loss					(1,660)
Balance, December 31, 1996	16,513	54,030	(37,129)	(434)	16,467
Exercise of stock options	435	1,909			1,909
Exercise of warrants	17	94			94
Conversion of debentures	1,403	14,465			14,465
Issuance of warrants	-	617			617
Comprehensive loss:					
Net loss			(14,404)		
Foreign currency translation				(139)	
Total comprehensive loss					(14,543)
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)		
Foreign currency translation				(151)	
Total comprehensive loss					(16,754)
Balance, December 31, 1998	19,740	\$79,521	\$ (68,136)	\$ (724)	\$10,661

</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, 1998, 1997 and 1996

<TABLE>

<CAPTION>

	1998	1997	1996
		(In thousands)	
<S>	<C>	<C>	<C>
Operating activities:			
Net loss	\$ (16,603)	\$ (14,404)	\$ (1,540)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Depreciation and amortization	3,170	2,007	1,228
Change in assets and liabilities:			
Accounts receivable	(973)	1,389	4,149
Inventory	(475)	(136)	(556)
Prepaid expenses and other assets	89	(20)	(359)
Account payable	82	24	303
Deferred revenue	142	(77)	107
Accrued liabilities	304	1,163	(252)
Net cash provided by (used for) operating activities	(14,264)	(10,054)	3,080
Investing activities:			
Purchase of marketable securities	(1,986)	(17,827)	(19,419)
Maturities of marketable securities	14,831	10,452	20,449
Purchase of fixed assets	(2,574)	(2,642)	(4,216)
Net cash provided by (used for) investing activities	10,271	(10,017)	(3,186)
Financing activities:			
Issuance of 5% Convertible Debentures, net of issuance costs	-	18,779	-
Secured borrowing	240	-	-
Net proceeds from sale of common stock	623	2,003	2,499
Issuance of Convertible Debentures, net of issuance costs	4,659	-	-
Repayment of stockholder notes	-	-	119
Principal payments on capital lease obligations	(79)	(25)	(13)
Net cash provided by financing activities	5,443	20,757	2,605
Effect of exchange rate changes on cash and cash equivalents	(88)	(241)	(164)
Net increase in cash and cash equivalents	1,362	445	2,335

Cash and cash equivalents at beginning of year	3,484	3,039	704
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 4,846	\$ 3,484	\$ 3,039
	-----	-----	-----
Non-Cash Financing Activities:			
Conversion of Convertible Debentures and accrued interest into Common Stock	7,733	14,465	-
Ascribed warrant value	50	617	-
Capital leases	-	150	-
Supplemental disclosure:			
Interest paid	\$ -	\$ 2	\$ 1
Income taxes paid (refunded)	\$ -	\$ (29)	\$ 91

</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, 1998

1. NATURE OF BUSINESS

The accompanying financial statements have been presented on the assumption that the Company is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During 1997 and 1998 the Company incurred significant operating losses and utilized significant amounts of cash to fund operations. The Company is reaching a critical stage in its growth as it transitions from a research and development company to a commercial company with complete sales, marketing and production capabilities. During this time the Company increased its overall operating expenses and overhead to be positioned to further increase its sales and production capabilities in anticipation of possible FDA approval. In order to be adequately positioned to meet these demands, the Company obtained equity financing. The Company continues to seek equity financing as its primary means of funding operations during this transition. On March 4, 1999, the Company announced that it had obtained a provisional equity financing commitment of \$8 million from a major institutional investor. The Company is unable to utilize this commitment at this time due to its stock price.

During the second half of 1998, the Company implemented a number of programs to reduce its consumption of cash, including operating expense reductions and the financing agreement with GE Capital, which enables the Company to obtain an upfront cash payment on certain domestic placement agreements. While the Company is encouraged by the recent developments with respect to FDA approval and the HCFA announcement that Medicare will provide coverage for TMR procedures performed with devices approved by the FDA, the historical absence of widespread reimbursement for the TMR procedure by third party payers, principally Medicare, Medicaid, and private health insurance plans, has limited demand for and use of The Heart Laser System in the United States. Although Medicare reimbursement is expected to begin in 1999 and some private insurance plans have begun reimbursing health care providers for TMR procedures using The Heart Laser System, the Company believes that operating losses are likely to continue until such time as third party payers begin to provide widespread reimbursement to healthcare providers for use of The Heart Laser System.

