

PLC Systems Inc.  
Annual Report  
2007



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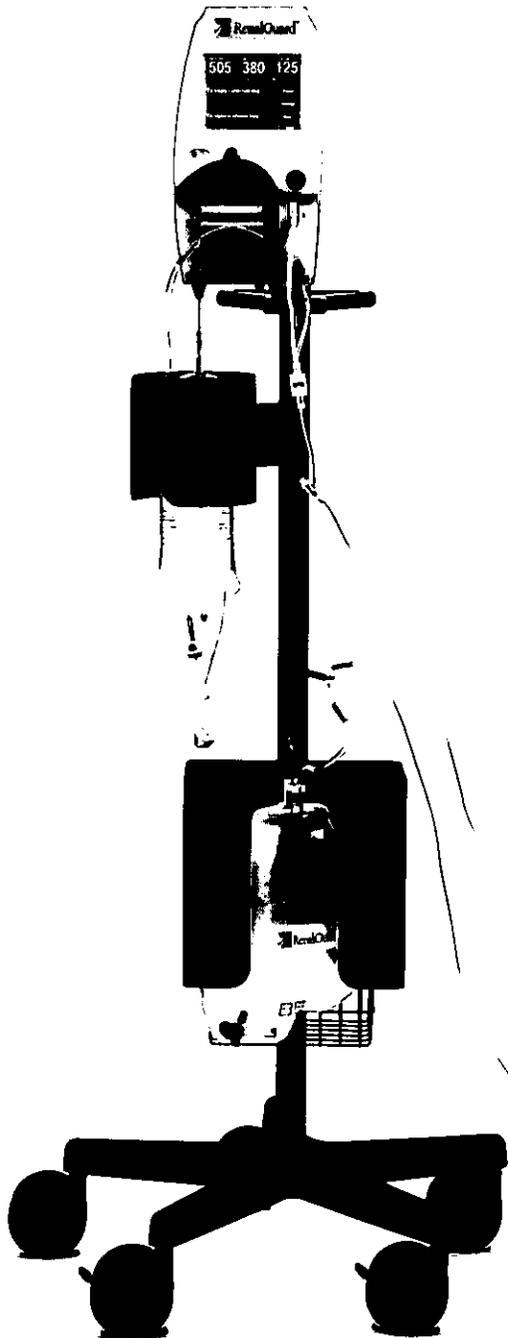
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PLC  
MEDICAL  
SYSTEMS, INC.

# ABOUT PLC SYSTEMS



PLC Systems Inc. is a medical technology company specializing in innovative technologies for the cardiac and vascular markets. Headquartered in Franklin, Mass., PLC pioneered the CO<sub>2</sub> Heart Laser System, which cardiac surgeons use to perform CO<sub>2</sub> transmyocardial revascularization (TMR) to alleviate symptoms of severe angina.

The company completed a pilot clinical safety study of its RenalGuard Therapy™ and RenalGuard System™, and received its CE Mark Certificate for RenalGuard System. PLC has also received FDA conditional approval to commence a U.S. pivotal trial to study the effectiveness of its RenalGuard Therapy and RenalGuard System in the prevention of Contrast-Induced Nephropathy (CIN). RenalGuard Therapy is designed to reduce the toxic effects that contrast media can have on the kidneys.

**RenalGuard Therapy induces high urine flow and the RenalGuard System design is intended to automatically and continuously match the amount of infused fluid to the patient's urine output.**

PLC Systems, PLC Medical Systems, PLC, CO<sub>2</sub> Heart Laser, RenalGuard, RenalGuard System and RenalGuard Therapy are trademarks of PLC Systems Inc.

Edwards Lifesciences, Edwards and Optiwave 980 are trademarks of Edwards Lifesciences Corporation.

Novadaq and SPY are trademarks of Novadaq Technologies, Inc.

 RenalGuard™

To our shareholders,

I am very pleased to share with you our progress in 2007 on our new product initiative, RenalGuard™, which we believe represents a significant opportunity to broaden and diversify PLC. Since we unveiled this effort in fall 2006, we have worked steadily to bring to fruition a patent-pending technology that we believe may dramatically improve patient care in a crucial arena.

Our RenalGuard Therapy™ and RenalGuard System™ address a large, unmet need in protecting against kidney damage in some of the millions of patients worldwide who are undergoing cardiovascular imaging procedures utilizing contrast each year. The condition we are targeting is called Contrast-Induced Nephropathy (CIN). It can be debilitating and deadly, and very costly to the healthcare system. Other companies have tried developing drugs and alternative therapies, with limited success. That's why we see a real opportunity for RenalGuard.

In 2007, we initiated and completed our U.S. pilot safety trial for RenalGuard. This study was designed to demonstrate the safety of our system and therapy. In February 2008, we submitted an Investigational Device Exemption supplement, to enable the U.S. Food & Drug Administration to approve our pivotal trial to study the efficacy of RenalGuard in preventing CIN in the at-risk population, and in March we secured conditional approval to commence this critical trial this spring. The study is designed as an adaptive trial, with at least 246 patients at up to 30 sites. It is expected to run through the end of 2009, and cost PLC approximately \$3 million over that period to enroll this number of patients.

As we prepare to commence this trial in the U.S. under the leadership of two experienced principal investigators, Drs. Charles Davidson, MD, Professor of Medicine, Northwestern University Medical School and Richard J. Solomon, MD, Professor of Medicine, University of Vermont College of Medicine, we continue to be excited by the overall market that RenalGuard addresses. Through our participation in industry tradeshows in late 2007, where we showcased RenalGuard and gained feedback from prominent interventional cardiologists and nephrologists, we confirmed that they remain very frustrated with the continuing high levels of CIN they see. Cardiovascular imaging procedures are increasing, and with one of the principal at-risk factors for CIN readily apparent through a simple standard blood test, practitioners are eager to find an effective solution to the problem.

It is our hope that RenalGuard will be this solution, with its unique automated closed-loop system that uses high urine flows with a real-time matched fluid replacement to reduce the naturally toxic effects of contrast on the kidneys. Furthermore, we believe that employing RenalGuard should reduce the need for such patients to stay overnight in the hospital before their procedures, and lower the incidence of CIN, providing important cost savings to the healthcare system.

In Europe, our progress in advancing RenalGuard has been faster. As anticipated, we secured a CE Mark in late 2007, and we have begun our limited launch in Italy in 2008.

You may wonder why we have chosen Italy for this launch. A new study of RenalGuard is expected to begin during the first half of 2008 in Italy, under the supervision of two internationally known experts on the prevention of CIN, Drs. Antonio Bartorelli and Giancarlo Marenzi. This study, at the Centro Cardiologico Monzino (CCM) in Milan, will compare RenalGuard's efficacy in preventing CIN to that of overnight hydration, a standard of care prevalent in much of Europe. Clearly, their work will augment our launch, which is targeting early adopters in 10 sites in Italy. As a small company with limited resources, it makes sense to carefully plan and execute our initial launch so that it provides a successful base upon which to build in the future. We anticipate working with our distributor and

generating modest revenues in the initial launch; we want to learn how best to position RenalGuard for long-term success with target customers.

We are very excited about the CCM study, which is expected to take 9-12 months to complete, since we believe it will provide us with important insights and strong scientific data well before the results of our pivotal trial in the U.S. are available. Once the CCM study is finished, we expect it will provide us with a clear market advantage in our efforts to build awareness in the EU market simultaneous with our plans to begin more comprehensive EU distribution in 2009.

We have been very pleased with the feedback from the physician community, which corroborates that we are targeting a key therapeutic area. With an addressable market worldwide of an estimated \$500 million, based upon average rates of CIN and anticipated price levels, we remain very confident that focusing our efforts on RenalGuard's forward progress in 2008 will provide long-term rewards for PLC and its shareholders.

As anticipated, 2007 was a transition year for our TMR business. Late in the first quarter, Novadaq Technologies Inc. replaced Edwards Lifesciences Corporation as our exclusive U.S. marketing and distribution partner for this business. Novadaq has generated excitement in the field with its SPY® Intra-Operative Imaging System that targets the same customer base as our TMR business. In fact, some cardiologists are already using these systems together for the valuable synergies they provide, one as a diagnostic tool and the other as a therapeutic device, for successful bypass surgeries.

In addition to normal transition issues associated with the change in distribution partners, Novadaq also encountered a shortage of a dye used with its SPY system. Until the dye supply was resolved in early October, this matter proved challenging for the sales team and affected sales results for TMR systems and kits.

We now believe these issues are behind us, and with the re-energized and expanded TMR sales force at Novadaq fully focused on the business, we hope that the improvement in kit sales that we saw in the U.S. from the third quarter to the fourth quarter last year will continue. We believe that Novadaq's sales proposition for the combined SPY and TMR business is a powerful one for this customer base, and that today, we are in a position to see the results of greater TMR adoption through increased kit sales.

We continued to produce small but important growth in our services and OEM laser operations, which together contributed about 35% of our total revenues in 2007, up from about 25% in 2006. These businesses require no additional investment from PLC, but pay dividends beyond their revenues through the valuable assistance they enable us to offer to current and new customers.

We appreciate your support as we work to commercialize our RenalGuard technology. We remain confident that we have identified a strong business opportunity, one which we are pursuing with speed and great progress. We look forward to updating you as we move forward in 2008.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark R. Tauscher". The signature is fluid and cursive, with a large loop at the end.

Mark R. Tauscher  
President and CEO

April 24, 2008

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

SEC Mail Processing  
Section

JUN 11 2008

**FORM 10-K**

Washington, DC

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

For the fiscal year ended December 31, 2007

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-11388

**PLC Systems Inc.**

*(Exact name of registrant as specified in its charter)*

Yukon Territory, Canada  
*(State or other jurisdiction of  
incorporation or organization)*

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

04-3153858  
*(I.R.S. Employer  
Identification No.)*

02038  
*(Zip Code)*

(508) 541-8800

*(Registrant's telephone number, including area code)*

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

<i>Title of Each Class</i>	<i>Name of Each Exchange on which Registered</i>
Common stock, no par value	American Stock Exchange

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2007, was \$15,554,618. As of March 14, 2008, 30,329,480 shares of common stock, no par value per share, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

### **Forward-Looking Statements**

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements containing terms such as "believes", "plans", "expects", "anticipates", "intends", "estimates" and similar expressions contain uncertainty and are forward-looking statements. Forward-looking statements are based on current plans and expectations and involve known and unknown important risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such important factors and uncertainties include, but are not limited to, the risk factors set forth in Item 1A.

## PART I

### Item 1. *Business*

#### Overview

We are a medical device company specializing in innovative technologies for the cardiac and vascular markets. We pioneered and manufacture the *CO<sub>2</sub> Heart Laser System* (the “Heart Laser System”) that cardiac surgeons use to perform carbon dioxide (CO<sub>2</sub>) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. In addition, we have commenced clinical trials for our RenalGuard Therapy and RenalGuard System (collectively “RenalGuard”), which is the primary growth initiative for our business. RenalGuard is designed to reduce the toxic effects that contrast media can have on the kidneys, which can lead to contrast-induced nephropathy (“CIN”), a potentially deadly form of acute kidney injury. We also manufacture CO<sub>2</sub> surgical laser tubes and provide contract assembly services on general purpose CO<sub>2</sub> lasers, which we sell to a single customer on an original equipment manufacturer (“OEM”) basis.

RenalGuard Therapy is based on the theory that creating and maintaining a high urine output is beneficial to patients undergoing imaging procedures where contrast agents are used. The real-time measurement and matched fluid replacement design of our RenalGuard System is intended to optimally administer RenalGuard Therapy and ensure that a high urine flow is maintained before, during and after these procedures, thus allowing the body to rapidly eliminate contrast, reducing its toxic effects. The RenalGuard System consists of a proprietary, closed loop, software-controlled console and accompanying single-use sets used for infusion and urine collection. The RenalGuard System, with its matched fluid replacement capability, is intended to minimize the risk of over- or under-hydration.

In December 2006, we received full Food and Drug Administration (“FDA”) approval to conduct our first human clinical trial utilizing RenalGuard under an investigational device exemption (“IDE”). This pilot clinical trial was designed to evaluate the safety of RenalGuard and the ability of our RenalGuard System to accurately measure and balance fluid inputs and outputs on up to 40 patients undergoing a catheterization imaging procedure where contrast media would be administered.

We enrolled a total of 23 patients in this pilot study. Based upon the positive safety data collected in the study and discussions we had with the FDA, we elected to stop enrolling new patients in the pilot study in November 2007. We submitted an IDE supplement to the FDA in February 2008 seeking approval to move from our pilot study to a pivotal clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN. In March 2008 the FDA granted us conditional approval to begin our pivotal study. We have received approval to study RenalGuard on 246 patients at up to 30 U.S. clinical sites. We expect to begin enrolling patients in this study this spring after obtaining necessary institutional review board approval at the clinical sites where the study will be conducted.

#### Other Recent Developments

##### *CE Mark*

On December 21, 2007, we announced that we had received the CE Mark Certificate for our RenalGuard System, clearing the way for us to begin our initial limited launch of the product in the European Union (“EU”).

##### *Appointment of Artech as Exclusive RenalGuard Distributor in Italy*

On March 27, 2008, we appointed Artech s.r.l. (“Artech”) as the exclusive distributor of our RenalGuard System in Italy. We signed a three year distribution agreement with Artech and they issued us purchase orders for an initial stocking order of RenalGuard System consoles and single-use sets totaling 90,000 Euros. We and Artech intend to focus our initial limited commercial launch activities

for RenalGuard on ten select hospital sites in Italy. In doing so we hope to interest early adopters of our technology who recognize the benefits of utilizing the unique fluid balancing capabilities of the RenalGuard System in a catheterization laboratory setting during cardiovascular imaging procedures for patients at higher risk of CIN.

### **The CO<sub>2</sub> Heart Laser System**

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

In August 1998, we received approval from the FDA to market our first generation CO<sub>2</sub> Heart Laser, the HL1, throughout the U.S. We were the first company to receive FDA approval to commercialize a product to perform TMR. In January 2001, we received approval from the FDA to market our smaller and lighter second generation CO<sub>2</sub> Heart Laser, the HL2.

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

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

### **Cardiovascular Disease and Current Therapies**

According to the Heart Disease and Stroke Statistics—2008 Update, or 2008 HSSU, which was published by the American Heart Association, an estimated 80.7 million Americans suffered from one or more types of cardiovascular disease in 2005, with an estimated 16 million suffering from coronary heart disease and 9.1 million suffering from angina pectoris (chest pain). This represents an increase over similar statistics published in the 2007 HSSU, when it was reported that 79.4 million Americans suffered from one or more types of cardiovascular disease in 2004, with an estimated 15.8 million suffering from coronary heart disease and 8.9 million suffering from angina pectoris.

Cardiovascular disease is the leading cause of death in the U.S., resulting in approximately 35% of the 2,448,000 deaths in 2005, or 1 of every 2.8 deaths in the U.S. The American Heart Association estimates that the direct and indirect costs of cardiovascular disease in 2008 will be approximately \$448.5 billion.

#### ***Angina—Current Treatments***

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

Drug therapy alleviates some of the symptoms of atherosclerosis, but is often ineffective in serious cases. Angioplasty is a less invasive treatment for arteriosclerosis than bypass surgery. The most common form of angioplasty involves inserting a catheter with a balloon at the tip into a diseased artery. By inflating the balloon at the site of blockage, the arterial plaque can be pressed against the arterial walls and reshaped, resulting in increased blood flow and decreased angina symptoms. According to the 2008 HSSU, an estimated 1,271,000 inpatient angioplasty procedures were performed in the U.S. in 2005.

Metallic stents were developed to help prevent abrupt closures that sometimes occur after angioplasty. These stents are inserted into the artery after balloon angioplasty to hold the expanded plaque in place. Because they are less traumatic and less costly, stenting procedures are preferred over bypass surgery when the blockages are not complicated and involve few coronary arteries. While offering certain benefits compared to bypass surgery, some studies suggest restenosis, or the reclosure of the stented portion of the artery over time, is a serious problem. A new generation of stents that are coated with drugs targeted at preventing restenosis have shown some success. Studies have shown significant reduction in restenosis when these drug-eluting stents are used. However, the results of a recent clinical study, the COURAGE trial, showed that, for those patients with stable angina, there was no long term mortality difference between drug-eluting stents and medical management. Other recent clinical studies of drug eluting stents have shown an increased risk of long term stent thrombosis complications when these devices are used. The results from these various clinical studies appear to have caused at least a temporary reduction in the use of drug-eluting stents and it could lead to an increase in bypass surgery procedures in the near term.

Conventional bypass surgery involves cutting open the patient's chest, cutting through the sternum, usually connecting the patient to a heart-lung machine, stopping the heart, attaching a vein or artery removed from another part of the patient's body to create a bypass around the diseased blood vessel and restarting the heart. According to the 2008 HSSU, an estimated 469,000 coronary artery bypass procedures were performed on 261,000 patients in the U.S. in 2005 (up from an estimated 427,000 bypass procedures performed on 249,000 patients in the U.S. in 2004). Certain patients, however, are not suited for bypass procedures, including some who have previously undergone bypass surgery, patients with extremely diffuse diseases, patients with vessels that are too small to graft, patients with chronic obstructive pulmonary disease, some patients with diabetes, and others who are considered too ill to survive surgery.

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

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

#### *TMR Using the Heart Laser Systems*

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

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

During a sole therapy TMR procedure, the patient is given general anesthesia and an incision is made in the patient's side between the ribs, exposing the heart. The Heart Laser Systems are synchronized with the patient's heartbeat, firing only when the left ventricle is filled with blood and is electrically insensitive. We believe that synchronization may reduce the risk of arrhythmias (irregular heartbeats) and their associated morbidity and mortality. Research studies conducted by the Texas Heart Institute in animal models indicated that performing TMR without synchronization may be associated with an increase in life threatening arrhythmias. The synchronization technology is covered under a patent that we own. The Heart Laser Systems are capable of creating a transmural channel in less than 0.1 second with a single laser pulse in a patient whose heart has not been stopped and who has not been placed on a heart-lung bypass machine. The surgeon can vary the pulse width of the laser using a touch key control panel to accommodate for the thickness of the patient's heart wall. Transesophageal echocardiography is used to confirm that complete channels are made by the laser. Generally, 15 to 25 new channels are created during the procedure.

We believe that, in addition to providing new temporary direct pathways for blood to reach the ischemic myocardium, the creation of transmural channels using the Heart Laser Systems also promotes angiogenesis, the formation of new blood vessels. We believe angiogenesis is the primary mechanism of action of TMR and the reason why patients who have undergone a TMR procedure have shown sustained angina relief.

#### ***Potential Benefits of TMR***

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

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

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

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

#### **RenalGuard Program**

Our near term focus is to conduct clinical trials of RenalGuard to determine whether it is safe and effective in preventing CIN in patients who have some form of pre-existing renal impairment or other

significant risk factors and who will be undergoing an imaging procedure where they will be exposed to potentially toxic contrast media. We believe if we can demonstrate through clinical studies that RenalGuard is safe and effective in preventing CIN in such patients that there will be substantial markets and revenue growth prospects for the RenalGuard System.

### *CIN*

The diagnosis and treatment of cardiovascular disease rely heavily on cardiovascular imaging. Interventional cardiologists and radiologists are increasingly becoming involved at earlier stages in the management and treatment of patients suffering from cardiovascular disease, as noninvasive imaging and interventional treatment techniques, such as angioplasty procedures and stent placements, increase in demand and outpace the use of invasive surgical options.