Recognizing the deliberate nature that accompanies a highly regulated process such as the above, management of the Company has outlined a plan of appropriate action steps to attempt to ensure that the Company has adequate sources of cash to meet its working capital needs for at least the next twelve months. In March 1999, management of the Company received approval from the Board of Directors to implement this action plan. The key elements of the plan are as follows:

- Further operating expense reductions to eliminate certain expenditures which are not essential to achieving critical business objectives at this time (e.g., discretionary spending, further development efforts)
- Strategic realignment of the Company's international sales organization.
- Pursuit of strategic alternatives related to the Company's domestic sales efforts that can help it further penetrate existing markets.
- Pursuit of strategic financing alternatives including the sale of debt securities, bank financing, strategic alliances, joint ventures or by other means.

As a result of implementing the above actions, management believes that its existing cash resources and cash from operations will meet working capital requirements over the next twelve months and improve operating results.

Unanticipated decreases in operating revenues, increases in expenses or further delays in the process of third

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party payers committing to provide reimbursement to healthcare providers, may

adversely impact the Company's cash position and require further cost reductions or the need to obtain additional financing. 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 financial statements do not include any adjustments to reflect the possible future effects of these uncertainties.

## 2. SIGNIFICANT ACCOUNTING POLICIES

### BASIS OF PRESENTATION

The consolidated financial statements include the accounts of PLC Systems Inc. (PLC or the "Company") and its seven wholly-owned subsidiaries, PLC Medical Systems, Inc., PLC Sistemas Medicos Internacionais, Lda, PLC Sistemas Medicos GmbH, PLC Medical Systems AG, PLC Medical Systems Asia/Pacific Pte Ltd, PLC Medical Systems France and PLC Medical Systems Australia Pty Ltd. All intercompany accounts and transactions have been eliminated.

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). Had the statements been prepared in accordance with Canadian GAAP, certain transactions would have been accounted for differently. Under Canadian GAAP, the Convertible Debentures, net of issuance costs, would be classified as equity since the Company has the right to settle the principal and interest amounts due on the debentures by issuing common stock.

Accordingly, if the accompanying financial statements had been prepared under Canadian GAAP at December 31, 1998 and 1997, common stock would be \$934,000 and \$3,697,000, respectively, greater due to the inclusion of the Convertible Debentures and accrued expenses would be reduced by \$33,000 in 1998 and \$75,000 in 1997 due to the elimination of accrued interest on the debt. In addition, the accumulated deficit would be reduced by \$252,000 in 1998 and \$197,000 in 1997 as a result of the elimination of interest and other debt issuance expenses included in the accompanying statement of operations for the year ended December 31, 1998 and 1997, as required under U.S. GAAP.

### 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. Cash equivalents and marketable securities, which are classified as available-for-sale securities, consist primarily of time deposits, bankers acceptances and obligations of U.S. government and agencies. There were no unrealized gains or losses at December 31, 1997. Maturities of marketable securities at December 31, 1997 were less than six months.

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### INVENTORY

Inventory is stated at the lower of average 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>	<C>
<S>	
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

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

### REVENUE RECOGNITION

Revenues from product sales, except sales to certain distributors, are recognized at the time of shipment. Shipments made to distributors, where payment is dependent on the resale of the product, are recognized at the time of payment from the distributor. Revenues from placement contracts are recognized as earned based on the terms of each placement contract. Placement contracts currently in place have either a "minimum billings" clause or a "pay per actual usage" clause. Revenues from service contracts are recognized ratably over the life of the contract.

### 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

In 1997, the Financial Accounting Standards Board issued Statement No. 128, "Earnings Per Share" ("Statement 128") which replaced the calculation of primary and fully diluted earnings per share with basic and diluted earnings per share. Unlike primary earnings per share, basic earnings per share excludes any dilutive effects of options, warrants and convertible securities. Diluted earnings per share is very similar to the previously reported fully diluted earnings per share. All loss per share amounts for all periods have been presented, and have been restated, to conform to Statement 128.

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#### STOCK BASED COMPENSATION

The Company grants stock options for a fixed number of shares to employees and certain other individuals with exercise prices equal to the fair value of the shares at the dates of grant. The Company has adopted the disclosure only provisions of Statement of Financial Accounting Standards No. 123, ACCOUNTING FOR STOCK-BASED COMPENSATION ("FAS 123") and will continue to account for its stock option plans in accordance with the provisions of APB 25 ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES. Accordingly, no compensation cost has been recognized for the stock option plans.

#### 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.

#### COMPREHENSIVE INCOME

As of January 1, 1998, the Company adopted Statement 130, Reporting Comprehensive Income ("Statement 130"). Statement 130 establishes new rules for the reporting and display of comprehensive income and its components in the financial statements. The Company has changed the format of its consolidated statements of stockholders' equity to present comprehensive income.

### 3. INVENTORY

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

	1998	1997
	----	----
<S>	<C>	<C>
Raw materials	\$1,035	\$1,141
Work in process	145	10
Finished goods	1,773	1,361
	-----	-----
	\$2,953	\$2,512
	-----	-----
	-----	-----

</TABLE>

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### 4. EQUIPMENT, FURNITURE AND LEASEHOLD IMPROVEMENTS

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

	1998	1997
	----	----
<S>	<C>	<C>
Equipment	\$2,461	\$2,010
Equipment under placement contracts	6,617	5,760
Office furniture and fixtures	929	1,082
Equipment under capital lease	429	455
	-----	-----
Leasehold improvements	587	587
	-----	-----
	11,023	9,894
	-----	-----
Less accumulated depreciation and amortization	5,932	4,258
	-----	-----
	\$5,091	\$5,636
	-----	-----
	-----	-----

</TABLE>

Equipment under placement contracts represents Heart Lasers that the Company has provided to customers under contracts which require the customers to pay a fee for each use of the equipment, subject to guaranteed annual minimum fees. The Company maintains title to the equipment, which is depreciated over the term of the contract, and is responsible for maintenance. Depreciation expense was \$3,116,000, \$1,894,000, and \$717,000 respectively for the years ended December 31, 1998, 1997, and 1996.

#### 5. LEGAL PROCEEDINGS

In September 1996, CardioGenesis Corporation, ("CardioGenesis") filed a civil lawsuit in the United States District Court for the Northern District of California asking the court to declare the Company's synchronization patent (U.S. Patent No. 5,125,926) invalid and unenforceable, or, alternatively, to find that CardioGenesis' TMR and PMR lasers do not infringe this patent. The Company filed a counterclaim alleging that all of CardioGenesis' TMR and PMR lasers infringe U.S. Patent No. 5,125,926. In January 1997, CardioGenesis filed an opposition in the European Patent Office to have the Company's German synchronization patent declared invalid. In April 1997, the Company filed an infringement lawsuit against CardioGenesis and one of its distributors in the Munich District Court alleging that CardioGenesis' TMR and PMR lasers infringe the Company's German synchronization patent.

The PLC patents at issue in these lawsuits cover the Company's synchronization technology, a critical factor in ensuring the safety of TMR and PMR procedures. In January 1999, the Company settled its outstanding patent infringement litigation with CardioGenesis. Under the settlement, CardioGenesis acknowledged that U.S. Patent No. 5,125,926 and related international patents of the Company are 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 must 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 Heart Laser System in the United States. Following this recommendation, the Company was named as defendant

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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 seek 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 have been consolidated by the court into a single action for pretrial purposes. Two of these suits have been dismissed. The Company moved to dismiss all of the remaining claims. On March 26, 1999, the court issued an order dismissing some, but not all of the remaining claims. The Company has also been named as a defendant in a lawsuit filed in Massachusetts Superior Court in September 1998. This suit seeks 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. The Company cannot make a meaningful estimate of the amount or range of loss that could result from an unfavorable outcome of these lawsuits, but an unfavorable outcome could have a material adverse affect on our business, financial position and results of operations. The Company believes that it has valid defenses to these litigation matters and it has and continues to vigorously defend itself in these matters.

In August 1997, the Company received from the United States Securities and Exchange Commission (the "Commission") an informal request for information relating to the decision by the FDA Advisory Panel not to recommend approval of The Heart Laser System in July 1997. The Company has responded and has not received any further communication from the Commission regarding this matter since June 1998.