We estimate that approximately seven million cardiovascular diagnostic and interventional imaging procedures are performed worldwide each year. These less invasive, image-guided medical procedures require the use of an iodine-based radiocontrast media, or dye, to facilitate the capture and display of x-ray images. These contrast agents are known to be toxic to the kidneys, whose main function is to filter and remove wastes and fluids, such as this dye, from the body. Patients who undergo a diagnostic or interventional imaging procedure and who present themselves with a certain level of pre-existing impaired renal (kidney) function are especially susceptible to the toxic effects of these contrast agents and to developing CIN.

CIN is a major and growing problem due to the increasing number of older patients, diabetics and patients with pre-existing renal failure requiring interventional procedures that use radiographic contrast media. It is the third most common cause of in-hospital acute renal failure. CIN is associated with increased in-hospital mortality rates, and increases in long-term mortality, major in-hospital adverse cardiac events, and risk of renal dialysis therapy. Any of these can result in prolonged hospital stays and increased medical costs. We believe that approximately 10% to 20% of all patients undergoing image-guided cardiology and radiology procedures are at risk of developing CIN. The estimated mortality rate for patients that develop CIN may be as high as 35%.

### *Potential Market Size*

Based on a market research study that was performed for us as well as other sources, we estimate that there are approximately 4 million diagnostic and interventional cardiology and radiology imaging procedures requiring the use of contrast agents that are performed annually in the U.S. alone. Patients with other significant risk factors besides renal insufficiency, such as congestive heart failure, anemia, peripheral vascular disease, diabetes and being over the age of 75, are also at risk for developing CIN. This population continues to grow. Specifically, the 2008 HSSU estimates that there were 171 million individuals with diabetes worldwide in 2000 and that number is projected to rise to 366 million by 2030. Heart failure affected an estimated 5.3 million people in the U.S. alone in 2005. An estimated 16.8% of U.S. adults aged 20 or older between 1999 and 2004 had either chronic kidney disease or chronic kidney disease indicators.

At-risk patients with renal insufficiency are easily identified with a routine blood analysis involving the level of a waste product in the blood called serum creatinine and an industry standard calculation called a creatinine clearance. Creatinine clearance can be accurately calculated using serum creatinine concentration and some or all of the following variables: sex, age, weight and race, as suggested by the National Diabetes Association. An increase in creatinine clearance is generally accepted as a good indicator of kidney disease. CIN is usually defined as an increase in serum creatinine of 25% over baseline within four days of a procedure where contrast is administered.

Of the estimated 7 million diagnostic and interventional imaging procedures performed worldwide each year that involve the use of contrast agents, we believe that 15% of these cases, or approximately 1 million patients, could benefit from the use of our RenalGuard System and Therapy.

#### *RenalGuard System and Therapy*

RenalGuard is designed to reduce the toxic effects that contrast media can have on the kidneys, which may lead to a reduction in the incidence of CIN in at-risk patients. RenalGuard Therapy is based on existing published literature, including the industry-recognized PRINCE study, that supports the theory that inducing and maintaining high urine output through the kidneys allows the body to rapidly eliminate contrast, reducing its toxic effects.

Our RenalGuard System is a real-time measurement and matched fluid replacement device. The system is comprised of a software-controlled, fluid balancing system and a console with a delivery mechanism for sterile replacement fluid, including detectors, monitors and alarms. It is a closed loop system where the urine produced by the patient through a standard Foley-type catheter is continuously measured. A unique sterile disposable kit is required for each procedure.

Our RenalGuard Therapy entails the use of a standard FDA approved loop diuretic that induces the required high urine output that is measured and in real-time replaced with an equal volume of sterile solution, such as saline, by the RenalGuard System. This matched fluid replacement is intended to minimize the risk of over- or under-hydration, which can lead to increased patient risks, including pulmonary edema—a swelling and/or fluid accumulation in the lungs which leads to impaired gas exchange and may cause respiratory failure.

#### *Potential Benefits of RenalGuard*

We are attempting to bring RenalGuard to market as the first product of its kind. We believe it is a safe, innovative technology capable of achieving significant market adoption due to its evidence-based therapy and straightforward integration into hospital environments where contrast agents are routinely used.

#### *Evidence-based Therapy*

We have successfully completed supporting pre-clinical and human trials of our RenalGuard Therapy. The aim of these studies was to determine if very high urine outputs with precise matching of intravascular volume significantly reduced the risk of CIN.

These feasibility studies have given us confidence in our proof of concept by concluding that high urine output with matched fluid replacement to maintain intravascular volume reduced the incidence of CIN. These studies indicated a reduction in CIN relative to accepted predictive models and current literature for the patients studied, without the occurrence of any serious long-lasting adverse events.

#### *Straightforward Hospital Integration*

We believe RenalGuard can easily be integrated into hospital environments where contrast agents are routinely used. It leverages existing hospital resources to protect at-risk patients within the current therapy window.

RenalGuard is designed to be simple to operate and to have features that are similar to devices currently used by hospital staff.

### *Development Timeline*

RenalGuard is currently an investigational device. In December 2006, we received full FDA approval to conduct our first human clinical trial utilizing RenalGuard under an IDE. This pilot clinical trial was designed to evaluate the safety of RenalGuard and the ability of our RenalGuard System to accurately measure and balance fluid inputs and outputs on up to 40 patients undergoing a catheterization imaging procedure where contrast media would be administered.

We enrolled a total of 23 patients in this pilot study. Based upon the positive safety data collected in the study and discussions we had with FDA, we elected to stop enrolling new patients in the pilot study in November 2007. We submitted an IDE supplement to the FDA in February 2008 seeking approval to move from our pilot study to a pivotal clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN. In March 2008 the FDA granted us conditional approval to begin our pivotal study. We have received approval to study RenalGuard on 246 patients at up to 30 U.S. clinical sites. We expect to begin enrolling patients in this study this spring after obtaining necessary institutional review board approval at the clinical sites where the study will be conducted.

### *Near Term Commercialization Strategy*

On December 21, 2007 we announced that we had received the CE Mark Certificate for our RenalGuard System, clearing the way for us to begin our initial limited launch of the product in the European Union. We expect to focus our initial limited commercial launch activities for RenalGuard in 2008 on ten select hospital sites in Italy and prepare for a broader EU launch in 2009.

### *Other Potential Markets*

We plan to focus our short-term marketing efforts on the interventional cardiovascular and radiology markets and the reduction of CIN in imaging procedures requiring the use of contrast. In addition, we believe that our RenalGuard Therapy and System may be effectively used for patients undergoing other diagnostic treatments that require the use of contrast, such as CT scans and other radiography procedures.

### *Current Treatment Methods for CIN*

The only clinically accepted and endorsed preventive measure for patients at risk for CIN is pre- and post- procedure overnight hydration. There is currently no FDA approved device or drug for CIN prevention. However, we believe that there are a number of other companies developing or investigating potential new CIN preventive drugs, devices and therapies.

Other preventive measures being used in clinical practice today include:

#### *Mucomyst®*

N-acetylcysteine (Mucomyst®) is both a renal vasodilator and antioxidant. It is prescribed by a doctor prior to the start of an interventional procedure and is taken by the patient in prearranged doses that may start the day before the procedure. This therapy is employed by most physicians due to an extremely low risk profile and cost. Clinical data linking Mucomyst to a reduction in CIN is to date inconclusive.

### *Sodium bicarbonate*

Sodium bicarbonate is a pre-mixed pharmaceutical solution that is given intravenously on the same day as the procedure, prior to the start. Currently, there are only a small number of published studies that have evaluated utilizing sodium bicarbonate as a preventive measure. There is some industry adoption of this measure to reduce the incidence of CIN simply due to the lack of expense and low risk to patients.

### *Device-Based Competition*

FlowMedica, Inc. has introduced their Benephit® CV Infusion System, which is a catheter designed to deliver drugs and/or fluid directly to the renal arteries during an interventional procedure. This system is FDA 510(k)-cleared and CE marked for the infusion of physician-specified agents in the peripheral vasculature. We believe market challenges for this approach may include concerns regarding complications of direct renal intervention and the cost of the catheter.

## **Sales and Marketing Strategy**

### *TMR Products—Sales Channel*

On March 20, 2007, we appointed Novadaq Corp. (“Novadaq”), a subsidiary of Novadaq Technologies Inc., to succeed Edwards Lifesciences LLC (“Edwards”) as our exclusive U.S. distributor for the HL2 and all TMR disposable procedure kits. Outside the U.S., we have established an independent distributor network to market our TMR products, although in some areas, principally Europe, we continue to sell our TMR products directly to hospitals.

Novadaq is a medical device company that develops and commercializes medical imaging devices for use in the operating room. Their proprietary SPY® Intra-operative Imaging System enables cardiac surgeons to visually assess coronary bypass graft functionality during the course of open-heart surgery by means of an intravenous administration of a fluorescent imaging agent, IC-Green™, coupled with a low level infrared laser source. We believe Novadaq will continue to market our Heart Laser System and the TMR procedure as a treatment option to be used intra-operatively by the cardiac surgeon if their SPY Imaging System shows the surgeon that a bypass graft is not adequately providing new blood flow to a specific region of the heart as intended.

We believe this strong synergistic multi-product offering of the SPY Imaging System, which can be used by the cardiac surgeon as a real-time diagnostic device, and the Heart Laser System, which can be used as a real-time treatment option when bypass grafts are shown not to be functioning as intended, can be an effective sales tool with cardiac surgeons.

Novadaq currently employs a direct sales force that is responsible for marketing our TMR products along with their own SPY Imaging System, as well as other imaging related product lines they market for non-cardiac applications.

International sales (by origin) accounted for 3% of our total revenue in 2007, 8% in 2006 and 6% in 2005. We had no sales by origin in Canada, our jurisdiction of incorporation.

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

### *Marketing Programs*

As the exclusive U.S. distributor of our TMR products, Novadaq determines the programs, including sale, lease, rental and usage-based offerings, that it believes will be most effective in the U.S. in selling our products to hospitals.

Novadaq's marketing efforts are directed primarily at cardiothoracic surgeons, whose influence is believed to be critical in a hospital's decision to purchase our products. Novadaq emphasizes the synergistic nature of the SPY Imaging System and the Heart Laser System in their sales process with cardiac surgeons, highlighting the benefits the use of both these technologies can provide them in their efforts to provide patients with the most complete revascularization treatment.

### **Products and Customers**

We currently sell and service one principal product line, the Heart Laser Systems, which accounted for approximately 87%, 95% and 89% of our revenues for the years ended December 31, 2007, 2006 and 2005, respectively.

Our U.S. distributor (Novadaq currently and Edwards prior to March 20, 2007) is our largest customer and accounted for 85%, 88% and 89% of our total revenues in the years ended December 31, 2007, 2006 and 2005, respectively. We expect this sales concentration with one customer to continue for the near future.

### **Manufacturing**

We manufacture and test our products at our facility in Franklin, Massachusetts, approximately 40 miles west of Boston. We believe that our manufacturing capacity will be sufficient to meet market demands anticipated in the coming year for all our products.

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

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

### **Government Regulation**

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

As a device manufacturer, we are also required to register with the FDA. As such, we are subject to inspection on a routine basis for compliance with the FDA's Quality Systems regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements for reporting. The FDC Act and medical device reporting regulations require that we provide information to the FDA on deaths or serious injuries alleged to have been caused or contributed to by the use of our products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA also prohibits an approved device from being marketed for unapproved uses. Our product promotion and advertising is subject to continuing FDA regulation. Our laser products are subject to periodic inspection under the radiation health and safety provisions of the FDC Act for compliance with labeling and other safety

regulations. The failure to comply with the applicable regulatory requirements may subject us to a variety of administrative or judicially imposed sanctions, including the FDA's refusal to approve pending or supplemental applications, withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil and criminal penalties against that company or its officers, directors or employees. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

As a condition of our original FDA approval for our TMR products, we were required by the FDA to perform a postmarket surveillance study. The FDA requested that we submit a PMA Postapproval Study report summarizing this postmarket surveillance study. As part of this report, the FDA requested that we analyze and discuss the adverse event and mortality rates seen in the postmarket study and compare these results to the premarket study that was presented as part of our initial FDA PMA application. We filed this postapproval study report with the FDA on February 28, 2007.

Because of the significant safety information collected in the postapproval study, and as the FDA has indicated it plans to do in other product areas, we believe that the FDA plans to present the results at a future meeting of the FDA Circulatory System Devices Advisory Panel and thereafter determine what, if any, actions should be taken with respect to our current Heart Laser Systems PMA.

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

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

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

### **Third-Party Reimbursement**

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

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

higher TMR procedure reimbursement payment. In these instances, the doctor also can bill an additional amount for performing multiple procedures.

Certain private insurance companies and health maintenance organizations also currently provide reimbursement for TMR procedures performed with our products, and physician reimbursement codes have been established for TMR when performed as a sole therapy or as an adjunct to bypass surgery; however, we have limited data as to the breadth of this coverage for the TMR procedure by private insurance companies and health maintenance organizations.

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

### **Proprietary Processes, Patents, Licenses and Other Rights**

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

Since April 1992, we have received 33 U.S. patents. These patents have terms which expire from 2009 through 2023 and cover, among other things, laser technology to create a pulsed, fast-flow laser system, the use of a laser on a beating heart to revascularize the heart using TMR related disposable components, and the system used to time the heart's contractions to synchronize the laser firing at the correct time. We also have U.S. patent applications pending relating to technology used in the Heart Laser Systems and technologies associated with percutaneous myocardial revascularization. In addition, we have two patents issued and three applications filed in the field of percutaneous valves.

In addition, we currently have nine patent applications pending at the U.S. patent office in connection with the prevention of contrast induced nephropathy. Seven of the applications are related to our RenalGuard System and RenalGuard Therapy. The two additional applications cover other systems and methods for preventing contrast induced nephropathy and acute renal failure.

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

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

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

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

### **Competition**

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

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

In addition to their TMR system, CardioGenesis has pursued a "percutaneous" method of performing myocardial revascularization, previously known as PMR, and recently rebranded as PMC (percutaneous myocardial channeling). PMC procedures are performed via a catheter inserted through an incision in a patient's leg and is a less invasive method than TMR of creating channels in a human heart. CardioGenesis' PMC system was reviewed by the FDA Circulatory System Devices Panel in July 2001. That panel, in a 7-2 vote, found the PMA application for their PMC system to be not approvable. CardioGenesis has previously announced that they have approval from the FDA under an Investigation Device Exemption ("IDE") to conduct a new clinical trial related to PMC; however, we do not believe at this time that they have initiated a study pursuant to this IDE. Presently there are no FDA approved PMC devices in the marketplace and we are unable to assess whether there ever will be an approved PMC device in the marketplace.

We believe 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. We believe that our competitive success will be based on our ability to create and maintain scientifically effective and safe technology, obtain and maintain required regulatory approvals, obtain and maintain third party reimbursement for use of our products, attract and retain key personnel, obtain and maintain patent or other protection for our products and successfully differentiate, price, manufacture and market our products either directly or indirectly through outside parties.

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

### **Research and Development**

Research and development expenses were \$2,382,000, \$1,924,000 and \$2,750,000 for the years ended December 31, 2007, 2006 and 2005, respectively. We expect to continue to incur significant new research and development expenditures in future years. Our current and near term development efforts will be focused on performing clinical trials of RenalGuard, which should result in increased research and development expenditures through at least 2009.

We continue to monitor technologies that may be applicable to TMR or the market for CIN prevention. No assurance can be given that our research and development goals will be implemented successfully.

### **Employees**

As of March 14, 2008, we had 31 full-time employees worldwide, including our executive officers. Of these, seven are in general and administrative positions, three are involved in sales, six are involved in research and development, two are involved in clinical affairs, six are involved in manufacturing, five are involved in service and two are involved in quality and regulatory affairs. We also employ one part-time employee in administration. None of our employees are represented by a union. We consider our relationship with our employees to be good.

### **Company Information**

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

### **Item 1A. Risk Factors**

The risks and uncertainties described below are not the only risks we face. Additional risks and uncertainties not presently known to us or currently deemed immaterial may also impair our business

operations. If any of the following risks actually occur, our financial condition and operating results could be materially adversely affected.

***We expect to incur significant operating losses in the near future.***

We expect to incur net losses in future quarters, at least through 2009, as we increase our research and development on clinical studies of RenalGuard. We cannot provide any assurance that we will be successful with our business strategy, that RenalGuard will receive FDA approval or commercial acceptance, or that we will ever return to profitability.

***Our company may be unable to raise needed capital.***

As of December 31, 2007, we had cash and cash equivalents totaling \$8,060,000. Based on our current operating plan, we anticipate that our existing capital resources should be sufficient to meet our working capital requirements for at least the next 12 months; however, we will need to raise additional capital for the future in order to implement our business plan. We may not be able to raise additional capital upon satisfactory terms, or at all, and our business, financial condition and results of operations could be materially and adversely affected. To the extent that we raise additional capital by issuing equity or convertible securities, ownership dilution to our shareholders will result. To the extent that we raise additional capital through the incurrence of debt, our activities may be restricted by the repayment obligations and other restrictive covenants related to the debt.

***If we are unable to raise additional capital during 2008, our common stock could be delisted from AMEX.***

Our stockholders' equity was \$4,950,000 as of December 31, 2007. Under the AMEX listing guidelines, our common stock could be delisted from AMEX if our stockholders' equity is less than \$4,000,000, and if we sustained losses from continuing operations and/or net losses in three of our four most recent fiscal years. Based on our current projections, our stockholders' equity will fall below \$4,000,000 as of December 31, 2008 if we are not able to raise additional capital prior to that time. We are considering a number of options for raising additional capital but there can be no assurance that we will be successful. If our common stock were delisted from AMEX, we could face a number of negative implications, including reduced liquidity in our common stock as a result of the loss of market efficiencies associated with AMEX and the loss of federal preemption of state securities laws, as well as the potential loss of confidence by investors, suppliers, customers and employees, fewer business development opportunities and greater difficulty in obtaining financing or credit.

***Our company is currently dependent on one principal customer.***

Pursuant to the terms of our TMR distribution agreement with Novadaq, Novadaq is our exclusive distributor for our HL2 laser and TMR kits in the U.S. As a result of this exclusive arrangement, our U.S. distributor (Novadaq currently and Edwards prior to March 20, 2007) accounted for 85%, 88% and 89% of total revenues in the years ended December 31, 2007, 2006 and 2005, respectively, and we expect Novadaq to account for the significant majority of our revenue in the near future. As a result of this expected concentration of sales with Novadaq, we bear an increased financial risk of timely sales collection if, for any reason, Novadaq's business condition should suffer.

***We are dependent on Novadaq in the U.S. to attempt to increase our TMR revenues.***

Novadaq's sales organization is responsible for selling a number of different products, including our TMR products. We will be largely dependent on the future success of Novadaq's sales and marketing efforts in the U.S. to increase the installed base of HL2 lasers and TMR procedural volumes and revenues. If our relationship with Novadaq does not progress, or if Novadaq's sales and marketing

strategies fail to generate sales of our products in the future, our revenue will decrease significantly and our business, financial condition and results of operations will be seriously harmed.