In February 1996, PLC Medical Systems, Inc. filed suit against Eclipse Surgical Technologies, Inc. ("Eclipse") in the United States District Court for the District of Massachusetts alleging copyright infringement and unfair and deceptive trade practices based on Eclipse's misappropriation and copying of one of PLC's confidential clinical study protocols. The Company is seeking injunctive relief and damages, as well as any profits derived by Eclipse as a result of the misappropriation, attorney's fees, treble damages and other relief.

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 is seeking reimbursement of lease payments made for the Heart Laser System. The Company intends to vigorously defend itself in this matter. This matter is in the earliest stage of litigation and a meaningful estimate of the loss that could result from this matter has not been made.

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

#### 6. ISSUANCE OF CONVERTIBLE DEBENTURES



a. 5% Convertible Debentures due July 17, 2002 and August 14, 2002

In July 1997, the Company entered into a \$20 million financing commitment. Under the terms of the financing, the Company received \$10,075,000 in July 1997 and \$10,075,000 in August 1997 from the issuance of five-year convertible debentures to accredited investors. In September 1997, the entire first tranche of convertible debentures and related accrued interest converted into 890,394 shares of common stock. In September 1997, \$5,825,000 of the second tranche of convertible debentures and related accrued interest converted into 512,572 shares of common stock. In January and February 1998, the remaining \$4,250,000 of the second tranche of convertible debentures and related accrued interest converted into 576,606 shares of common stock.

In connection with the issuance of the first tranche of convertible debentures, the Company issued 69,875 redeemable warrants to purchase shares of its Common Stock at \$27.81 per share. In connection with the issuance of the second tranche of convertible debentures, the Company issued 80,125 redeemable warrants to purchase shares of its Common Stock at \$15.78 per share. If the average closing sale price of its Common Stock for any consecutive 30 trading day period commencing January 17, 1999 exceeds the exercise price by more than 50%, the Company has the right, exercisable at any time upon 30 days notice to the holder, to redeem the warrant at a price of \$.10 per warrant share. The warrants issued in connection with the first tranche expire on July 17, 2002. The warrants issued in connection with the second tranche expire on August 14, 2002. The detachable warrants were valued at \$617,000 (using the Black-Scholes formula), classified as a component of equity, and disclosed separately in the Consolidated Statement of Stockholders' Equity.

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b. Convertible Debentures due April 23, 2003

In April 1998, the Company obtained a \$10 million financing commitment from three institutional investors. Pursuant to the terms of the financing, the Company received approximately \$5 million in April 1998 from the issuance of non-interest bearing, five-year convertible debentures. As of December 31, 1998, \$4,000,000 of the convertible debentures outstanding converted into 653,063 shares of the Company's Common Stock. In January 1999, the remaining \$1,000,000 of the convertible debentures outstanding converted into 163,264 shares of the Company's Common Stock. The remaining \$5 million of the commitment expired on December 31, 1998.

In connection with the First Tranche, the Company issued 4,864 redeemable warrants to purchase shares of its Common Stock at \$19.53 per share. If the average closing sale price of its Common Stock for any consecutive thirty trading day period commencing April 23, 1999 exceeds the exercise price by more than 50%, the Company has the right, exercisable at any time upon 30 days notice to the holder, to redeem the warrants at a price of \$.10 per warrant. The warrants expire on April 23, 2003. The detachable warrants were valued at \$50,000 (using the Black-Scholes formula), classified as a component of equity, and disclosed separately in the Consolidated Statement of Stockholders' Equity.

7. STOCKHOLDERS' EQUITY

The Company's 1992 Stock Option Plan ("1992 Plan"), the 1993 Stock Option Plan ("1993 Plan") and the 1995 Stock Option Plan ("1995 Plan") allow for the granting of options aggregating 2,505,000 shares of common stock. All of the Plans consist of both incentive stock options and non-qualified options. 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 three years from the date of grant, or based on the attainment of specific performance criteria, and expire ten years from the date of grant.

The Company's 1993 Formula Stock Option Plan (the "Formula Plan") provides for the grant of non-qualified options to non-employee directors to purchase up to 250,000 shares of common stock. The Plan is administered by the Board of Directors. Annually, the Company grants 10,000 options to each of its non-employee directors. A director must attend at least 60% of all Board meetings, as well as committee meetings, to receive the grant. 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. In addition, in 1995, the Company granted 10,000 non-qualified options at \$12.88 per share to the Company's Lead Outside Director. As of December 31, 1998, the options are fully exercisable and expire ten years from the date of grant.

The Company's 1997 Executive Stock Option Plan ("1997 Executive Plan") provides for the grant of non-qualified options to officers and directors of the Company to purchase up to 650,000 shares of common stock. In 1998, the Board of Directors voted to increase the shares available in this plan to 1,000,000. The options vest over a combination of time and the attainment of specific performance criteria.

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.

During 1998, the Board of Directors (together with 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)

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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 our 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 under the SMIP. Furthermore, the Company has 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 was repriced to \$4.875 per share.

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

<TABLE>  
<CAPTION>

	1998	1997	1996
	----	----	----
<S>	<C>	<C>	<C>
Outstanding at beginning of year	2,187	1,914	1,635
Granted	823	938	500
Exercised	(142)	(435)	(220)
Canceled	(80)	(230)	(1)
	-----	-----	-----
Outstanding at end of year	2,788	2,187	1,914
	-----	-----	-----
Exercisable at end of year	1,711	878	874
Available for grant at end of year	71	463	521

</TABLE>

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<TABLE>  
<CAPTION>

	1998	1997	1996
	----	----	----
<S>	<C>	<C>	<C>
Weighted - average exercise			
Outstanding at	\$8.75	\$ 8.18	\$ 4.67
Granted	\$5.39	\$13.56	\$17.83
Canceled	\$9.09	\$11.50	\$ 3.97
Exercised	\$4.39	\$ 4.39	\$ 3.73
Outstanding at end of	\$5.16	\$10.84	\$ 8.18
Exercisable at end of	\$4.88	\$ 8.75	\$ 5.34
Weighted - average fair value of			
Options granted during the	\$3.33	\$ 8.20	\$ 5.56

<CAPTION>

Range of Exercise Prices

	\$3.69 - \$5.00	\$5.13 - \$8.88	\$3.69 - \$8.88
	-----	-----	-----
<S>	<C>	<C>	<C>
Options Outstanding:			
Number (in thousands)	1,283	1,505	2,788

Weighted-Average Contractual Life	6.6	8.6	7.7
Weighted-Average Exercise Price	\$4.39	\$5.81	\$5.16
Options Exercisable:			
Number (in thousands)	1,023	688	1,711
Weighted-Average Exercise Price	\$4.28	\$5.77	\$4.88

</TABLE>

Pursuant to the requirements of FAS 123, the following are the pro forma net loss and net loss per share for 1998, 1997 and 1996, as if the compensation cost for the option plans had been determined based on the fair value at the grant date for grants in 1998, 1997 and 1996, consistent with the provisions of FAS 123.

<TABLE>

<CAPTION>

	1998	1997	1996
	----	----	----
<S>	<C>	<C>	<C>
Proforma net loss (in thousands)	\$ (22,438)	\$ (16,523)	\$ (2,404)
Proforma net loss per share	\$ (1.17)	\$ (.97)	\$ (.15)

</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>

	1998	1997	1996
	----	----	----
<S>	<C>	<C>	<C>
Expected life (years)	2	2	2
Interest rate	5.53%	6.01%	5.65%
Volatility	.761	1.141	.576

</TABLE>

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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. Because FAS 123 is applicable only to options granted subsequent to October 28, 1995, the pro forma effect has been fully reflected in the year ended December 31, 1998.

As of December 31, 1998, 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 and 4,864 shares at \$19.53 per share expiring April 23, 2003.

At December 31, 1998, there were 3,023,026 shares of authorized but unissued common stock reserved for issuance under all stock option plans and stock warrants. In conjunction with the conversion of the debentures, the Company has reserved an additional 163,264 shares. See Note 6 for a further discussion.

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. In addition, the Company has unlimited authorized shares of common stock.

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.

#### 8. LEASE COMMITMENTS

The Company occupies its worldwide facilities under operating lease agreements, which expire through March 2002. The Company has the option to renew the U.S. facilities lease for up to five 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. The Company also leases certain equipment.