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

We currently sell one principal product line, the Heart Laser Systems, which accounts for the majority of our total revenues. Approximately 87%, 95% and 89% of our revenues in the years ended December 31, 2007, 2006 and 2005, respectively, were derived from the sales and service of our Heart Laser Systems. This absence of a diversified product line means that we are directly and materially impacted by changes in the market for Heart Laser Systems. We believe that the number of opportunities for new TMR laser sales to hospital customers, and specifically sales of our HL2 laser, is likely to continue to decline in future quarters as a result of (1) a diminishing number of available hospitals that have not already implemented a TMR program that are still likely to in the future and (2) continuing financial pressures that hospitals face, in particular for the funding of new capital equipment purchases, in light of ongoing cutbacks in both Medicare and private insurance reimbursement rates for all medical procedures. In addition, we have seen a recent downward trend in the price that new TMR lasers are being sold at in the market, as competition for the remaining available customers increases. These market factors and our dependency on revenues related to sales of the Heart Laser System poses a serious risk to our ongoing ability to generate sufficient cash to fund our operations, which may seriously harm our business, financial condition and results of operations in future quarters.

***Our company is dependent on certain suppliers.***

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

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

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

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

Our current TMR products may never achieve widespread commercial acceptance. To be successful, we and Novadaq need to:

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

To date, only a limited number of heart surgeons have been trained in the use of TMR using the Heart Laser Systems. We are dependent on Novadaq to expand related marketing and training efforts in the U.S. for the use of our products.

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

If we are unable to achieve widespread commercial acceptance of the Heart Laser Systems, our business, financial condition and results of operations will be materially and adversely affected.

*Our newest product, RenalGuard, has only had limited testing in a clinical setting and we may need to modify it in the future to be commercially acceptable.*

We have only completed the first generation product design for our RenalGuard System and we have only been able to perform a limited amount of testing of this device in a clinical hospital setting as part of our recently completed initial pilot human clinical study. We may need to make substantial modifications to the design, features or functions of our device in order for it to obtain FDA approval or meet customer expectations. These changes may not be able to be completed in a timely fashion, if at all. Should any such modifications prove to be significantly more costly or time consuming to engineer than we estimate, our ability to bring this product to market may be severely and negatively impacted.

*Our planned future U.S. pivotal clinical trial to study the safety and effectiveness of RenalGuard in preventing contrast-induced nephropathy will take us a significant amount of time to complete, if we can complete it at all, and the results of this clinical trial may not show sufficient safety and efficacy for us to either obtain FDA approval or otherwise be able to successfully market and sell the product.*

Our business strategy to grow our revenues and profitability is largely dependent on our success in timely completion of our planned future U.S. pivotal clinical trial of RenalGuard. We hope to be able to demonstrate through this clinical trial that RenalGuard is safe and effective in preventing CIN.

We can provide no assurance that when studied in humans, RenalGuard will be shown to be safe or effective in preventing CIN, or that the degree of any positive safety and efficacy results will be sufficient to either obtain FDA approval or otherwise successfully market our product. Furthermore, the completion of our planned clinical trial is dependent upon many factors, some of which are not entirely within our control, including, but not limited to, our ability to successfully recruit investigators, the availability of patients meeting the inclusion criteria of our clinical study, the competition for these

particular study patients amongst other clinical trials being conducted by other companies at these same study sites, the ability of the sites participating in our study to successfully enroll patients in our trial, and proper data gathering on the part of the investigating sites.

Should our U.S. pivotal clinical trial take longer than we expect, our competitive position relative to existing preventative measures, or relative to new devices, drugs or therapies that may be developed, could be seriously harmed and our ability to successfully fund the completion of the trial and bring RenalGuard to market may be adversely affected.

*We will need to build a direct sales and marketing organization or otherwise enter into one or more distribution arrangements in order to market our RenalGuard System in the U.S, if and when it is approved for sale, and in the EU, as we prepare for a sales launch in this market in 2009.*

We currently do not have a direct sales force. Instead, we market our existing TMR products through Novadaq in the U.S. and through independent distributors outside the U.S. We do not plan to use Novadaq or our current international TMR distributors to market our RenalGuard System if and when it becomes commercially available to customers. We will need to either build an internal direct sales and marketing organization or find new distribution partners in order to successfully market our RenalGuard System.

If we choose to build a direct sales force, we may not be able to attract qualified individuals with the requisite training or experience to sell our product. In addition, we would need to devote substantial management time instituting policies, procedures and controls to oversee and effectively manage this new part of our organization, which could adversely impact our daily operations and would require us to invest significant financial resources, the cost of which could be prohibitive.

If we instead choose to pursue an indirect distribution strategy, which is our current plan for the EU market, we may not be able to identify suitable distribution partners with sufficient industry experience, brand recognition, sales capacity and willingness or ability to maximize sales. Further, we may not be able to negotiate distribution agreements with terms and conditions that are acceptable to us, including ensuring that our product receives adequate sales force focus and attention.

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

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

*Rapid technological changes in our industry could make our products obsolete.*

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

Many potential competitors have substantially greater financial resources and are in a better financial position to exploit marketing and research and development opportunities.

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

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

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

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

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

- warning letters;
- patient or physician notification;
- restrictions on our products or manufacturing processes;
- voluntary or mandatory recalls;
- product seizures;
- refusal to approve pending applications or supplements to approved applications that we submit;
- refusal to permit the import or export of our products;

- fines;
- injunctions;
- suspension or withdrawal of marketing approvals or clearances; and
- civil and criminal penalties.

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

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

***Heart Laser Systems***

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

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

In addition, as a condition of our original FDA approval for our TMR products, we were required by the FDA to perform a postmarket surveillance study. The FDA requested that we submit a PMA Postapproval Study report summarizing this postmarket surveillance study. As part of this report, the FDA requested that we analyze and discuss the adverse event and mortality rates seen in the postmarket study and compare these results to the premarket study which was presented as part of our initial FDA PMA application. We filed this postapproval study report with the FDA on February 28, 2007.

Because of the significant safety information collected in the postapproval study, and as the FDA has indicated it plans to do in other product areas, we believe that the FDA plans to present the results at a future meeting of the FDA Circulatory System Devices Advisory Panel and thereafter determine what, if any, actions should be taken with respect to our current Heart Laser Systems PMA.

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

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

*Japan*—Our HL1 Heart Laser System received marketing approval from the Japanese Ministry of Health, Labor and Welfare (“MHLW”) in May 2006. However, the MHLW could impose restrictions in the future or reverse its ruling and prohibit use of the Heart Laser Systems at any time.

In addition, it is unclear what impact the introduction of the HL2 into the U.S. and other international markets will have on the ability of our Japanese distributor to market our older, first generation HL1 in Japan. Although our Japanese distributor has indicated to us that it plans to seek MHLW approval in the future to market our newer HL2, we can provide no assurance that the distributor will be successful in obtaining the necessary approvals or how long it may take to secure the required approvals.

### *RenalGuard*

We presently have approval to market RenalGuard only in the EU. We must receive either FDA approval or clearance before we can market RenalGuard in the United States. Other countries may require their own approvals prior to our being able to market RenalGuard in those countries.

The process of obtaining and maintaining regulatory approvals and clearances to market a medical device can be costly and time consuming, and we cannot predict when, if ever, such approvals or clearances will be granted. Pursuant to FDA regulations, unless an exemption is available, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved PMA application. The FDA will clear marketing of a medical device through the 510(k) process only if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products.

At the present time we are not aware of any clear predicates with substantially the same proposed indications for use which would enable us to conclude that RenalGuard is likely to be cleared by the FDA as a 510(k) device. Therefore, we believe RenalGuard most likely will need to go through the PMA application process.

Because the PMA application process is more costly, lengthy and uncertain than the 510(k) process and must be supported by extensive data, including data from preclinical studies and human clinical trials, we cannot predict when RenalGuard may eventually come to market in the U.S. Should we be unable to obtain FDA approval for RenalGuard, or should the approval process take longer than we anticipate, our future revenue growth prospects will be materially and adversely affected.

### *Changes in third party reimbursement for TMR procedures or our inability to obtain third party reimbursement for RenalGuard could materially affect future demand for our products.*

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

Certain private insurance companies and health maintenance organizations also currently provide reimbursement for TMR procedures performed with our products and physician reimbursement codes have been established for both surgical procedures.

No assurance can be given, however, that these payers will continue to reimburse healthcare providers who perform TMR procedures using our products now or in the future. Further, no assurance can be given that additional payers will reimburse healthcare providers who perform TMR procedures using our products or that reimbursement, if provided, will be timely or adequate.

Should third party insurance reimbursement for TMR procedures be reduced or eliminated in the future, our business, financial condition and results of operations would be materially and adversely affected.

Furthermore, we know of no existing Medicare coverage or other third party reimbursement that would be available to either hospitals or physicians that would help defray the additional cost that would result from the future purchase and/or use of our RenalGuard System. We also can provide no

assurance that we will ever be able to obtain Medicare coverage or other third party reimbursement for the use of RenalGuard, which could materially and adversely affect the potential future demand for this product.

In addition, the market for our all our products could be adversely affected by future legislation to reform the nation's healthcare system or by changes in industry practices regarding reimbursement policies and procedures.

***Securing intellectual property rights for our RenalGuard System is critical to our future business plans, but may prove to be difficult or impossible for us to obtain.***

We have filed nine patent applications with the U.S. patent office related to our RenalGuard System, RenalGuard Therapy and other intellectual property in the general field of preventing contrast-induced nephropathy and acute renal failure. Securing patent protection over our intellectual property ideas in this field is, we believe, critical to our plans to successfully differentiate and market our RenalGuard System and grow our future revenues. We can provide no assurance, however, that we will be successful in securing any patent protection for our intellectual property ideas in this field or that our efforts to obtain patent protection will not prove more difficult, and therefore more costly, than we are otherwise expecting. Furthermore, even if we are successful in securing patent protection for some or all of our intellectual property ideas in this field, we cannot predict when in the future any such potential patents may be issued, how strong such patent protection will prove to be, or whether these patents will be issued in a timely enough fashion to afford us any commercially meaningful advantage in marketing our RenalGuard System against other potentially competitive devices.

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

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

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

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

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

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

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

***We are subject to risks associated with international operations.***

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

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

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

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

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

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

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

Certain current shareholders hold large amounts of our stock, which they could seek to sell in the public market from time to time. Sales of a substantial number of shares of our common stock within a

short period of time would cause our stock price to fall. In addition, the sale of these shares could impair our ability to raise capital through the sale of additional stock.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

We maintain our principal executive offices and manufacturing and development operations in 24,000 square feet of leased space in Franklin, Massachusetts. The lease on this space expires on August 31, 2009. The total base rental payments for the fiscal years ending December 31, 2008 and for the eight months ending August 31, 2009 are approximately \$261,000 and \$176,000, respectively. We are also responsible for certain operating and maintenance costs and real estate taxes.

**Item 3. Legal Proceedings**

We are not presently involved in any material litigation proceedings.

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

Not applicable.

**PART II**

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

Since September 17, 1992, our common stock has traded on the American Stock Exchange ("AMEX") under the symbol "PLC". On March 14, 2008, the last sale price of our common stock was \$0.42 per share.

For the periods indicated, the following table sets forth the range of high and low sales prices for our common stock from January 1, 2006.

<u>2006</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$0.86	\$0.49
Second Quarter .....	\$1.25	\$0.61
Third Quarter .....	\$1.30	\$0.80
Fourth Quarter .....	\$0.97	\$0.53
<u>2007</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$0.65	\$0.51
Second Quarter .....	\$1.12	\$0.56
Third Quarter .....	\$0.64	\$0.43
Fourth Quarter .....	\$0.78	\$0.25

As of March 14, 2008, there were 719 record holders of our common stock. We believe that there are approximately 7,624 beneficial owners of our common stock.

**Dividends**

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

## Canadian Tax Matters

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

This summary is based on the current provisions of the Income Tax Act (Canada), the regulations thereunder and the Canada—United States Income Tax Convention (1980), as amended (the “Tax Convention”). This summary is not exhaustive of all possible Canadian federal income tax consequences and does not take into account provincial, territorial or foreign income tax considerations. This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice to any holder of the common stock and no representation with respect to Canadian federal income tax consequences to any holder of common stock is made herein. Accordingly, prospective purchasers and holders of the common stock should consult their own tax advisers with respect to their individual circumstances.

### *Sales or Other Dispositions of Shares*

A capital gain realized on the disposition of common stock by a person resident in the U.S. (a “non-resident”) will not be subject to tax under the Income Tax Act (Canada) unless the shares held by the non-resident are “taxable Canadian property” at the time of disposition. In general, common stock will be taxable Canadian property if the particular non-resident used (or in the case of a non-resident insurer, used or held) the common stock in carrying on business in Canada or where at any time during the five-year period immediately preceding the realization of the gain, not less than 25% of the issued and outstanding shares of any class or series of shares of the company, which were listed on a prescribed stock exchange, were owned by the particular non-resident, by persons with whom the particular non-resident did not deal at arms’ length, or by any combination thereof. The AMEX is a prescribed stock exchange for the purposes of the Income Tax Act (Canada). If common stock constitutes taxable Canadian property, relief nevertheless may be available under the Tax Convention. Under the Tax Convention, gains from the alienation of common stock owned by a non-resident who has never been resident in Canada generally will be exempt from Canadian capital gains tax if the shares do not relate to a permanent establishment or fixed base which the non-resident has or had in Canada, and if not more than 50% of the value of the shares was derived from real property situated in Canada. With regard to a non-resident qualifying for benefits under the Tax Convention, it is the Canada Revenue Agency’s published administrative position that certain entities that are treated as being fiscally transparent for U.S. federal income tax purposes (i.e., limited liability companies) will not qualify as residents of the U.S. for the purposes of the Tax Convention.

### *Taxation of Dividends on Common Stock*

In the event that dividends on our common stock are paid, credited or deemed to be paid or credited to a non-resident, the non-resident will be subject to Canadian withholding tax at a rate of 25% of the gross amount of the dividend. Under the Tax Convention, the withholding tax rate is reduced to 15% of the gross amount of the dividend. Also under the Tax Convention, dividends may be exempt from Canadian withholding tax if paid to certain non-residents (i.e., certain tax exempt organizations). Prospective purchasers and holders of our common stock should consult their own tax advisers with regard to any possible exemption from withholding tax on dividends paid on our common stock.

*Passive Foreign Investment Company Implications*

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

**Item 6. Selected Financial Data**

The following selected financial data for the five years ended December 31, 2007 are derived from our audited consolidated financial statements. This data should be read in conjunction with the consolidated financial statements, related notes and other financial information included elsewhere herein.

	For the years ended December 31,				
	2007	2006	2005	2004	2003
	<i>(All amounts are in thousands except per share data)</i>				
<b>Statement of Operations Data:</b>					
Revenues:					
Product sales	\$ 4,564	\$ 5,662	\$ 6,097	\$ 5,982	\$ 6,899
Service fees	1,440	1,484	1,539	1,591	1,435
Total revenues	<u>6,004</u>	<u>7,146</u>	<u>7,636</u>	<u>7,573</u>	<u>8,334</u>
Cost of revenues	2,635	2,732	3,066	3,069	3,343
Gross profit	<u>3,369</u>	<u>4,414</u>	<u>4,570</u>	<u>4,504</u>	<u>4,991</u>
Operating expenses:					
Selling, general and administrative	3,794	3,014	3,336	3,329	3,297
Research and development	2,382	1,924	2,750	2,130	980
Total operating expenses	6,176	4,938	6,086	5,459	4,277
Gain on sale of manufacturing rights	—	1,432	—	—	—
Income (loss) from operations	(2,807)	908	(1,516)	(955)	714
Other income, net	426	436	248	175	60
Liquidation of subsidiary:					
Foreign currency loss	—	—	—	—	(257)
Income (loss) before income taxes	(2,381)	1,344	(1,268)	(780)	517
Provision for (benefit from) income taxes	(14)	25	—	53	—
Net income (loss)	<u>\$ (2,367)</u>	<u>\$ 1,319</u>	<u>\$ (1,268)</u>	<u>\$ (833)</u>	<u>\$ 517</u>
Basic and diluted earnings (loss) per share	<u>\$ (0.08)</u>	<u>\$ 0.04</u>	<u>\$ (0.04)</u>	<u>\$ (0.03)</u>	<u>\$ 0.02</u>
Average shares outstanding:					
Basic	30,318	30,170	30,074	30,025	29,826
Diluted	30,318	30,572	30,074	30,025	30,414

	As of December 31,				
	2007	2006	2005	2004	2003
	<i>(All amounts are in thousands)</i>				
<b>Balance Sheet Data:</b>					
Working capital	\$ 6,922	\$ 9,849	\$ 8,964	\$ 10,658	\$ 7,405
Total assets	11,200	13,176	12,467	13,327	9,849
Stockholders' equity	4,950	7,129	5,543	6,829	7,556

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

### **Overview**

We are a medical device company specializing in innovative technologies for the cardiac and vascular markets. We pioneered and manufacture the Heart Laser System that cardiac surgeons use to perform TMR to alleviate symptoms of severe angina. We also manufacture  $CO_2$  surgical laser tubes and provide contract assembly services on general purpose  $CO_2$  lasers.

In addition, in 2007, we began treating patients in our initial pilot clinical safety trial for our RenalGuard Therapy and RenalGuard System. RenalGuard Therapy is designed to reduce the toxic effects that contrast media can have on the kidneys. This therapy is based on the theory that creating and maintaining a high urine output is beneficial to patients undergoing cardiovascular imaging procedures where contrast agents are used. The real-time measurement and matched fluid replacement design of our RenalGuard System is intended to ensure that a high urine flow is maintained before, during and after these procedures, thus allowing the body to rapidly eliminate contrast, reducing its toxic effects. The RenalGuard System, with its matched fluid replacement capability, is intended to minimize the risk of over- or under-hydration.

We enrolled a total of 23 patients in our initial pilot safety study. Based upon the positive safety data collected in the study and discussions we had with the FDA, we elected to stop enrolling new patients in the pilot study in November 2007. We submitted an IDE supplement to the FDA in February 2008 seeking approval to move from our pilot study to a pivotal clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN. In March 2008 the FDA granted us conditional approval to begin our pivotal study. We have received approval to study RenalGuard on 246 patients at up to 30 U.S. clinical sites. We expect to begin enrolling patients in this study this spring after obtaining necessary institutional review board approval at the clinical sites where the study will be conducted.

Our U.S. distributor for the Heart Laser System (Novadaq currently and Edwards prior to March 20, 2007) is our largest customer, accounting for 85%, 88% and 89% of our total revenues in the years ended December 31, 2007, 2006 and 2005, respectively. We expect a high level of sales concentration to continue in the near future with Novadaq as our largest customer now that it holds the exclusive U.S. distribution rights for our TMR products.

Approximately 87%, 95% and 89% of our revenues in the years ended December 31, 2007, 2006 and 2005, respectively, came from the sale and service of TMR lasers and related disposable kits. We believe that the number of opportunities for new TMR laser sales to hospital customers, and specifically sales of our HL2 laser, is likely to continue to decline in future quarters as a result of (1) a diminishing number of available hospitals that have not already implemented a TMR program that are still likely to in the future and (2) continuing financial pressures that hospitals face, in particular for the funding of new capital equipment purchases, in light of ongoing cutbacks in both Medicare and private insurance reimbursement rates for all medical procedures. In addition, we have seen a recent downward trend in the price that new TMR lasers are being sold at in the market as competition for the remaining available customers increases. As such, we expect to continue to see a decline in revenue generated from the sale of HL2 lasers in future quarters and TMR revenues in future quarters will be more dependent on the sale of TMR kits and service revenues.

Aggregate TMR kit shipments to U.S. hospitals through Novadaq and Edwards decreased approximately 20% and 22% in the three and twelve months ended December 31, 2007 as compared to the three and twelve months ended December 31, 2006, respectively. We believe the decline in fourth quarter TMR kit shipments was primarily the result of the transition from an experienced Edwards' sales force to the new Novadaq sales team.