As of December 31, 1998, future minimum lease payments are as follows (in thousands):

<TABLE>

<CAPTION>

	Year	
	----	
<S>		<C>
	1999	\$374
	2000	338
	2001	224
	2002	7
		----
		\$943
		----
		----

</TABLE>

Total rent expense was \$375,000 in 1998, \$458,000 in 1997 and \$370,000 in 1996.

#### 9. INCOME TAXES

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

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<TABLE>

<CAPTION>

	1998 ----	1997 ----
<S>	<C>	<C>
Net U.S. operating loss carryforwards	\$ 13,791	\$ 7,682
Net foreign operating loss carryforwards	2,263	1,482
Intercompany profit	313	637
Accrued clinical costs	406	516
Research & development credits	679	561
Inventory and warranty reserves	497	331
Alternative minimum tax credit	63	63
Accrued salaries	195	-
Deferred revenue	173	-
Other	4	56
	-----	-----
Total deferred tax assets	18,384	11,328
Valuation allowance	(18,384)	(11,328)
	-----	-----
Net deferred tax assets	\$ --	\$ -
	-----	-----

</TABLE>

The valuation allowance increased by approximately \$7,000,000 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 \$18,384,000.

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

<TABLE>

<CAPTION>

	1998 ----	1997 ----	1996 ----
<S>	<C>	<C>	<C>
Domestic	\$ (14,137)	\$ (11,340)	\$ (1,244)
Foreign	(2,472)	(3,064)	(296)
	-----	-----	-----
	\$ (16,603)	\$ (14,404)	\$ (1,540)
	-----	-----	-----

</TABLE>

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

<TABLE>

<CAPTION>

	1998 ----	1997 ----	1996 ----
<S>	<C>	<C>	<C>
Statutory income tax provision	\$ (5,645)	\$ (4,898)	\$ (524)
Utilization of loss carryforwards	(85)	-	-
Unbenefited U.S. losses	4,807	3,856	423
Unbenefited foreign losses	923	1,042	100
Other	-	-	1
	-----	-----	-----
Provision for income taxes	\$ -	\$ -	\$ -
	-----	-----	-----

</TABLE>

At December 31, 1998 the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$34.5 million which expire at various dates through 2012. In addition, the Company had foreign net operating loss carryforwards of approximately \$5.7 million.

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#### 10. SEGMENT INFORMATION

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

<TABLE>

<CAPTION>

North

	America	Europe	Other	Eliminations	Total
<S>	<C>	<C>	<C>	<C>	<C>
1998					
Net sales to unaffiliated customers	\$3,992	\$1,615	\$ 86	\$ -	\$ 5,693
Long-lived assets	\$ 558	\$ -	\$ -	\$ -	\$ 558
1997					
Net sales to unaffiliated Customers	\$4,092	\$4,683	\$ 166	\$ -	\$ 8,941
Long-lived assets	\$ 701	\$ -	\$ -	\$ -	\$ 701
1996					
Net sales to unaffiliated Customers	\$5,657	\$6,215	\$ -	\$ -	\$11,872
Long-lived assets	\$ 537	\$ -	\$ -	\$ -	\$ 537

No one customer accounted for more than 10% of the Company's revenues for the year ended December 31, 1998. Approximately 20% of the Company's revenues for the year ended December 31, 1997 came from one customer, Imatron Japan. No one customer accounted for more than 10% of the Company's revenues for the year ended December 31, 1996. 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 does not believe its future revenues to be dependent on those generated from any single customer.

#### 11. SUBSEQUENT EVENT

On March 4, 1999, the Company announced that it had obtained a provisional equity financing commitment of \$8 million from a major institutional investor. The commitment contemplates the sale by the Company of up to \$2 million in common stock during consecutive 20 day periods at prices based on the trailing volume weighted average price of the common stock on the American Stock Exchange on each day during such periods, less a seven percent discount. The Company is unable to use the commitment on any trading day to the extent that the volume weighted average price of the Company's common stock is less than \$3.50 per share, unless the Company and the investor mutually agree to a reduction in such price. If the Company is unable to use the commitment on any given trading day, the commitment amount is automatically reduced by \$100,000 on such day.