We believe the decline in TMR kit shipments between the respective twelve month periods is due to (1) lower than normal TMR sales activities conducted by Edwards during the first quarter of 2007, as Edwards focused its sales force on product lines other than TMR in anticipation of assigning its TMR distribution rights, (2) initial sales channel transition issues, which included the need to train the Novadaq sales force on TMR and the Heart Laser System, and (3) reduced TMR marketing activities during the third quarter of 2007, as Novadaq was forced to divert attention to a critical inventory component supply shortage for its principal product line (the SPY Imaging System), as well as disruptions brought on by Novadaq's implementation of a new sales force structure in the third quarter.

While we believe it is likely that our first and second quarter revenues and results of operations in 2008 will be lower than the corresponding periods in 2007, we believe that during the second half of 2008 TMR kit shipments from Novadaq to U.S. hospitals may equal or slightly exceed the corresponding TMR kit shipments to U.S. hospitals in the second half of 2007.

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

### **Critical Accounting Policies and Estimates**

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

#### ***Inventories***

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

#### ***Accounts Receivable***

Accounts receivable is stated at the amount we expect to collect from the outstanding balance. We continuously monitor collections from customers, and we maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues that we have identified. Historically, we have not experienced significant losses related to our accounts receivable, primarily from Edwards and, more recently, Novadaq. Collateral is not generally required. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

#### ***Research and Development***

Research and development costs are expensed as incurred.

### *Warranty and Preventative Maintenance Costs*

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

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

### *Revenue Recognition*

We record revenue from the sale of TMR kits at the time of shipment to Novadaq. TMR kit revenues include the amount invoiced to Novadaq for kits shipped pursuant to purchase orders received, as well as an amortized portion of deferred revenue related to a payment of \$4,533,333 received in February 2004. This payment was made in exchange for a reduction in the prospective purchase price we receive upon a sale of the kits. We are amortizing this payment into our Consolidated Statements of Operations as revenue over a seven year period (culminating in 2010) under the units-of-revenue method as prescribed by Emerging Issues Task Force 88-18, "Sales of Future Revenue". We determined that a seven year timeframe was the most appropriate amortization period based on a valuation model we used to assess the economic fairness of the payment. Factors we considered in developing this valuation model included the estimated foregone revenues over a seven year period resulting from the reduction in the prospective purchase price payable to us, a discount rate deemed appropriate to this transaction and an estimate of the remaining economic useful life of the current TMR kit design, without any benefit being given to potential future product improvements we may make. We review annually, and adjust if necessary, the prospective revenue amortization rate for kits based on our best estimate of the total number of kits likely remaining to be shipped to hospital customers by Novadaq through 2010. We recorded amortization of \$660,000, \$630,000 and \$356,000 in the years ended December 31, 2007, 2006 and 2005, respectively, which is included in revenues in our Consolidated Statements of Operations.

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

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

We record all other product revenue, including sales of TMR lasers and kits to international customers and OEM sales of surgical tubes and general purpose CO<sub>2</sub> lasers, at the time of shipment.

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

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

## Results of Operations

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

	2007		2006		2005	
	(dollars in thousands)					
Total revenues	\$ 6,004	100%	\$ 7,146	100%	\$ 7,636	100%
Total cost of sales	2,635	44	2,732	38	3,066	40
Gross profit	3,369	56	4,414	62	4,570	60
Selling, general and administrative	3,794	63	3,014	42	3,336	44
Research and development	2,382	40	1,924	27	2,750	36
Gain on sale of manufacturing rights	—	—	1,432	20	—	—
Income (loss) from operations	(2,807)	(47)	908	13	(1,516)	(20)
Other income	426	7	436	6	248	3
Income (loss) before income taxes	(2,381)	(40)	1,344	19	(1,268)	(17)
Provision for (benefit from) income taxes	(14)	1	25	1	—	—
Net income (loss)	<u>\$(2,367)</u>	<u>(39)%</u>	<u>\$1,319</u>	<u>18%</u>	<u>\$(1,268)</u>	<u>(17)%</u>

	2007	Increase (decrease) over 2006	2006	Increase (decrease) over 2005	2005		
	(dollars in thousands)						
Product sales	\$ 4,564	\$(1,098)	(19)% \$5,662	\$ (435)	(7)% \$ 6,097		
Service fees	1,440	(44)	(3)	1,484	(55)	(4)	1,539
Total revenues	6,004	(1,142)	(16)	7,146	(490)	(6)	7,636
Product cost of sales	1,829	(202)	(10)	2,031	(285)	(12)	2,316
Service fees cost of sales	806	105	15	701	(49)	(7)	750
Total cost of revenues	2,635	(97)	(4)	2,732	(334)	(11)	3,066
Gross profit	3,369	(1,045)	(24)	4,414	(156)	(3)	4,570
Selling, general and administrative expenses	3,794	780	26	3,014	(322)	(10)	3,336
Research and development expenses	2,382	458	24	1,924	(826)	(30)	2,750
Total operating expenses	6,176	1,238	25	4,938	(1,148)	(19)	6,086
Gain on sale of manufacturing rights	—	(1,432)	(100)	1,432	1,432	100	—
Other income	426	(10)	(2)	436	188	76	248
Income (loss) before income taxes	(2,381)	(3,725)	(277)	1,344	2,612	206	(1,268)
Provision for (benefit from) income taxes	(14)	(39)	(156)	25	25	100	—
Net income (loss)	<u>\$(2,367)</u>	<u>\$(3,686)</u>	<u>(279)%</u>	<u>\$1,319</u>	<u>\$ 2,587</u>	<u>204%</u>	<u>\$(1,268)</u>

### Product Sales

Disposable TMR kit revenues, the largest component of product sales in 2007, decreased by \$586,000, or 21%, in 2007 as compared to 2006. Domestic disposable TMR kit revenues decreased \$548,000 resulting from a lower volume of kit shipments to Novadaq than to Edwards in 2006. This decrease in TMR kit shipments to Novadaq was offset in part by a \$30,000 increase in deferred kit revenue amortization. International disposable TMR kit revenues decreased \$68,000 due to a lower volume of TMR kit shipments to international customers.

TMR laser revenues, the second largest component of product sales in 2007, decreased by \$930,000, or 37%, as compared to 2006. This decrease is primarily attributable to a \$662,000, or 30%, decrease in domestic TMR laser revenues primarily as a result of (1) decreased revenue sharing earned under our TMR distribution agreements with Edwards and Novadaq and (2) a lower average selling price on new TMR lasers sold. International TMR laser revenues decreased \$268,000 due to the sale of two lasers to international customers in 2006, whereas there were no international TMR laser sales in 2007.

Other product sales increased \$418,000, or 112%, in 2007 as compared to 2006. This increase was driven primarily by (1) new manufacturing contract assembly product revenues, which we commenced as a new source of revenue during the fourth quarter of 2006, (2) increased sales of new and refurbished surgical tubes to a single OEM customer and (3) increased Optiwave 980 revenues to Edwards. In December 2006, Edwards announced the discontinuation of the Optiwave 980, which we manufactured for Edwards under a supply agreement prior to its being discontinued. We do not expect to generate any revenues from this product line in the future. We believe we will record a similar level of other product sales in 2008 as in 2007.

Disposable TMR kit revenues, the largest component of product sales in 2006, increased by \$471,000, or 20%, in 2006 as compared to 2005. The increase is primarily related to a \$442,000, or 20%, increase in domestic disposable revenues resulting from a \$274,000 increase in deferred revenue amortization related to the \$4,533,333 payment by Edwards and a higher volume of kit shipments to Edwards. International disposable TMR kit revenues increased \$29,000, or 24%, in 2006 as compared to 2005.

TMR laser revenues, the second largest component of product sales in 2006, decreased by \$472,000, or 16%, in 2006 as compared to 2005. This decrease is primarily attributable to a \$675,000, or 23%, decrease in domestic TMR laser revenues generated through our Edwards sales channel. The \$675,000 decline in domestic TMR laser revenues is primarily a result of (1) decreased revenue sharing earned under the TMR distribution agreement with Edwards and (2) a decrease in the number of new TMR lasers sold by Edwards in 2006 compared to 2005. International TMR laser revenues increased \$203,000 due to the sale of two TMR lasers in 2006, while there were no TMR laser sales in 2005.

Optiwave 980 revenues to Edwards decreased \$325,000, or 94% in 2006, as compared to 2005 due to a lower number of Optiwave 980 units sold to Edwards in 2006.

Other product sales, which related to sales of new and refurbished surgical tubes in 2006 and 2005, decreased \$109,000, or 24%, as compared to 2005.

#### ***Service Fee Revenues***

Service fees decreased \$44,000, or 3%, in 2007 as compared to 2006, and decreased \$55,000, or 4%, in 2006 as compared to 2005. These decreases were primarily a result of decreased international service fee revenues due to decreased service billings to international customers.

#### ***Gross Profit***

Total gross profit was \$3,369,000, or 56% of total revenues, in 2007 as compared with gross profit of \$4,414,000, or 62% of total revenues, in 2006. The decrease in gross profit is due to (1) lower disposable TMR kit revenues, (2) a decrease in revenue sharing earned under our U.S. TMR distribution agreements with Edwards and Novadaq and (3) a lower average selling price on new TMR lasers sold. These decreases were offset in part by higher gross profit dollars generated from (1) increased revenues from new and refurbished surgical tubes and contract assembly services and (2) lower period manufacturing expenses.

Total gross profit was \$4,414,000, or 62% of total revenues, in 2006 as compared with gross profit of \$4,570,000, or 60% of total revenues, in 2005. The decrease in gross profit dollars in 2006 as compared to 2005 is due to (1) a decrease in additional revenue sharing earned under the TMR distribution agreement, (2) a decrease in the number of new TMR lasers sold, (3) a decrease in the number of Optiwave 980 units sold, (4) an obsolescence reserve related to the net realizable value of Optiwave 980 inventory due to Edwards' discontinuance of the Optiwave 980 program and (5) lower sales of new and refurbished surgical tubes. These decreases were offset in part by (1) higher disposable TMR revenues and (2) higher international TMR laser revenues. The gross margin percent increased in 2006 over 2005 due to a more favorable sales mix of higher margin items.

#### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenditures increased 26% in 2007 as compared to 2006. This increase was related to increased headcount and higher compensation expense, increased overall spending on sales and marketing activities related to RenalGuard, as well as higher corporate and legal expenditures incurred in connection with (1) the transfer of the U.S. TMR distribution agreement and (2) RenalGuard clinical trial contracts.

Selling, general and administrative expenditures decreased 10% in 2006 as compared to 2005. This decrease is related to lower incentive compensation, corporate and legal expenditures offset in part by increased consulting and bad debt expenses.

#### ***Research and Development Expenses***

Research and development expenditures increased 24% in 2007 as compared to 2006. This increase was primarily due to an increase in clinical trial expenditures for RenalGuard, partially offset by decreases in expenditures in connection with new product development costs related to RenalGuard.

Research and development expenditures decreased 30% in 2006 as compared to 2005. There was a decrease in expenditures in connection with both the Optiwave 980 and RenalGuard products.

We expect to continue to incur significant new research and development expenditures in 2008 and 2009 as we progress with our clinical trials of RenalGuard.

#### ***Other Income***

The largest component of other income consists of interest income earned on our cash, cash equivalents and short-term investments. Interest income decreased \$10,000 in 2007 as compared to 2006 due to lower average investable balances in 2007 offset in part by higher interest rates earned on those investable balances. Interest income increased \$188,000 in 2006 as compared to 2005 primarily due to higher interest rates earned on our cash, cash equivalents and short-term investments.

#### ***Provision for (Benefit from) Income Taxes***

In 2007, we recorded a benefit for income taxes resulting from an income tax refund related to the year ended December 31, 2006.

In 2006, we recorded a provision for income taxes due to limitations on the utilization of U.S. net operating loss carryforwards being available to reduce taxable income. Under the Internal Revenue Code of 1986, as amended (the "Code"), certain substantial changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in any one year to offset future taxable income.

### *Net Income (Loss)*

In 2007, we recorded a net loss of \$2,367,000 as compared to net income of \$1,319,000 in 2006. We recorded lower sales, lower gross margin and higher operating expenses in 2007 as compared to 2006. The 2006 period also included a non-recurring gain from the sale of our Optiwave 980 manufacturing rights to Edwards.

In 2006, we recorded a gain from the sale of our Optiwave 980 disposable manufacturing rights to Edwards. This non-recurring gain as well as a decrease in overall operating expenses resulted in net income of \$1,319,000 as compared to a net loss of \$1,268,000 in 2005.

### *Kit Shipments*

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

	2007	% Increase (Decrease) Over 2006	2006	% Increase (Decrease) Over 2005	2005
Domestic (U.S. Distributor) . . . . .	1,566	(22)%	1,996	(3)%	2,056
International . . . . .	32	(60)	81	(7)	87
Total . . . . .	1,598	(23)%	2,077	(3)%	2,143

In addition to the impact of factors previously discussed that we believe affected kit shipments in 2007, it is our belief that TMR kit shipments in recent years were also largely affected by what we believe was an ongoing downward trend in the number of bypass surgeries being performed. We believe the proliferation in the number of interventional cardiac procedures being performed, particularly with the increased use of drug-eluting stents, was causing a delay in the number of patients being referred to cardiac surgeons for treatment of their cardiovascular disease. Because a significant number of the total TMR procedures performed each year by cardiac surgeons are done in combination with bypass surgery, we believe the number of TMR procedures in years prior to 2007 was adversely impacted by a reduction in the number of bypass surgeries performed.

### **Liquidity and Capital Resources**

Cash, cash equivalents and short-term investments totaled \$8,060,000 as of December 31, 2007, a decrease of \$1,974,000 from \$10,034,000 as of December 31, 2006. We have no debt obligations. We believe that our existing cash resources will meet our working capital requirements through at least the next 12 months.

Cash used for operating activities in 2007 was \$1,803,000 due to our net loss, partially offset by favorable working capital changes, non-cash depreciation and amortization and compensation related to stock options. We used \$200,000 for the purchase of equipment. Additional cash of \$9,000 resulted from the exercise of stock options and proceeds from our employee stock purchase plan and \$20,000 was provided by the effect of exchange rate changes.

We will be largely dependent on the future success of Novadaq's sales and marketing efforts in the U.S. to continue to increase the installed base of HL2 lasers and to substantially increase TMR procedural volumes and revenues. Should the installed base of HL2 lasers or TMR procedural volume not increase sufficiently, our liquidity and capital resources will be negatively impacted. Additionally, other unanticipated decreases in operating revenues or increases in expenses or changes or delays in

third-party reimbursement to healthcare providers using our products would adversely impact our cash position and require further cost reductions or the need to obtain additional capital. It is not certain that we, working with Novadaq and our international distributors, will be successful in achieving broad commercial acceptance of the Heart Laser Systems, or that we will be able to operate profitably in the future on a consistent basis, if at all.

Some hospital customers prefer to acquire the Heart Laser Systems on a usage basis rather than as a capital equipment purchase. We believe this is the result of limitations many hospitals currently have on acquiring expensive capital equipment as well as competitive pressures in the marketplace. A usage business model will result in a longer recovery period for Novadaq to recoup its investment in lasers it may purchase from us in the future. This results in (1) a delay in our ability to receive additional shared revenue, if any, that we otherwise are entitled to receive under the terms of our new distribution agreement with Novadaq and (2) a potential delay in the purchase of new lasers by Novadaq if the installed base of lasers placed under usage contracts are under-performing and Novadaq chooses to re-deploy these lasers to other hospital sites in lieu of purchasing a new laser from us.

We believe we will incur losses at least through 2009 as we increase our research and development spending in order to conduct the clinical trials that are necessary to obtain the regulatory approval to market RenalGuard. We cannot be certain that future sales, if any, of RenalGuard will justify the investments we plan to make. If we are unsuccessful in implementing our business strategy to introduce RenalGuard, or if the introduction of RenalGuard takes longer or costs more than anticipated, our liquidity and capital resources will be adversely affected.

There can be no assurance that the future capital we will need to implement our business plan will be available on terms and conditions acceptable to us, especially considering the current uncertainty in the global credit markets. Should additional financing not be available on terms and conditions acceptable to us, our AMEX listing may be jeopardized, and we might need to curtail our RenalGuard program and take additional actions that could adversely impact our ability to continue to realize assets and satisfy liabilities in the normal course of business. The consolidated financial statements set forth in this report do not include any adjustments to reflect the possible future effects of these uncertainties.

**Contractual Obligations**

Our long-term contractual commitments as of December 31, 2007 consisted of an operating lease for our facility in Franklin, Massachusetts, which expires in August 2009, and purchase commitments to make payments to suppliers. Future annual minimum payments for these contractual obligations are as follows:

<u>Contractual Obligations</u>	<u>Payment due by period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
		(dollars in thousands)			
Operating Lease Obligations . . . . .	\$ 437	\$ 261	\$176	—	—
Purchase Obligations . . . . .	770	770	—	—	—
Total . . . . .	\$1,207	\$1,031	\$176	—	—

**Off-Balance Sheet Arrangements**

None.

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

A portion of our operations consists of sales activities in foreign jurisdictions. We manufacture our products exclusively in the U.S. and sell our products in the U.S. and abroad. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in exchange rates between the U.S. dollar and foreign currencies, especially the Euro. When the U.S. dollar strengthens against the Euro, the value of foreign sales decreases. When the U.S. dollar weakens, the functional currency amount of sales increases. No assurance can be given that foreign currency fluctuations in the future will not adversely affect our business, financial condition and results of operations, although at present we do not believe that our exposure is significant, as international sales represented only 3% of our consolidated sales in 2007. We do not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates.

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

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

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

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

Not applicable.

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

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's (the "SEC") rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Control over Financial Reporting***

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2007 that

has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. The term "internal control over financial reporting" is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on this assessment, our management has concluded that, as of December 31, 2007, our internal control over financial reporting was effective based on those criteria.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report.

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

None.

### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance

##### Board of Directors

The following table lists the members of our board of directors:

Name	Age	Date First Became a Director	Position	Class	Expiration of Term at Annual Meeting
Edward H. Pendergast . . . . .	74	09/24/92	Chairman of the Board	II	2009
Kevin J. Dunn . . . . .	55	09/24/99	Director	III	2008
Benjamin L. Holmes . . . . .	73	05/24/00	Director	II	2009
Alan H. Magazine . . . . .	63	09/24/99	Director	II	2009
Brent Norton, M.D. . . . .	47	06/10/94	Director	III	2008
Robert I. Rudko, Ph.D. . . . .	65	04/14/92	Director and Chief Scientific Officer	I	2010
Mark R. Tauscher . . . . .	55	12/17/99	Director, President and Chief Executive Officer	I	2010

**Edward H. Pendergast** has served as Chairman of the Board since October 1998 and as a director since September 1992. Mr. Pendergast also served as PLC's interim President and Chief Executive Officer from September 1999 to December 1999 and Lead Outside Director from March 1995 to October 1998. In addition, Mr. Pendergast served as a director of PLC Medical Systems, Inc., a wholly owned subsidiary of PLC, from its incorporation in 1989 until 1991. Since June 1989, Mr. Pendergast has served as the President of Pendergast & Company, a privately-held management consulting firm. He also currently serves on the board of directors of several private companies. Mr. Pendergast received his M.S. degree in Taxation and his B.S. degree in Accounting from Bentley College. Mr. Pendergast is a certified public accountant.

**Kevin J. Dunn** has served as a director of PLC since September 1999. Mr. Dunn currently serves as President and Chief Executive Officer of the U.S. operations of Canaccord Adams Inc., an investment banking firm. From January 2005 to January 2006, Mr. Dunn served as President and Chief Executive Officer of Adams Harkness. From September 2002 to January 2005, Mr. Dunn served as Managing Director of Adams Harkness. From June 1999 to June 2002, Mr. Dunn served as Senior Managing Director of SunTrust Robinson Humphrey. From 1984 to June 1999, Mr. Dunn served as Executive Vice President of Tucker Anthony Inc. Mr. Dunn received his M.B.A. degree from the University of Chicago Graduate School of Business and his B.A. degree from Harvard College.

**Benjamin L. Holmes** has served as a director of PLC since May 2000. Since December 1994, Mr. Holmes has served as President of The Holmes Company, a consulting firm that specializes in healthcare in the medical device industry. From 1985 to 1994, he served as General Manager and Vice President of Hewlett-Packard Medical Products Group. Currently, Mr. Holmes serves as a director of the UCLA Foundation and St. Luke's Wood River Medical Foundation. Mr. Holmes received his M.B.A. degree from the University of Southern California and his B.S. degree in Applied Physics from the University of California Los Angeles.

**Alan H. Magazine** has served as a director of PLC since September 1999. From 1990 to May 1999, Mr. Magazine served as President of the Health Industry Manufacturers Association, a worldwide association for medical technology companies. Prior to that, Mr. Magazine was the President of the Foundation for American Economic Competitiveness and its operating arm, the Council on Competitiveness. Mr. Magazine serves as a director of Innotech Corp., a medical technology company. Mr. Magazine received his Ph.D. degree from the University of Maryland, his M.P.A. degree from Kent State University and his B.A. degree from Monmouth College (Illinois).

**Brent Norton, M.D.** has served as a director of PLC since June 1994. Since 1992, Dr. Norton has served as President, Chief Executive Officer and a director of PreMD Inc. (formerly IMI International Medical Innovations Inc.), a publicly traded predictive medicine company. He is also a director of Novadaq Technologies Inc., a publicly traded medical device company. Dr. Norton completed his medical training at McGill University and conducted post-graduate work in biomedical engineering at Ecole Polytechnique at the University of Montreal. Dr. Norton received his M.B.A. degree from the Ivey School of Business, University of Western Ontario.

**Robert I. Rudko, Ph.D.** has served as a director of PLC since 1992 and as Chief Scientific Officer since October 1993. He also served as acting Chief Executive Officer from February 1997 to August 1997. In addition, Dr. Rudko served as Chairman of the Board from April 1992 to October 1998 and as President from April 1992 to October 1993. Dr. Rudko founded Laser Engineering, Inc., the predecessor to PLC Medical Systems, Inc., in 1981 and served as President from 1981 to October 1993. Prior to 1981, Dr. Rudko spent 14 years at Raytheon Corp. doing laser research. Dr. Rudko received his Ph.D. degree in Electrical Engineering from Cornell University.

**Mark R. Tauscher** has served as President, Chief Executive Officer and a director of PLC since December 1999. Mr. Tauscher has also served as President, Chief Executive Officer and a director of PLC Medical Systems, Inc. since January 2001. Prior to joining PLC, from November 1998 to December 1999, Mr. Tauscher served as Executive Vice President of Sales and Marketing at Quinton Instrument Company, a developer, manufacturer and marketer of cardiology products, medical devices and fitness equipment. From November 1996 to November 1998, Mr. Tauscher served as Division President of Marquette Medical Systems, Medical Supplies. From May 1994 to November 1996, Mr. Tauscher served as General Manager of Hewlett-Packard, Medical Supplies. Mr. Tauscher received his B.S. degree from Southern Illinois University.

#### **Executive Officers**

**Kenneth J. Luppi**, age 47, has served as Vice President of Operations of PLC Medical Systems, Inc. since September 1997. Mr. Luppi served as Acting Vice President of Operations from May 1997 to September 1997. Mr. Luppi was hired in August 1993 as PLC Medical Systems, Inc.'s Director of Service Operations. Prior to joining PLC Medical Systems, Inc., Mr. Luppi was employed as National Service Manager of Candela Laser Corporation, a medical laser company. Mr. Luppi received his B.S. degree in Biomedical Engineering from Boston University.

**Vincent C. Puglisi**, age 59, has served as Managing Director, International of PLC Medical Systems, Inc. since June 1998. Mr. Puglisi served as Vice President, Corporate Sales from December 1997 to June 1998. From January 1984 to June 1997, Mr. Puglisi was CEO and founder of Medrep Corp., a medical device sales and marketing consulting firm. From July 1981 to November 1983, Mr. Puglisi served as Vice President, Sales and Marketing for Professional Disposables, Inc., a manufacturer of medical products. From September 1975 to June 1981, Mr. Puglisi held several sales and management positions with the American Hospital Supply Corporation. From June 1970 to August 1975, Mr. Puglisi served as an Officer in the U.S. Air Force with an honorable discharge at the rank of Captain. Mr. Puglisi graduated from the U.S. Air Force Academy in 1970 with a B.S. degree.

**Robert I. Rudko, Ph.D.**, see biography above.

**Mark R. Tauscher**, see biography above.

**James G. Thomasch**, age 48, has served as Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer of PLC since November 1999. In addition, Mr. Thomasch has served as Chief Financial Officer, Treasurer, Secretary and a director of PLC Medical Systems, Inc. since January 2001. From May 1996 to March 1999, Mr. Thomasch served as Division President and Chief Operating Officer of XRE Corporation, a subsidiary of Trex Medical Corporation, a medical

device company. From October 1989 to May 1996, Mr. Thomasch served as Chief Financial Officer for both XRE Corporation and Angiographic Devices Corporation, a medical device company and affiliate of XRE Corporation. Mr. Thomasch received his B.S. degree in Management with an Accounting Concentration from The Carroll School of Management of Boston College. Mr. Thomasch is a certified public accountant.

Each executive officer serves at the discretion of the board of directors and holds office until his successor is elected and qualified or until his earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Based solely on our review of copies of reports filed by all of our officers, directors and 10% shareholders who are persons required to file reports pursuant to Section 16(a) of the Exchange Act, or written representations from those reporting persons, we believe that during the fiscal year ended December 31, 2007, all filings required to be made by the reporting persons were timely made in accordance with the requirements of the Exchange Act.

#### **Code of Ethics**

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

#### **Director Nomination Process**

Our nominating and corporate governance committee does not have a formal policy with regard to the consideration of director candidates recommended by shareholders. The board of directors does not feel a formal policy is necessary, as the nominating and corporate governance committee does consider director nominees recommended by shareholders. There has been no change in the procedure by which shareholders may recommend nominees to the board of directors. The names of such nominees should be addressed to the Nominating and Corporate Governance Committee, c/o Secretary, PLC Systems Inc., 10 Forge Park, Franklin, Massachusetts 02038.

#### **Audit Committee**

The members of our audit committee are Messrs. Dunn (chairman) and Pendergast and Dr. Norton. The board of directors has determined that Mr. Pendergast is an "audit committee financial expert" as defined by applicable SEC rules. The board of directors has determined that all of the members of our audit committee are independent as defined under AMEX rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

## Item 11. Executive Compensation

### Compensation of Directors

The compensation committee of our board of directors evaluates the compensation levels for all of our non-employee directors on an annual basis. Factors that the compensation committee considers in determining the appropriate level of compensation include, but are not limited to, the compensation paid to the directors of our competitor in the TMR market and the compensation paid to directors of other companies in all industries of a similar size, as determined by relative sales levels. The compensation committee makes a recommendation to the board of directors as to any proposed adjustments to director compensation and the board of directors votes as to whether to approve those recommendations.

The following table sets forth information with respect to the compensation, exclusive of reimbursed out-of-pocket expenses, received by our directors for their service during the fiscal year ended December 31, 2007:

#### DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash (\$) (b)	Stock Awards (\$) (c)	Option Awards \$(1) (d)	Non-Equity Incentive Plan Compensation (\$) (e)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$) (f)	All Other Compensation (\$) (g)	Total (\$) (h)
Kevin J. Dunn	16,000	—	6,450(2)	—	—	—	22,450
Benjamin L. Holmes	16,000	—	6,450(2)	—	—	—	22,450
Alan H. Magazine	12,000	—	6,450(2)	—	—	—	18,450
Brent Norton, M.D.	14,000	—	6,450(3)	—	—	—	20,450
Edward H. Pendergast	24,000	—	12,900(4)	—	—	—	36,900
Robert I. Rudko, Ph.D.(5)	—	—	—	—	—	—	—
Mark R. Tauscher(5)	—	—	—	—	—	—	—

- (1) The high and low trading prices of our common stock on AMEX during the 30-day period prior to June 13, 2007, the date of grant, were \$0.72 and \$0.59.
- (2) On June 13, 2007, Messrs. Dunn, Holmes and Magazine were each granted an option to purchase 15,000 shares of our common stock with a grant date fair value of \$0.43, which is estimated in accordance with the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment" ("SFAS No. 123R"). See Note 7 to our consolidated financial statements for the year ended December 31, 2007, which accompany this Annual Report on Form 10-K, regarding assumptions underlying the valuation of our equity awards. As of December 31, 2007, each of Messrs. Dunn, Holmes and Magazine held options to purchase an aggregate of 110,000 shares of our common stock.
- (3) On June 13, 2007, Dr. Norton was granted an option to purchase 15,000 shares of our common stock with a grant date fair value of \$0.43, which is estimated in accordance with the provisions of SFAS No. 123R. See Note 7 to our consolidated financial statements for the year ended December 31, 2007, which accompany this Annual Report on Form 10-K, regarding assumptions underlying the valuation of our equity awards. As of December 31, 2007, Dr. Norton held options to purchase an aggregate of 130,500 shares of our common stock.
- (4) On June 13, 2007, Mr. Pendergast was granted of an option to purchase 30,000 shares of our common stock with a grant date fair value of \$0.43, which is estimated in accordance with the

provisions of SFAS No. 123R. See Note 7 to our consolidated financial statements for the year ended December 31, 2007, which accompany this Annual Report on Form 10-K, regarding assumptions underlying the valuation of our equity awards. As of December 31, 2007, Mr. Pendergast held options to purchase an aggregate of 297,000 shares of our common stock.

- (5) As employee directors, Mr. Tauscher and Dr. Rudko are not eligible to receive either compensation or an annual stock grant for service in their capacity as a director. Compensation received by Mr. Tauscher and Dr. Rudko for their service as employees is discussed below under the heading "Executive Compensation."

Each of our non-employee directors (other than the chairman of the board) receives \$12,000 per year and the chairman of the board receives \$24,000 per year, paid in quarterly installments. In addition, non-employee directors (other than the chairman of the board) who serve as chairman of a committee receive an additional \$500 per quarter and those who serve on more than one committee also receive an additional \$500 per quarter. We reimburse our directors for reasonable out-of-pocket expenses incurred in attending meetings of the board of directors and committees of the board of directors.

We also grant stock options to our non-employee directors. Generally, on the date of their initial election to the board of directors, new non-employee directors receive an initial grant of an option to purchase 30,000 shares of our common stock that vests in installments over three years. Once the initial grant has fully vested, non-employee directors (other than the chairman of the board) receive an annual grant of an option to purchase 15,000 shares of our common stock that generally vests in four equal quarterly installments. The chairman of the board receives an annual grant of an option to purchase 30,000 shares of our common stock that generally vests in four equal quarterly installments. The annual grants are generally made on the date of our annual meeting of shareholders. All such options have an exercise price equal to the fair market value of the common stock on the date of grant.

### **Compensation Discussion and Analysis**

This section discusses the principles underlying our executive compensation policies and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executives and is intended to place in perspective the data presented in the tables and narrative that follow.

The compensation committee of our board of directors oversees our executive compensation program. In this role, the compensation committee reviews and approves annually all compensation decisions relating to our executive officers.

#### ***Objectives and Philosophy of our Executive Compensation Program***

Our primary objectives with respect to executive compensation are to:

- retain, motivate and attract the best possible executive talent;
- ensure executive compensation is aligned with our corporate strategies and business objectives;
- promote the achievement of key strategic and financial performance measures by linking short- and long-term cash and equity incentives to the achievement of measurable corporate and individual performance goals; and
- align executives' incentives with the creation of shareholder value.

To achieve these objectives, the compensation committee evaluates our executive compensation program with the goal of setting compensation at levels the committee believes are competitive with those of other companies in our industry and our region that compete with us for executive talent. In addition, our executive compensation program ties a substantial portion of each executive's overall compensation to key strategic, financial and operational goals, which include, for example:

- the attainment of measurable development milestones, such as the number of patients we enroll in our RenalGuard clinical studies; and
- the profitability of our TMR operations.

We also provide a portion of our executive compensation in the form of stock options that vest over time, which we believe helps to retain our executives and aligns their interests with those of our shareholders by allowing them to participate in the longer term success of our company as reflected in stock price appreciation.

#### *Overview of our Executive Compensation Process*

To assist the compensation committee in discharging its responsibilities, the committee has retained Insight Performance Improvement, Inc., which we refer to as Insight, an independent human resources consulting firm, to assist in developing and implementing our executive compensation program. Insight assists the committee by providing comparative market data on compensation practices and programs based on an analysis of comparable peer companies. Insight also advised the compensation committee when assessing base salaries and bonus levels for executives.

In making compensation decisions, the compensation committee compares our executive compensation against that paid by our competitor in the TMR market, as well as other companies in all industries in the New England region of a similar size, as determined by relative sales levels. The latter survey data of peer group companies is developed for the compensation committee by Insight. The survey data is periodically reviewed and updated by Insight for the committee and is used to benchmark executive compensation levels against companies that are generally comparable to our company, that have executive positions with responsibilities similar in breadth and scope to ours, and that compete with us for executive talent. With this information, the compensation committee reviews and analyzes compensation for each executive and makes adjustments as appropriate.

The compensation committee generally targets overall compensation for our executive team between the 50<sup>th</sup> and 75<sup>th</sup> percentiles of compensation paid to similarly situated executives of the companies in the peer group. Variations to this general target may occur as dictated by the experience level of the individual and market factors.

Annually, corporate goals and objectives deemed to be appropriate for the upcoming calendar year are proposed by management to the compensation committee and the board of directors. These goals are reviewed, revised as necessary and then approved, first by the compensation committee and then by the entire board of directors. These corporate goals target, among other things, the achievement of specific research, clinical, regulatory and operational milestones thought to be instrumental to our primary goal of building long-term shareholder value.

Our executive team is primarily responsible for implementing specific plans to achieve these agreed upon annual goals, as well as other longer term strategic goals established by the board of directors. At the end of each calendar year, the compensation committee reviews the performance of the executive team by means of assessing the degree to which each of the established goals was achieved. Annual salary increases, annual bonuses and annual stock option awards granted to our executives are determined by the compensation committee after considering the degree of achievement of these corporate performance goals, as well as the updated competitive salary data for similar executives in the peer group as reported by Insight.

Annual base salary increases, if any, are implemented as of the first day of the calendar year and annual bonuses, if any, are customarily paid on or before March 15<sup>th</sup> of each year for the prior year. New stock option grants may be made at any time during the calendar year, but customarily are done at least once a year in conjunction with our annual meeting of shareholders.

#### *Components of our Executive Compensation Program*

The primary elements of our executive compensation program are:

- base salary;
- annual cash incentive bonuses;
- stock option awards;
- employee benefits; and
- severance and change in control benefits.

We do not have any formal or informal policies or targets for allocating compensation between long-term and short-term compensation, between cash and non-cash compensation or among the different forms of non-cash compensation. Instead, the compensation committee, after reviewing information provided by Insight, determines subjectively what it believes to be the appropriate level and mix of the various compensation components.

#### **Base Salary**

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our executives. When establishing base salaries for 2007, the compensation committee considered the survey data of compensation in the peer group, as well as a variety of other factors, including the seniority of the individual, the level of the individual's responsibility, the skills and performance of the individual relative to targeted performance criteria and our financial performance. Generally, we believe that executive base salaries should be targeted near or slightly above the median of the range of salaries for executives in similar positions at comparable companies.

Base salaries are reviewed at least annually by our compensation committee, and are adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. The compensation committee also takes into account the Social Security Administration's cost of living adjustment when annually reviewing base salaries.

In determining annual base salary increases for the executive team for 2007, the compensation committee considered the peer group data gathered by Insight, as well as the performance of the executive team in achieving the 2006 corporate goals and objectives, and determined that a 4% overall base salary increase was appropriate.

#### **Annual Cash Incentive Bonus**

We have an annual cash incentive bonus plan for our executives. The annual cash incentive bonuses are intended to compensate for the achievement of company strategic, operational and financial goals. Amounts payable under the annual cash incentive bonus plan are calculated as a percentage of the applicable executive's base salary, with higher ranked executives typically being compensated at a higher percentage of base salary. The compensation committee works with the chief executive officer to develop goals that they believe can be reasonably achieved over the next year and the formula for determining potential bonus amounts based on achievement of those goals.

For 2007, our executive officers (except for Mr. Puglisi) were eligible to receive a bonus based 65% on the attainment of defined milestones related to our RenalGuard program. An additional 25%

of eligible bonus was tied to the attainment of defined milestones in our TMR business and 10% was tied to the financial performance of our TMR, Optiwave 980 and surgical tube businesses. The target bonus payment for Mr. Tauscher was 50% of his base salary, for Mr. Thomasch was 40% of his base salary, and for Mr. Luppi and Dr. Rudko was 30% of each of their respective base salaries. The percentages representing the targeted bonuses were established for Messrs. Tauscher and Thomasch by the terms of their employment agreements with us. The bonus payments would be below the target amounts if the financial performance of our business did not meet certain targets or we did not attain the defined program milestones.

We met some but not all of the pre-defined milestones related to both our RenalGuard program and our TMR business and our executives earned a partial bonus related to the financial performance of our TMR, Optiwave 980 and surgical tube businesses during 2007. As a result, the compensation committee awarded bonuses for 2007 to our employees, including the executive team, totaling approximately \$277,000.

Our compensation committee also reserves the right to award discretionary bonuses to executives outside the annual cash incentive bonus plan. Such discretionary bonuses are intended to compensate executive officers for achieving financial and operational goals that were not contemplated in the annual cash incentive bonus plan. No such discretionary bonuses were granted during 2007.

### **Stock Options**

Our equity award program is the primary vehicle for offering long-term incentives to our executives. We believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our shareholders. In addition, the standard vesting feature of our equity grants should further our goal of executive retention because this feature provides an incentive to our executives to remain in our employ during the vesting period. Our equity awards have typically taken the form of stock option grants. All grants of options to our executives are approved by the compensation committee.

In determining the size of equity grants to our executives, including those options granted during 2007, our compensation committee considers a number of factors, including:

- our company-level performance;
- the executive's performance, position and level of seniority;
- the amount of equity previously awarded to the executive, the amount of such equity still held by the executive and the amount of such equity that is in-the-money;
- the executive's percent ownership of our common stock on a fully-diluted basis, both before and after taking into account the contemplated grant;
- the vesting schedule of the executive's outstanding equity awards; and
- with respect to our other executives, the recommendation of our chief executive officer.

The compensation committee reviews all components of the executive's compensation when determining annual stock option awards to ensure that an executive's total compensation conforms to our overall philosophy and objectives.