The use of the commitment is also dependent upon the Company being eligible to sell shares of its common stock under a Form S-3 Registration Statement under the Securities Act of 1933, as amended, which form requires,

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among other things, that the Company have a market capitalization of at least \$75 million held by non-affiliates of the Company during the immediately preceding 60-day period. There can be no assurance that the Company will be able to use this commitment in the future or that the Company will maintain its eligibility to use Form S-3. As of March 31, 1999, the Company had sold 323,231 shares of common stock under this commitment, resulting in proceeds to the Company (net of all issuance costs payable upon closing) of \$885,000 and had \$6 million in unused availability under the commitment.

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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	Additions Charged to Costs and Expenses	Deductions	Balance at End of Period
<S>	<C>	<C>	<C>	<C>	<C>
For the Year Ended December 31, 1998					
Allowance for Doubtful Accounts		\$140,000	\$100,000	\$12,000	\$228,000
For the Year Ended December 31, 1997					
Allowance for Doubtful Accounts		\$ 28,000	\$112,000	\$ 0	\$140,000
For the Year Ended December 31, 1996					
Allowance for Doubtful Accounts		\$ 29,000	\$ 0	\$ 1,000	\$28,000

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##### PLC SYSTEMS INC. QUARTERLY DATA (UNAUDITED)

<TABLE>

<CAPTION>	March 31	June 30	September 30	December 31	Total
<S>	<C>	<C>	<C>	<C>	<C>
TOTAL REVENUE	\$ 945	\$ 680	\$1,615	\$2,453	\$ 5,693
GROSS PROFIT (LOSS)	257	(351)	320	900	1,126
LOSS FROM OPERATIONS	(4,087)	(5,569)	(4,032)	(3,372)	(17,060)
NET LOSS	(3,936)	(5,402)	(4,006)	(3,259)	(16,603)
LOSS PER SHARE, BASIC AND DILUTED	(.21)	(.28)	(.21)	(.17)	(.86)
1997					
Total revenue	\$1,588	\$3,422	\$1,885	\$2,046	\$8,941
Gross profit	758	1,952	666	249	3,625
Loss from operations	(3,130)	(2,712)	(3,590)	(5,150)	(14,582)
Net loss	(3,022)	(2,697)	(3,562)	(5,123)	(14,404)
Loss per share, basic and diluted	(.18)	(.16)	(.21)	(.28)	(.84)

EXHIBIT INDEX

<TABLE>	<CAPTION>
Exhibit	Title
No.	-----
<S>	<C>
21	Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP.
27	Financial Data Schedule.

PLC SYSTEMS INC.

SUBSIDIARIES OF REGISTRANT

- 1.) *PLC Medical Systems, Inc., a Delaware Corporation*
- 2.) *PLC Sistemas Medicos Internacionais Lda, a Madeira Corporation*
- 3.) *PLC Sistemas Medicos Internacionais GmbH, a German Corporation*
- 4.) *PLC Medical Systems France SARL, a French Corporation*
- 5.) *PLC Medical Systems AG, a Swiss Corporation*
- 6.) *PLC Medical Systems Asia/Pacific Pte Ltd, a Singapore Corporation*
- 7.) *PLC Medical Systems Australia Pty Ltd, an Australian Corporation*

*Consent of Independent Auditors*

*We consent to the incorporation by reference in this Annual Report (Form 10-K) of PLC Systems Inc. of our report dated February 19, 1999, except for Note 11, as to which the date is March 4, 1999, included in the 1998 Annual Report to Shareholders of PLC Systems Inc.*

*Our audits also included the financial statement schedule of PLC Systems Inc. listed in Item 14(a). These schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on this schedule based on our audits. In our opinion, the financial statement schedules referred to above, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.*

*We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 33-98744, 333-34315, 333-53649 and 333-68923 and Form S-8 Nos. 33-95168 and 333-51547) of PLC Systems Inc. of our report dated February 19, 1999, except for Note 11, as to which the date is March 4, 1999, with respect to the consolidated financial statements incorporated herein by reference, and our report included in the preceding paragraph with respect to the financial statement schedules included in this Annual Report (Form 10-K) of PLC Systems Inc. for the year ended December 31, 1998.*

*Ernst & Young LLP*

*Boston, Massachusetts  
March 25, 1999*



<TABLE> <S> <C>

<ARTICLE> 5

<LEGEND>

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

</LEGEND>

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<MULTIPLIER> 1000

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