Our compensation committee's practice has been to grant stock options (other than to new hires) at the time of its regularly scheduled meetings. During 2007, the compensation committee only granted stock options at its regularly scheduled meeting held in conjunction with our annual meeting of shareholders. The compensation committee has also delegated to our chief executive officer certain authority to grant stock options to non-executive new hires. Our chief executive officer granted two stock options to non-executive new hires during 2007, each of which was granted on the employee's

date of hire. We set the exercise price of all stock options to equal the closing price of our common stock on AMEX on the date of grant.

The stock options that were granted to our executives in 2007 vest at a rate of one-third per year over the first three years of the ten year option term. This vesting schedule is typical of prior option grants, with the exception of the annual grants made in 2004 and 2005, which were fully vested upon grant. The compensation committee determined that it was in our best interest to have those options be fully vested upon grant in order to avoid an income statement charge to future earnings that would otherwise have been required after adoption of SFAS No. 123R on January 1, 2006.

Vesting rights cease upon termination of employment and exercise rights cease ninety days after termination (or one year in the case of death or disability). Prior to the exercise of an option, the holder has no rights as a shareholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents.

Our compensation committee also reserves the right to make discretionary stock option grants to executives for extraordinary contributions. No stock options were granted to executives outside of our annual stock option program during 2007.

We do not have any required equity ownership guidelines for our executives.

### **Benefits and Other Compensation**

We maintain broad-based benefits that are provided to all employees, including health and dental insurance, life and disability insurance and a 401(k) plan. Executives are eligible to participate in all of our employee benefit plans, in each case on the same basis as other employees, with the exception that our executives are required to pay their portion of any long term disability contribution with after-tax payroll contributions, as opposed to non-executive employees, who contribute toward this plan with pre-tax payroll contributions. We do not have a pension plan and have not adopted a mandatory matching contribution formula for our 401(k) plan.

Our executives are also generally provided a car allowance ranging from \$500 to \$1,000 a month. This allowance is reported as additional wages for tax reporting purposes and is considered by the compensation committee when assessing our executives' total compensation arrangements.

### **Severance and Change in Control Benefits**

Pursuant to employment agreements we have entered into with our executives, our executives are entitled to specified benefits in the event of the termination of their employment under specified circumstances, including termination following a change in control of our company. We have provided more detailed information about these benefits under the caption "Employment Contracts, Termination of Employment and Change in Control Arrangements" below.

We believe providing these benefits help us retain and compete for executive talent. After reviewing the practices of other companies comparable to ours, we believe that our severance and change in control benefits are generally in line with severance packages offered to other executives with similar experience.

Our practice in the case of change in control benefits has been to structure these as "double trigger" benefits. In other words, the change in control does not itself trigger benefits; rather, benefits are paid only if the employment of the executive is terminated during a specified period after the change in control. We believe a "double trigger" benefit maximizes shareholder value because it prevents an unintended windfall to executives in the event of a friendly change in control, while still providing them appropriate incentives to cooperate in negotiating any change in control in which they believe they may lose their jobs.

## Tax Considerations

Section 162(m) of the Code generally prohibits public companies from taking a tax deduction for compensation over \$1.0 million paid to its chief executive officer and each other officer whose compensation is required to be reported to its shareholders pursuant to the Exchange Act by reason of being among the four most highly compensated executive officers. Certain compensation, including qualified performance-based compensation is exempt from the Section 162(m) deduction limitation if certain requirements are satisfied. Although we do not believe that the limitations of Section 162(m) have a material impact on us at the current compensation levels, we periodically review the potential consequences of Section 162(m) and we generally intend to structure the performance-based portion of our executive compensation, where feasible, to comply with exemptions under Section 162(m) so that the compensation would remain tax deductible to us. However, the compensation committee may, in its judgment, authorize compensation payments that do not comply with the exemptions under Section 162(m) when it believes that such payments are appropriate to attract and retain executive talent.

## Executive Compensation

### Summary Compensation Table

The following table sets forth certain information concerning the compensation for each of the last three fiscal years of our chief executive officer and our other four executive officers. We refer to these individuals as the named executive officers.

Name and Principal Position (a)	Year (b)	Salary (\$) (c)	Bonus (\$) (d)	Stock Awards (\$) (e)	Option Awards (\$) (f)	Non-Equity Incentive Plan Compensation (\$) (g)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$) (h)	All Other Compensation (\$) (i)	Total (\$) (j)
Mark R. Tauscher . . . . . President, Chief Executive Officer and Director	2007	298,314	73,833	—	15,739	—	—	12,000	399,886
	2006	286,841	—	—	9,319	—	—	12,000	308,160
	2005	278,486	97,766	—	—	—	—	12,000	388,252
James G. Thomasch . . . . . Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer	2007	187,285	37,082	—	15,739	—	—	12,000	252,106
	2006	180,081	—	—	9,319	—	—	12,000	201,400
	2005	174,836	49,102	—	—	—	—	12,000	235,938
Kenneth J. Luppi . . . . . Vice President of Operations	2007	153,486	22,793	—	12,107	—	—	6,000	194,386
	2006	147,583	—	—	6,692	—	—	6,000	160,275
	2005	143,284	30,181	—	—	—	—	6,000	179,465
Vincent C. Puglisi . . . . . Managing Director, International	2007	155,324	—	—	3,632	—	—	6,000	164,956
	2006	149,350	—	—	1,500	—	—	6,000	156,850
	2005	145,000	—	—	—	—	—	6,000	151,000
Robert I. Rudko, Ph.D. . . . . Chief Scientific Officer	2007	206,206	30,622	—	7,264	—	—	6,000	250,092
	2006	198,275	50,000(3)	—	12,075	—	—	6,000	266,350
	2005	192,500	90,548(3)	—	—	—	—	6,000	289,048

(1) Amounts calculated utilizing the provisions of SFAS No. 123R. See Note 7 to our consolidated financial statements for the year ended December 31, 2007, which accompany this Annual Report on Form 10-K, regarding assumptions underlying the valuation of our equity awards.

(2) Consists of a cash car allowance.

- (3) Includes a retention bonus of \$50,000 paid pursuant to Dr. Rudko's employment agreement, which is discussed under the caption "Employment Contracts, Termination of Employment and Change in Control Arrangements—Rudko Employment Agreement."

**Grants of Plan-Based Awards**

The following table sets forth certain information concerning grants of stock options made during the fiscal year ended December 31, 2007 to each of our named executive officers.

Name (a)	Grant Date (b)	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#) (i)	All Other Option Awards: Number of Securities Underlying Options (#)(1) (j)	Exercise or Base Price of Option Awards (\$/Sh)(2) (k)	Grant Date Fair Value of Stock and Option Awards (l)
		Threshold (\$) (c)	Target (\$) (d)	Maximum (\$) (e)	Threshold (#) (f)	Target (#) (g)	Maximum (#) (h)				
Mark R. Tauscher . . . . .	6/13/07	—	—	—	—	—	—	—	65,000	0.64	0.44
James G. Thomasch . . . . .	6/13/07	—	—	—	—	—	—	—	65,000	0.64	0.44
Kenneth J. Luppi . . . . .	6/13/07	—	—	—	—	—	—	—	50,000	0.64	0.44
Vincent C. Puglisi . . . . .	6/13/07	—	—	—	—	—	—	—	15,000	0.64	0.44
Robert I. Rudko, Ph.D. . . . .	6/13/07	—	—	—	—	—	—	—	30,000	0.64	0.44

- (1) These stock options were granted pursuant to our 2005 Stock Incentive Plan. We granted stock options to purchase an aggregate of 618,000 shares of common stock to our employees and the employees of our subsidiaries during the fiscal year ended December 31, 2007.
- (2) These stock options vest at a rate of one-third per year over the first three years of the ten year option term. The exercise price is equal to the closing price of our common stock on AMEX on June 13, 2007, the date of grant. The high and low trading prices of our common stock on AMEX during the 30-day period prior to June 13, 2007 were \$0.72 and \$0.59.

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information concerning stock options held by each of our named executive officers as of December 31, 2007. We do not have any restricted stock outstanding.

Name (a)	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price (\$) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock that Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) (j)
Mark R. Tauscher . . . . .	175,000	—	—	0.5625	10/25/10	—	—	—	—
	50,000	—	—	0.8125	1/6/11	—	—	—	—
	75,000	—	—	0.55	12/17/11	—	—	—	—
	350,000	—	—	0.45	3/23/13	—	—	—	—
	50,000	—	—	0.69	8/3/13	—	—	—	—
	130,000	—	—	0.81	5/17/14	—	—	—	—
	96,970	—	—	0.55	5/22/15	—	—	—	—
	21,667(1)	43,333(1)	—	0.67	5/14/16	—	—	—	—
—	65,000(1)	—	0.64	6/10/17	—	—	—	—	
James G. Thomasch . . . . .	72,500	—	—	0.5625	10/25/10	—	—	—	—
	35,000	—	—	0.8125	1/6/11	—	—	—	—
	20,000	—	—	0.62	7/28/11	—	—	—	—
	75,000	—	—	0.55	12/17/11	—	—	—	—
	145,000	—	—	0.45	3/23/13	—	—	—	—
	50,000	—	—	0.69	8/3/13	—	—	—	—
	125,000	—	—	0.81	5/17/14	—	—	—	—
	96,970	—	—	0.55	5/22/15	—	—	—	—
21,667(1)	43,333(1)	—	0.67	5/14/16	—	—	—	—	
—	65,000(1)	—	0.64	6/10/17	—	—	—	—	
Kenneth J. Luppi . . . . .	15,500	—	—	0.5625	10/25/10	—	—	—	—
	10,000	—	—	0.65	7/8/11	—	—	—	—
	50,000	—	—	0.55	12/17/11	—	—	—	—
	55,333	—	—	0.45	3/23/13	—	—	—	—
	30,000	—	—	0.69	8/3/13	—	—	—	—
	80,000	—	—	0.81	5/17/14	—	—	—	—
	72,727	—	—	0.55	5/22/15	—	—	—	—
	16,667(1)	33,333(1)	—	0.67	5/14/16	—	—	—	—
—	50,000(1)	—	0.64	6/10/17	—	—	—	—	
Vincent C. Puglisi . . . . .	38,750	—	—	0.5625	10/25/10	—	—	—	—
	155,000	—	—	0.45	3/23/13	—	—	—	—
	8,152	—	—	0.55	5/22/15	—	—	—	—
	5,000(1)	10,000(1)	—	0.67	5/14/16	—	—	—	—
	—	15,000(1)	—	0.64	6/10/17	—	—	—	—
Robert I. Rudko, Ph.D. . . . .	18,225	—	—	0.5625	10/25/10	—	—	—	—
	30,000	—	—	0.55	12/17/11	—	—	—	—
	72,900	—	—	0.45	3/23/13	—	—	—	—
	45,000	—	—	1.25	11/2/13	—	—	—	—
	50,000	—	—	0.81	5/17/14	—	—	—	—
	60,606	—	—	0.55	5/22/15	—	—	—	—
	10,000(1)	20,000(1)	—	0.67	5/14/16	—	—	—	—
	—	30,000(1)	—	0.64	6/10/17	—	—	—	—

(1) These stock options vest at a rate of one-third per year over the first three years of the option term.

### *Option Exercises and Stock Vested*

Our named executive officers did not exercise any stock options during the fiscal year ended December 31, 2007. We do not have any restricted stock outstanding.

### **Employment Contracts, Termination of Employment and Change in Control Arrangements**

We have arrangements with our named executive officers to compensate them in the event of termination of employment or change in responsibilities following a change in control of PLC.

#### *Tauscher Employment Agreement*

We entered into an employment agreement with Mr. Tauscher in December 1999 providing for an annual base salary of not less than \$250,000 and an annual bonus targeted at 50% of his salary (however, his bonus may exceed this amount in certain circumstances) based upon the achievement of certain performance goals. This agreement also provides for the payment to Mr. Tauscher of 150% of the sum of his highest annualized base salary during the preceding three-year period and his previous calendar year's bonus if Mr. Tauscher's employment is terminated by us without cause or, within 12 months after a sale or change in control of PLC, by Mr. Tauscher following a reduction in his position, authority or responsibilities, a material reduction in salary or benefits or his relocation more than 100 miles from Franklin, Massachusetts. If such a termination had occurred on December 31, 2007, Mr. Tauscher would have been entitled to receive payments equal to \$447,472, a portion of which would have been payable upon termination and the remainder of which would have been payable in monthly installments thereafter through September 30, 2008. If such termination had occurred on March 14, 2008, Mr. Tauscher would have been entitled to receive payments equal to \$576,120 since he earned a bonus in 2007, but not in 2006.

#### *Thomasch Employment Agreement*

We entered into an employment agreement with Mr. Thomasch in November 1999 providing for an annual base salary of not less than \$160,000 and an annual bonus of up to 40% of his salary based upon the achievement of certain performance goals. The agreement also provides for the payment to Mr. Thomasch of 100% of his highest annualized base salary plus bonus during the preceding three-year period plus the continuation of any other benefits available to Mr. Thomasch and his family on his last day of service for a period of 12 months if Mr. Thomasch's employment is terminated by us without cause or, within 12 months after a sale or change in control of PLC, by Mr. Thomasch following a reduction in his position, authority or responsibilities, a material reduction in salary or benefits or his relocation more than 30 miles from Franklin, Massachusetts. If such a termination had occurred on December 31, 2007, Mr. Thomasch would have been entitled to receive payments equal to \$224,367, a portion of which would have been payable upon termination and the remainder of which would have been payable in monthly installments thereafter through September 30, 2008, and the continuation of benefits through December 31, 2008, which has an estimated value of \$28,805.

#### *Rudko Employment Agreement*

We entered into an employment agreement with Dr. Rudko in October 2003, which was amended on March 15, 2005, providing for an annual base salary of \$192,500 and an annual bonus under any discretionary bonus programs that we may establish and make available to our vice presidents. The agreement also provided for a retention bonus of \$150,000 to be paid to Dr. Rudko in three equal annual installments, which were made on October 1, 2004, October 1, 2005 and October 1, 2006. Dr. Rudko was required within ten days of his receipt of each retention bonus installment to repay a portion of the loans that we originally made to him in October 1991 and March 1992, which loans have now been repaid in full.

The agreement further provides for certain severance benefits payable to Dr. Rudko. Specifically, for each of the forty-eight months following the execution of the agreement that Dr. Rudko remains employed by us on a full-time basis, we will allocate \$8,020, less all applicable taxes and withholdings, towards the potential severance pay for which he will be eligible upon the termination of his employment with us for any reason, other than by us for cause, provided that, following his termination, Dr. Rudko signs a severance agreement and release of claims drafted by us. If Dr. Rudko works for us on a less than full-time basis at any time during his employment, or if he takes a leave of absence from us for any reason, but we continue to pay his base salary as if he continued to work on a full-time basis during such period, our allocation towards the potential severance pay will be reduced proportionally to account for his reduced work schedule or absence. Further, if Dr. Rudko works for us on a less than full time basis at any time during his employment, or if he takes a leave of absence from us for any reason, and we reduce his base salary in proportion to his reduced schedule during such period, we will allocate towards the potential severance pay the amount we would have allocated had he worked full-time during such period.

If Dr. Rudko's employment is terminated by him or us for any reason other than by us for cause on or after October 28, 2007, he will receive as severance pay the gross amount previously allocated by us towards the potential severance pay. Dr. Rudko will not be eligible to receive any severance pay if his employment is terminated at any time by us for cause.

Any severance pay is subject to all applicable taxes and withholdings and may not exceed \$385,000 gross plus the applicable amount contemplated as an extra severance payment as discussed in the preceding paragraph. Any severance pay that Dr. Rudko may receive will be paid in equal monthly installments over the twenty-four month period following the termination of his employment. If Dr. Rudko's employment had been terminated by us without cause or by himself for any reason on December 31, 2007, he would have been entitled to receive severance pay equal to \$385,000.

#### *Luppi and Puglisi Severance Arrangements*

Pursuant to resolutions adopted by our board of directors on December 19, 2001, Messrs. Luppi and Puglisi are entitled to receive payments equal to 26 weeks of their respective base salaries in the event that they are terminated within one year after the date of a change in control of PLC. If such terminations had occurred on December 31, 2007, Messrs. Luppi and Puglisi would have been entitled to receive lump sum payments equal to \$76,743 and \$77,662, respectively.

#### **Compensation Committee Report**

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with our management. Based on this review and discussion, the compensation committee recommended to the board of directors that the Compensation Discussion and Analysis be included in this report.

By the compensation committee of the board of directors of PLC Systems Inc.

Benjamin L. Holmes, Chairman  
Alan H. Magazine  
Brent Norton, M.D.

## Compensation Committee Interlocks and Insider Participation

All decisions regarding the compensation of our executive officers for the fiscal year ended December 31, 2007 were made by our compensation committee, consisting of Messrs. Holmes and Magazine and Dr. Norton. No member of the compensation committee was at any time during 2007, or formerly, an officer or employee of ours or any of our subsidiaries. No member of the compensation committee had any relationship with us requiring disclosure under Item 404 of Regulation S-K under the Exchange Act.

None of our executive officers have served as a director or member of the compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as one of our directors or a member of our compensation committee.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

### Security Ownership of Certain Beneficial Owners and Management

The following table sets forth as of March 14, 2008 certain information with respect to the beneficial ownership of our common stock by (i) each person known by us to own beneficially more than 5% of our outstanding shares of common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting and investment power with respect to shares. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. Unless otherwise indicated, the address of each person named in the table is c/o PLC Systems Inc., 10 Forge Park, Franklin, Massachusetts 02038.

<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percent of Class</u>
<b>5% Shareholders:</b>		
Edwards Lifesciences Corporation(1) . . . . . One Edwards Way Irvine, California 92614	5,333,333	17.6%
Fred Kayne(2) . . . . . c/o Fortune Financial 1800 Avenue of the Stars, Suite 310 Los Angeles, California 90067	3,074,800	10.1%
<b>Directors and Named Executive Officers:</b>		
Kevin J. Dunn(3) . . . . .	111,250	*
Benjamin L. Holmes(4) . . . . .	116,250	*
Kenneth J. Luppi(5) . . . . .	335,294	1.1%
Alan H. Magazine(6) . . . . .	108,250	*
Brent Norton, M.D.(7) . . . . .	126,750	*
Edward H. Pendergast(8) . . . . .	351,992	1.1%
Vincent C. Puglisi(9) . . . . .	206,902	*
Robert I. Rudko, Ph.D.(10) . . . . .	1,378,593	4.5%
Mark R. Tauscher(11) . . . . .	1,097,205	3.5%
James G. Thomasch(12) . . . . .	643,137	2.1%
All directors and executive officers as a group (10 persons)(13) . . . . .	4,475,623	13.4%

\* Less than 1%.

- (1) Based solely on a Schedule 13D filed with the SEC on April 5, 2001, for which no amendments have been filed.
- (2) Based solely on a Schedule 13G filed with the SEC on February 11, 2003, for which no amendments have been filed, and includes 576,000 shares of common stock held by FF Industries, Inc., of which Mr. Kayne is the sole shareholder.
- (3) Includes 106,250 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (4) Includes 106,250 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (5) Includes 330,227 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (6) Includes 106,250 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (7) Consists of 126,750 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (8) Includes 289,500 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (9) Consists of 206,902 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (10) Includes 286,731 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008 and 84,762 shares held of record by Dr. Rudko's spouse.
- (11) Includes 948,637 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (12) Includes 641,137 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.
- (13) Includes 3,148,634 shares of common stock issuable upon the exercise of options exercisable within 60 days after March 14, 2008.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information about the securities authorized for issuance under our equity compensation plans as of December 31, 2007:

<u>Plan Category</u>	<u>(a)</u> Number of securities to be issued upon exercise of outstanding options, warrants and rights	<u>(b)</u> Weighted-average exercise price of outstanding options, warrants and rights	<u>(c)</u> Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders(1) .....	3,948,851	\$0.80	776,407(2)
Equity compensation plans not approved by security holders(3) .....	1,348,809	\$1.43	—
Total .....	<u>5,297,660</u>	<u>\$0.96</u>	<u>776,407</u>

- (1) Consists of the following equity compensation plans: (i) 1993 Formula Stock Option Plan; (ii) 1993 Stock Option Plan; (iii) 1995 Stock Option Plan; (iv) 2000 Employee Stock Purchase Plan, as amended (the "2000 ESPP"); (v) 2000 Equity Incentive Plan; and (vi) 2005 Stock Incentive Plan.
- (2) Includes 316,073 shares issuable under the 2000 ESPP, including shares issuable in connection with the current offering period, which ends on May 31, 2008.
- (3) Consists of the following equity compensation plans and arrangements: (i) 1997 Executive Stock Option Plan; (ii) 2000 Non-Statutory Stock Option Plan; and (iii) 2000 Non-Qualified Performance and Retention Equity Plan.

### Item 13. *Certain Relationships and Related Transactions, and Director Independence*

#### Board Determination of Independence

Under applicable AMEX rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that none of Messrs. Dunn, Holmes, Magazine and Pendergast and Dr. Norton has a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as defined under Rule 121A of the AMEX Company Guide.

Our board of directors has also determined that all of the current members of the audit, compensation and nominating and corporate governance committees are independent as defined under AMEX rules.

#### Certain Relationships and Related Transactions

We have adopted a policy providing that all material transactions between us and our officers, directors and other affiliates must be:

- approved by our audit committee;
- approved by a majority of the members of our board of directors;
- approved by a majority of the disinterested members of our board of directors; and
- on terms no less favorable to us than could be obtained from unaffiliated third parties.

No executive officer, director, nominee for election as a director or 5% shareholder of ours, and no associate or affiliate of the foregoing persons, has or has had any material interest, direct or indirect, in any transaction since January 1, 2006 or in any proposed transaction which in either such case has materially affected or will materially affect us, except as described below.

*Edwards and Novadaq Agreements*

*TMR Distribution Agreement.* On January 9, 2001, we entered into an exclusive distribution agreement with a subsidiary of Edwards, which currently owns in excess of 5% of our outstanding common stock. Under this agreement, Edwards was appointed our exclusive distributor for our TMR products in the U.S.

On March 20, 2007, we entered into a distribution agreement with Novadaq, a subsidiary of Novadaq Technologies Inc., pursuant to which we appointed Novadaq as our exclusive distributor in the U.S. for our TMR business. The agreement amended and restated the exclusive distribution agreement between us and Edwards, which had been assigned by Edwards to Novadaq on the same date. The agreement with Novadaq reflects substantially the same roles, responsibilities and financial terms as the previous agreement with Edwards.

Dr. Norton, one of our directors, is also a director of Novadaq Technologies Inc. Dr. Norton did not participate in any voting of our board of directors with respect to our entering into the distribution agreement with Novadaq.

*Optiwave 980 System Agreements.* In February 2004, we signed an agreement with Edwards to assume the product development and manufacturing of the Edwards Optiwave 980 surgical ablation system, which we refer to as the "Optiwave 980 System." The Optiwave 980 System consists of (1) a diode-based laser, which we refer to as the Optiwave 980, and (2) related system disposables. The laser and related system disposables are used together to treat cardiac arrhythmias, or heart rhythm disorders.

In March 2006, we terminated this agreement and entered into a new modified supply agreement with Edwards such that we would prospectively only manufacture the Optiwave 980 for Edwards and Edwards would prospectively assume all development and manufacturing responsibilities for the Optiwave 980 related system disposables. We received a cash payment of \$1,500,000 in consideration for selling our Optiwave 980 related system disposable manufacturing and development rights to Edwards. We hold the exclusive manufacturing rights to the current generation of Optiwave 980 for Edwards and have certain rights of first refusal related to the development and manufacture of any next generation laser.

Separately, Edwards is obligated to pay us a royalty on all future Optiwave 980 related system disposable sales, until such time, if ever, that cumulative royalty payments from Edwards reach \$1,700,000.

In December 2006, Edwards announced the discontinuation of its Optiwave 980 program and, therefore, we do not expect to generate any additional revenues from this product line in the future.

*Shareholders Agreement.* We entered into a shareholders agreement with Edwards on January 9, 2001, which was amended on February 24, 2004 and April 6, 2006. This shareholders agreement, with the exception of Articles VI and VII which provide for certain tax indemnifications to Edwards, was terminated on March 20, 2007 in connection with Edwards' assignment of our exclusive distribution agreement to Novadaq.

*Securities Purchase Agreement and Manufacturing License Agreement.* We entered into a securities purchase agreement, dated January 7, 2001, and a manufacturing license agreement, dated January 9, 2001, with Edwards. Both of these agreements were terminated on March 20, 2007 in connection with Edwards' assignment of our exclusive distribution agreement to Novadaq.

### **Rudko Loan**

Dr. Rudko, a director and our Chief Scientific Officer, had a loan from us that originated in 1991. In 1999, this loan was restructured to provide for interest from the inception of the loan to be calculated on the simple interest method at a rate of 6% per annum (a reduction of 2.65% from the original interest rate of this loan). This loan was paid in full on October 20, 2006. During the fiscal year ended December 31, 2006, the largest outstanding loan balance was approximately \$36,011.34. See "Employment Contracts, Termination of Employment and Change in Control Arrangements—Rudko Employment Agreement."

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

The following table summarizes the fees of Vitale, Caturano & Company, Ltd., our independent registered public accounting firm for 2007 and 2006, billed to us for each of the last two fiscal years:

<u>Fee Category</u>	<u>2007</u>	<u>2006</u>
Audit Fees(1) . . . . .	\$ 96,389	\$ 99,340
Tax Fees(2) . . . . .	\$ 33,000	\$ 35,300
Total Fees . . . . .	<u>\$129,389</u>	<u>\$134,640</u>

- (1) Audit fees consist of fees for the audit of our financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings or engagements. Audit fees for 2007 include an estimate of amounts agreed to with, but not yet billed by, Vitale, Caturano & Company, Ltd. in connection with their audit of our 2007 financial statements. The amounts also include \$4,800 billed by Ernst & Young LLP in 2006 for an issuance of their consent.
- (2) Tax fees consist of fees for tax compliance, tax advice and tax planning services. Tax compliance services, which relate to the preparation of corporate tax returns, accounted for \$28,000 of the fees paid in 2007 and all of the fees paid in 2006. Tax planning services accounted for the remaining \$5,000 in 2007. Tax advice and tax planning services relate to assistance with general tax matters, tax audits and employee benefits.

### **Pre-Approval Policy and Procedures**

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by the audit committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our registered public accounting firm during the next 12 months. Any such pre-approval must be detailed as to the particular service or type of services to be provided and must also be generally subject to a maximum dollar amount.

Our audit committee has also delegated to the chairman of the audit committee the authority to approve any audit or non-audit services to be provided to us by our registered public accounting firm. Any approval of services by the chairman of the audit committee pursuant to this delegated authority must be reported on at the next meeting of the audit committee.

**PART IV**

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

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

	<u>Page</u>
Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005 . . . . .	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 . . . . .	F-6
Notes to Consolidated Financial Statements . . . . .	F-7
Schedule II—Valuation and Qualifying Accounts . . . . .	S-1

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

(b) *Exhibits.*

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

(c) *Financial Statement Schedules.*

See Item 15(a) above.



**APPENDIX A**

**PLC SYSTEMS INC.  
CONSOLIDATED FINANCIAL STATEMENTS  
For the years ended December 31, 2007, 2006 and 2005**

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**PLC SYSTEMS INC.**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005 . .	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 . .	F-6
Notes to Consolidated Financial Statements . . . . .	F-7
Financial Statement Schedule:	
Schedule II—Valuation and Qualifying Accounts . . . . .	S-1

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of  
PLC Systems Inc.

We have audited the accompanying consolidated balance sheets of PLC Systems Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three year period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal controls over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe 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 financial position of PLC Systems Inc. as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

Our audits were performed for the purpose of forming an opinion on the consolidated financial statements taken as a whole. The schedule listed in the Index at Item 15 is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. In our opinion, the schedule referred to above presents fairly, in all material respects, the financial data required to be set forth therein in relation to the basic financial statements taken as a whole for each of the years in the three year period ended December 31, 2007.

/s/ Vitale, Caturano & Company, Ltd.

Boston, Massachusetts  
March 14, 2008

**PLC SYSTEMS INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2007 and 2006**  
(In thousands)

	<u>2007</u>	<u>2006</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 8,060	\$ 6,034
Short-term investments .....	—	4,000
Accounts receivable—other, net of allowance of \$23 and \$51 at December 31, 2007 and 2006, respectively .....	998	918
Inventories, net .....	852	1,255
Prepaid expenses and other current assets .....	823	595
Total current assets .....	10,733	12,802
Equipment, furniture and leasehold improvements, net .....	269	166
Other assets .....	198	208
Total assets .....	\$ 11,200	\$ 13,176
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 623	\$ 456
Accrued compensation .....	766	396
Accrued other .....	326	317
Deferred revenue .....	2,096	1,784
Total current liabilities .....	3,811	2,953
Deferred revenue .....	2,439	3,094
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, no par value, unlimited shares authorized, none issued and outstanding .....	—	—
Common stock, no par value, unlimited shares authorized, 30,329 and 30,311 shares issued and outstanding at December 31, 2007 and 2006, respectively .....	93,891	93,882
Additional paid in capital .....	270	101
Accumulated deficit .....	(88,898)	(86,531)
Accumulated other comprehensive loss .....	(313)	(323)
Total stockholders' equity .....	4,950	7,129
Total liabilities and stockholders' equity .....	\$ 11,200	\$ 13,176

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

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**9. Income Taxes (Continued)**

Under the Internal Revenue Code of 1986, as amended, certain substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards that can be utilized in any one year to offset future taxable income. Any carryforwards that will expire prior to utilization as the result of any limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate.

The Company maintained a reserve of \$70,000 as of December 31, 2007 for any potential tax matters that could arise in the future. The reserve did not change during the year ended December 31, 2007. As of December 31, 2007, the total amount of unrecognized tax benefits was \$0. The Company's policy is to record estimated interest and penalties related to the underpayment of income taxes as a component of its income tax provision. As of January 1, 2007 and December 31, 2007, the Company had no accrued interest or tax penalties recorded.

The Company files income tax returns in the U.S. federal jurisdiction and in several state and foreign jurisdictions. For U.S. federal and state tax purposes, the tax years 2004 through 2006 remain open to examination. In addition, the amount of the Company's federal and state net operating loss carryforwards may be subject to examination and adjustment. The open examination periods for the Company's foreign jurisdictions range from 1997 through 2006.

**10. Segment Information**

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

	<u>North America</u>	<u>Europe</u>	<u>Total</u>
<b>2007</b>			
Net sales .....	\$5,817	\$187	\$6,004
<b>2006</b>			
Net sales .....	\$6,588	\$558	\$7,146
<b>2005</b>			
Net sales .....	\$7,213	\$423	\$7,636

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

**PLC SYSTEMS INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2007 and 2006**  
(In thousands)

	2007	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 8,060	\$ 6,034
Short-term investments .....	—	4,000
Accounts receivable—other, net of allowance of \$23 and \$51 at December 31, 2007 and 2006, respectively .....	998	918
Inventories, net .....	852	1,255
Prepaid expenses and other current assets .....	823	595
Total current assets .....	10,733	12,802
Equipment, furniture and leasehold improvements, net .....	269	166
Other assets .....	198	208
Total assets .....	\$ 11,200	\$ 13,176
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 623	\$ 456
Accrued compensation .....	766	396
Accrued other .....	326	317
Deferred revenue .....	2,096	1,784
Total current liabilities .....	3,811	2,953
Deferred revenue .....	2,439	3,094
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, no par value, unlimited shares authorized, none issued and outstanding .....	—	—
Common stock, no par value, unlimited shares authorized, 30,329 and 30,311 shares issued and outstanding at December 31, 2007 and 2006, respectively .....	93,891	93,882
Additional paid in capital .....	270	101
Accumulated deficit .....	(88,898)	(86,531)
Accumulated other comprehensive loss .....	(313)	(323)
Total stockholders' equity .....	4,950	7,129
Total liabilities and stockholders' equity .....	\$ 11,200	\$ 13,176

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

**PLC SYSTEMS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For The Years Ended December 31, 2007, 2006 and 2005**  
(In thousands, except per share data)

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Revenues:			
Product sales .....	\$ 4,564	\$ 5,662	\$ 6,097
Service fees .....	1,440	1,484	1,539
Total revenues .....	<u>6,004</u>	<u>7,146</u>	<u>7,636</u>
Cost of revenues:			
Product sales .....	1,829	2,031	2,316
Service fees .....	806	701	750
Total cost of revenues .....	<u>2,635</u>	<u>2,732</u>	<u>3,066</u>
Gross profit .....	<u>3,369</u>	<u>4,414</u>	<u>4,570</u>
Operating expenses:			
Selling, general and administrative .....	3,794	3,014	3,336
Research and development .....	2,382	1,924	2,750
Total operating expenses .....	6,176	4,938	6,086
Gain on the sale of manufacturing rights .....	—	1,432	—
Income (loss) from operations .....	(2,807)	908	(1,516)
Other income .....	426	436	248
Income (loss) before income taxes .....	(2,381)	1,344	(1,268)
Provision for (benefit from) income taxes .....	(14)	25	—
Net income (loss) .....	<u>\$ (2,367)</u>	<u>\$ 1,319</u>	<u>\$ (1,268)</u>
Basic and diluted earnings (loss) per share .....	\$ (0.08)	\$ 0.04	\$ (0.04)
Average shares outstanding:			
Basic .....	30,318	30,170	30,074
Diluted .....	30,318	30,572	30,074

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

**PLC SYSTEMS INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For The Years Ended December 31, 2007, 2006 and 2005**  
(In thousands)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance, December 31, 2004 . . . . .	30,068	\$93,731	\$ —	\$(86,582)	\$(320)	\$ 6,829
Issuance of common stock . . . . .	12	6	—	—	—	6
Comprehensive loss:						
Net loss . . . . .	—	—	—	(1,268)	—	(1,268)
Foreign currency translation, net . . . .	—	—	—	—	(24)	(24)
Total comprehensive loss . . . . .						(1,292)
Balance, December 31, 2005 . . . . .	30,080	93,737	—	(87,850)	(344)	5,543
Exercise of stock options . . . . .	230	144	—	—	—	144
Issuance of common stock . . . . .	1	1	—	—	—	1
Stock based compensation . . . . .	—	—	101	—	—	101
Comprehensive income:						
Net income . . . . .	—	—	—	1,319	—	1,319
Foreign currency translation, net . . . .	—	—	—	—	21	21
Total comprehensive income . . . . .						1,340
Balance, December 31, 2006 . . . . .	30,311	93,882	101	(86,531)	(323)	7,129
Exercise of stock options . . . . .	13	7	—	—	—	7
Issuance of common stock . . . . .	5	2	—	—	—	2
Stock based compensation . . . . .	—	—	169	—	—	169
Comprehensive income:						
Net loss . . . . .	—	—	—	(2,367)	—	(2,367)
Foreign currency translation, net . . . .	—	—	—	—	10	10
Total comprehensive loss . . . . .						(2,357)
Balance, December 31, 2007 . . . . .	<u>30,329</u>	<u>\$93,891</u>	<u>\$270</u>	<u>\$(88,898)</u>	<u>\$(313)</u>	<u>\$ 4,950</u>

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

**PLC SYSTEMS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For The Years Ended December 31, 2007, 2006 and 2005**  
(In thousands)

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Operating activities:			
Net income (loss) . . . . .	\$(2,367)	\$ 1,319	\$(1,268)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation and amortization . . . . .	109	118	140
Loss on retirement of equipment . . . . .	—	77	—
Compensation expense from stock options . . . . .	169	101	—
Change in assets and liabilities:			
Accounts receivable . . . . .	(80)	(141)	629
Inventory . . . . .	403	(292)	148
Prepaid expenses and other assets . . . . .	(231)	195	(208)
Accounts payable . . . . .	167	104	24
Deferred revenue . . . . .	(347)	(688)	127
Accrued liabilities . . . . .	374	(299)	281
Net cash provided by (used for) operating activities . . . . .	<u>(1,803)</u>	<u>494</u>	<u>(127)</u>
Investing activities:			
Purchase of investments . . . . .	—	(4,000)	(8,400)
Maturity of investments . . . . .	4,000	6,900	1,500
Purchase of equipment . . . . .	(200)	(102)	(57)
Net cash provided by (used for) investing activities . . . . .	<u>3,800</u>	<u>2,798</u>	<u>(6,957)</u>
Financing activities:			
Net proceeds from exercise of stock options . . . . .	7	144	—
Net proceeds from issuance of common stock . . . . .	2	1	6
Net cash provided by financing activities . . . . .	<u>9</u>	<u>145</u>	<u>6</u>
Effect of exchange rate changes on cash and cash equivalents . . . . .	20	37	(40)
Net increase (decrease) in cash and cash equivalents . . . . .	2,026	3,474	(7,118)
Cash and cash equivalents at beginning of year . . . . .	6,034	2,560	9,678
Cash and cash equivalents at end of year . . . . .	<u>\$ 8,060</u>	<u>\$ 6,034</u>	<u>\$ 2,560</u>
Supplemental disclosure of cash flow information			
Cash paid (refunded) during the year for:			
Income taxes . . . . .	\$ (14)	\$ 15	\$ —
Interest . . . . .	—	—	—

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

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2007**

**1. Business**

PLC Systems Inc. ("PLC" or the "Company") is a medical device company specializing in innovative technologies for the cardiac and vascular markets. The Company pioneered and manufactures the *CO<sub>2</sub> Heart Laser System* (the "Heart Laser System") that cardiac surgeons use to perform carbon dioxide (CO<sub>2</sub>) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. In addition, the Company has commenced clinical trials for its RenalGuard Therapy and RenalGuard System (collectively "RenalGuard"), which is the primary growth initiative for its business. RenalGuard is designed to reduce the toxic effects that contrast media can have on the kidneys, which can lead to contrast-induced nephropathy ("CIN"), a potentially deadly form of acute kidney injury. The Company also manufactures CO<sub>2</sub> surgical laser tubes and provides contract assembly services on general purpose CO<sub>2</sub> lasers, which it sells to a single customer on an original equipment manufacturer ("OEM") basis.

RenalGuard Therapy is based on the theory that creating and maintaining a high urine output is beneficial to patients undergoing imaging procedures where contrast agents are used. The real-time measurement and matched fluid replacement design of the Company's RenalGuard System is intended to optimally administer RenalGuard Therapy and ensure that a high urine flow is maintained before, during and after these procedures, thus allowing the body to rapidly eliminate contrast, reducing its toxic effects. The RenalGuard System consists of a proprietary, closed loop, software-controlled console and accompanying single-use sets used for infusion and urine collection. The RenalGuard System, with its matched fluid replacement capability, is intended to minimize the risk of over- or under-hydration.

In December 2006, the Company received full Food and Drug Administration ("FDA") approval to conduct its first human clinical trial utilizing its RenalGuard System and Therapy under an investigational device exemption ("IDE"). This pilot clinical trial was designed to evaluate the safety of the RenalGuard System and its ability to accurately measure and balance fluid inputs and outputs on patients undergoing a catheterization imaging procedure where contrast media would be administered. In February 2008, the Company submitted an IDE supplement to the FDA seeking approval to move from its pilot study to a pivotal clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN. In March 2008, the FDA granted the Company conditional approval to begin this pivotal study.

On March 20, 2007, the Company entered into a distribution agreement with Novadaq Corp. ("Novadaq"), a subsidiary of Novadaq Technologies Inc., pursuant to which the Company appointed Novadaq as its exclusive distributor in the United States for its TMR business. The agreement amended and restated the exclusive distribution agreement between the Company and Edwards Lifesciences LLC ("Edwards"), which had been assigned by Edwards to Novadaq on the same date. The agreement with Novadaq reflects substantially the same roles, responsibilities and financial terms as the previous agreement with Edwards.

**2. Significant Accounting Policies**

*Basis of Presentation*

The consolidated financial statements include the accounts of PLC and its two wholly owned subsidiaries, PLC Medical Systems, Inc. and PLC Sistemas Medicos Internacionais

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

(Deutschland) GmbH. All intercompany accounts and transactions have been eliminated. Certain prior year amounts have been reclassified to confirm to the current year's presentation.

*Use of Estimates*

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

*Cash, Cash Equivalents and Short-Term Investments*

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents at December 31, 2007 and 2006 consist of an overnight sweep to repurchase agreements. Short-term investments consist of monies invested in bank certificates of deposits with remaining maturities greater than three months and less than one year. These investments are carried at cost, which approximates fair value.

*Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents and short-term investments and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing its cash equivalents and short-term investments in high-quality financial instruments with a high quality institution. At December 31, 2007 and 2006, the majority of the cash, cash equivalents and short-term investments balance was invested with a single financial institution.

The Company has a concentration of credit risk due to its exclusive TMR supply arrangements with Novadaq and formerly with Edwards. Novadaq accounted for 94% of the Company's net accounts receivable at December 31, 2007, while Edwards accounted for 81% at December 31, 2006. Novadaq and Edwards also accounted for 85%, 88% and 89% of the Company's revenues for the years ended December 31, 2007, 2006 and 2005, respectively. Collateral is not required on sales to Novadaq.

*Concentration of Revenues*

Approximately 87%, 95% and 89% of the Company's revenues for the years ended December 31, 2007, 2006 and 2005, respectively, were derived from the sales and service of the Heart Laser System.

*Accounts Receivable*

Accounts receivable is stated at the amount the Company expects to collect from the outstanding balances. The Company continuously monitors collections from customers, its principal customer being Novadaq, and maintains a provision for estimated credit losses based upon historical experience and any specific customer collection issues that the Company has identified. Historically, the Company has not experienced significant losses related to its accounts receivable. Collateral is generally not required.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

If the financial condition of its customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

*Inventories*

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

*Equipment, Furniture, Leasehold Improvements and Long-Lived Assets*

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

Depreciation and amortization are based on the following useful lives:

Equipment . . . . .	2-5 years
Office furniture and fixtures . . . . .	5 years
Leasehold improvements . . . . .	Shorter of life of lease or useful life

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

*Warranty and Preventative Maintenance Costs*

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

The Company evaluates the estimated future unrecoverable costs of warranty and preventative maintenance services for its installed base of lasers on a quarterly basis and adjusts its warranty reserve accordingly. The Company considers all available evidence, including historical experience and information obtained from supplier audits. Accrued warranty costs were \$60,000 at December 31, 2007 and 2006. There were no changes to the warranty accrual during the years ended December 31, 2007 and 2006.

*Revenue Recognition*

The Company records revenue from the sale of TMR kits at the time of shipment to Novadaq. TMR kit revenues include the amount invoiced to Novadaq for kits shipped pursuant to purchase

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

orders received, as well as an amortized portion of deferred revenue related to a payment of \$4,533,333 received in February 2004. This payment was made in exchange for a reduction in the prospective purchase price the Company receives upon a sale of the kits. The Company is amortizing this payment into its Consolidated Statements of Operations as revenue over a seven year period (culminating in 2010) under the units-of-revenue method as prescribed by Emerging Issues Task Force 88-18, "Sales of Future Revenue". The Company determined that a seven year timeframe was the most appropriate amortization period based on a valuation model it used to assess the economic fairness of the payment. Factors the Company considered in developing this valuation model included the estimated foregone revenues over a seven year period resulting from the reduction in the prospective purchase price payable to the Company, a discount rate deemed appropriate to this transaction and an estimate of the remaining economic useful life of the current TMR kit design, without any benefit being given to potential future product improvements the Company may make. The Company reviews annually, and adjusts if necessary, the prospective revenue amortization rate for kits based on its best estimate of the total number of kits likely remaining to be shipped to hospital customers by Novadaq through 2010. The Company recorded amortization of \$660,000, \$630,000 and \$356,000 for the years ended December 31, 2007, 2006 and 2005, respectively, which is included in revenues in the Consolidated Statements of Operations.

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

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

The Company records all other product revenue, including sales of TMR lasers and kits to international customers and OEM sales of surgical tubes and general purpose CO2 lasers, at the time of shipment.

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

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

*Foreign Currency Translation*

Assets and liabilities are translated into U.S. dollars at end-of-period 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.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

*Income Taxes*

The Company follows the liability method of accounting for income taxes, as set forth in Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting For Income Taxes." Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amount and the tax basis of assets and liabilities. The Company records a valuation allowance against deferred tax assets unless it is more likely than not that such asset will be realized in future periods.

In June 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109" ("FIN 48"). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. FIN 48 prescribes a recognition threshold of more-likely-than-not, and a measurement attribute for all tax positions taken or expected to be taken on a tax return, in order for those tax positions to be recognized in the financial statements.

Effective January 1, 2007, the Company adopted the provisions of FIN 48. The adoption of FIN 48 did not have an impact on the Company's consolidated financial statements. Effective with the adoption of FIN 48, the Company recognizes interest and penalties related to uncertain tax positions as a component of the provision for income taxes.

*Research and Development*

Research and development costs are expensed as incurred.

*Earnings (Loss) per Share*

In 2007 and 2005, basic and diluted loss per share have been computed using only the weighted average number of common shares outstanding during the period without giving effect to any potential future issuances of common stock related to stock option programs and warrants, since their inclusion would be antidilutive.

In 2006, basic earnings per share has been computed using only the weighted average number of common shares outstanding during the period, while diluted earnings per share was computed using the weighted average number of common shares outstanding during the period plus the effect of outstanding stock options using the treasury stock method. In calculating diluted earnings per share, the dilutive effect of stock options is computed using the average market price for the respective period.

For the years ended December 31, 2007, 2006 and 2005, 5,298,000, 1,595,000 and 5,788,000 shares, respectively, attributable to outstanding stock options and warrants were excluded from the calculation

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

of diluted earnings per share because the effect would have been antidilutive. The following table sets forth the computation of basic and diluted earnings per share:

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except per share data)		
<b>Basic:</b>			
Net income (loss) . . . . .	\$ (2,367)	\$ 1,319	\$ (1,268)
Weighted average shares outstanding . . . . .	30,318	30,170	30,074
Basic earnings (loss) per share . . . . .	<u>\$ (0.08)</u>	<u>\$ 0.04</u>	<u>\$ (0.04)</u>
<b>Diluted:</b>			
Net income (loss) . . . . .	\$ (2,367)	\$ 1,319	\$ (1,268)
Weighted average shares outstanding . . . . .	30,318	30,170	30,074
Assumed impact of the exercise of outstanding dilutive stock options using the treasury stock method . . . . .	—	402	—
Weighted average common and common equivalent shares . . . . .	30,318	30,572	30,074
Diluted earnings (loss) per share . . . . .	<u>\$ (0.08)</u>	<u>\$ 0.04</u>	<u>\$ (0.04)</u>

*Stock Based Compensation*

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), "Share-based Payment" ("SFAS No. 123R"), using the modified-prospective transition method, which did not require restatement of prior period results.

*Recent Accounting Pronouncements*

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. On February 6, 2008, the FASB announced it will issue a FASB Staff Position to allow a one-year deferral of adoption of SFAS No. 157 for non-financial assets and non-financial liabilities that are recognized at fair value on a nonrecurring basis. SFAS No. 157 provides a common fair value hierarchy for companies to follow in determining fair value measurements in the preparation of financial statements and expands disclosure requirements relating to how such fair value measurements are developed. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions that the marketplace would use when pricing an asset or liability, rather than company specific data. The Company is currently assessing the impact that SFAS No. 157 will have on its results of operations and financial position.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**2. Significant Accounting Policies (Continued)**

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"). SFAS No. 159, which includes an amendment to SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities", permits entities the option to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company does not believe the adoption of SFAS 159 will have a material effect on its results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS No. 141(R)"), which replaces SFAS No. 141. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition related costs as incurred. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning after December 15, 2008 and will apply prospectively to business combinations completed on or after that date. The impact of the adoption of SFAS No. 141(R) on the Company's results of operations and cash flows will depend on the terms and timing of future acquisitions, if any.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51" ("SFAS No. 160"). SFAS No. 160 changes the accounting and reporting for minority interests, which will be recharacterized as non-controlling interests and classified as a component of equity. SFAS No. 160 is effective for the Company on a prospective basis for business combinations with an acquisition date beginning in the first quarter of fiscal year 2009. As of December 31, 2007, the Company did not have any minority interests.

**3. Gain on Sale of Manufacturing Rights**

In February 2004, the Company signed an agreement with Edwards to assume development and manufacturing of the Optiwave 980 Cardiac Laser Ablation System ("Optiwave 980") and related system disposables. In March 2006, the Company and Edwards terminated this agreement. The Company received \$1,500,000 in consideration for selling its Optiwave 980 system related disposable manufacturing rights to Edwards. In conjunction with the sale, the Company wrote off certain inventory and capital assets acquired to manufacture the Optiwave 980 disposables and recorded a net gain of \$1,432,000 in its Consolidated Statement of Operations during the year ended December 31, 2006.

**4. Inventories**

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

	<u>2007</u>	<u>2006</u>
Raw materials . . . . .	\$560	\$ 791
Work in process . . . . .	151	118
Finished goods . . . . .	141	346
	<u>\$852</u>	<u>\$1,255</u>

At December 31, 2007 and 2006, inventories are stated net of a specific obsolescence allowance of \$524,000 and \$548,000, respectively.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**5. Equipment, Furniture and Leasehold Improvements**

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

	2007	2006
Equipment . . . . .	\$1,220	\$1,020
Office furniture and fixtures . . . . .	218	218
Leasehold improvements . . . . .	349	349
	1,787	1,587
Less accumulated depreciation and amortization . . . . .	1,518	1,421
	<b>\$ 269</b>	<b>\$ 166</b>

Depreciation expense was \$98,000, \$94,000 and \$114,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**6. Stockholders' Equity**

At December 31, 2007, there were 6,074,000 shares of authorized but unissued common stock reserved for issuance under the Company's stock option plans and employee stock purchase plan.

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

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

**7. Stock Based Compensation**

*Stock Option Plans*

In May 2005, the Company's shareholders approved the 2005 Stock Incentive Plan (the "2005 Plan"). The 2005 Plan has replaced the 1997 Executive Stock Option Plan, 2000 Equity Incentive Plan, 2000 Non-Statutory Stock Option Plan and 2000 Non-Qualified Performance and Retention Equity Plan (collectively, the "Previous Plans"), under which no further awards can be granted.

The number of stock options that may be granted under the 2005 Plan is equal to 2,156,175 shares of common stock (subject to adjustment in the event of stock splits and other similar events), plus such number of shares as may become available under the Previous Plans after the date of the adoption of the 2005 Plan because any award previously granted under any such plan expires or is terminated, surrendered or cancelled without having been fully exercised or is forfeited in whole or in part or results in any common stock not being issued, provided that such number of additional shares may not exceed 2,535,492. 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 the Previous Plans and the 2005 Plan become exercisable either immediately, or ratably over one to four years from the date of grant, and expire ten years from the date of grant. The per share exercise price of incentive stock options may not be less than the fair

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**7. Stock Based Compensation (Continued)**

market value of the common stock on the date the option is granted. The 2005 Plan provides that the Company may not grant non-qualified options at an exercise price less than 85% of the fair market value of the Company's common stock.

The Company grants stock options to its non-employee directors. Generally, new non-employee directors receive an initial grant of an option to purchase 30,000 shares of the Company's common stock that vests in installments over three years. Once the initial grant has fully vested, non-employee directors (other than the Chairman of the Board) receive an annual grant of an option to purchase 15,000 shares of the Company's common stock that generally vests in four equal quarterly installments. The Chairman of the Board receives an annual grant of an option to purchase 30,000 shares of the Company's common stock that generally vests in four equal quarterly installments. All such options have an exercise price equal to the fair market value of the Company's common stock on the date of grant.

Options granted during 2007 and 2006 will vest ratably annually over a three year period for employees and ratably quarterly over a one year period for non-employee directors. Options granted during 2005 to both employees and non-employee directors vested immediately upon granting.

The following is a summary of option activity under all of the Company's stock option plans (in thousands, except per option data):

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2004	4,070	\$1.38		
Granted	690	0.55		
Exercised	—	—		
Forfeited	(2)	0.81		
Expired	(70)	5.94		
Outstanding, December 31, 2005	4,688	\$1.19		
Granted	596	0.69		
Exercised	(230)	0.63		
Forfeited	(232)	2.27		
Expired	(55)	5.35		
Outstanding, December 31, 2006	4,767	\$1.05		
Granted	618	0.64		
Exercised	(13)	0.47		
Forfeited	(8)	0.75		
Expired	(66)	4.74		
Outstanding, December 31, 2007	5,298	\$0.96	5.75	—
Exercisable, December 31, 2007	4,403	\$1.02	5.08	—

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**7. Stock Based Compensation (Continued)**

	2007	2006	2005
Intrinsic value of options exercised during the year . . . . .	\$ 2	\$61	\$ —
Total fair value of shares vested during the year . . . . .	\$124	\$55	\$290

The following table summarizes unvested option activity during the year ended December 31, 2007:

	Number of Options	Weighted Average Grant Date Fair Value
	(in thousands, except weighted average data)	
Unvested, December 31, 2006 . . . . .	531	\$0.51
Granted . . . . .	618	0.44
Vested . . . . .	(251)	0.50
Forfeited . . . . .	(3)	0.50
Unvested, December 31, 2007 . . . . .	895	\$0.47

*SFAS No. 123R*

The Company recorded compensation expense of \$169,000 and \$101,000 in the years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, the Company had \$388,000 of total unrecognized compensation cost related to its unvested options, which is expected to be recognized over a weighted average period of 1.8 years.

The weighted average fair value of options issued during the years ended December 31, 2007 and 2006 were estimated using the Black-Scholes model.

	Year Ended December 31,	
	2007	2006
Expected life (years) . . . . .	5.50–6.00	5.50–6.00
Interest rate . . . . .	4.62–5.20%	4.07–5.05%
Volatility . . . . .	74.7–77.4%	91.2–93.9%
Expected dividend yield . . . . .	None	None
Value of option granted . . . . .	\$0.43–0.45	\$0.48–0.68

The expected life is calculated using the simplified method. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of the grant for the expected term period. Expected volatility is based exclusively on historical volatility data of the Company's common stock. The Company estimates an expected forfeiture rate based on its historical forfeiture activity. Actual results, and future changes in estimates, may differ substantially from the Company's current estimates. The weighted average fair value of options granted during the years ended December 31, 2007 and 2006 was \$0.44 and \$0.51, respectively.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**7. Stock Based Compensation (Continued)**

*Pro Forma Information for Period Prior to SFAS No. 123R Adoption*

Through December 31, 2005, the Company adopted the disclosure only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), and accounted for its stock option plans in accordance with the provisions of Accounting Principals Board Opinion No. 25, "Accounting for Stock Issued to Employees". The following table illustrates the effect on net loss and basic loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock based employee compensation during the year ended December 31, 2005.

	Year Ended December 31, 2005
	(In thousands, except per share data)
Net loss attributable to common shareholders—	
As reported . . . . .	\$(1,268)
Deduct total stock based compensation expense determined under fair value based method for all stock option awards . . . . .	(186)
Net loss attributable to common shareholders—	
Pro forma . . . . .	\$(1,454)
Loss per basic and diluted share attributable to common shareholders—As reported . . . . .	\$ (0.04)
Loss per basic and diluted share attributable to common shareholders—Pro forma . . . . .	\$ (0.05)

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

	Year Ended December 31, 2005
Expected life (years) . . . . .	3
Interest rate . . . . .	3.68%
Volatility . . . . .	40.7%
Expected dividend yield . . . . .	None
Weighted average fair value of options granted during the year . . . .	\$0.17

*Stock Purchase Plan*

The Company has a 2000 Employee Stock Purchase Plan (the "Purchase Plan") for all eligible employees whereby shares of the Company's common stock may be purchased at six-month intervals at 95% of the closing price of the Company's common stock on the last business day of the relevant plan period. Employees may purchase shares having a value not exceeding 10% of their gross compensation during an offering period, subject to certain additional limitations. Under the Purchase Plan, employees of the Company purchased 5,179 shares of common stock in 2007, 1,235 shares of common stock in 2006, and 12,044 shares of common stock in 2005 at average prices of \$0.47, \$0.65 and \$0.51 per share,

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**7. Stock Based Compensation (Continued)**

respectively. At December 31, 2007, 316,073 shares were reserved for future issuance under the Purchase Plan.

**8. Commitments**

*Lease Commitments*

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

As of December 31, 2007, future minimum lease payments are estimated to be as follows (in thousands):

<u>Year</u>	<u>Future Minimum Lease Payments</u>
2008 .....	261
2009 .....	176
	<u>\$437</u>

Total rent expense was \$253,000 in 2007, \$263,000 in 2006 and \$316,000 in 2005.

*Bonus Commitment*

The Company has a bonus plan for all employees calculated based on predetermined Company milestones and targets. The Board of Directors has the discretion to adjust the bonus amounts prior to approval and payment. At December 31, 2007 and 2006, \$277,000 and \$0 of bonuses were accrued on the accompanying Consolidated Balance Sheets.

**9. Income Taxes**

The provision for income taxes in the year ended December 31, 2006 shown in the Consolidated Statement of Operations represents current federal income taxes payable.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**9. Income Taxes (Continued)**

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

	<u>2007</u>	<u>2006</u>
Net U.S. operating loss carryforwards . . . . .	\$ 20,747	\$ 20,489
Net foreign operating loss carryforwards . . . . .	451	367
Accrued expenses and reserves . . . . .	735	679
Tax credits . . . . .	1,170	1,071
Other . . . . .	<u>1,797</u>	<u>1,892</u>
Total deferred tax assets . . . . .	24,900	24,498
Valuation allowance . . . . .	<u>(24,900)</u>	<u>(24,498)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance increased by approximately \$402,000 in 2007 primarily due to a net loss and the reversal of temporary differences associated with deferred revenue in 2007. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset of \$24,900,000.

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

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Domestic . . . . .	\$(1,948)	\$1,441	\$(1,167)
Foreign . . . . .	<u>(419)</u>	<u>(122)</u>	<u>(101)</u>
	<u>\$ (2,367)</u>	<u>\$ 1,319</u>	<u>\$ (1,268)</u>

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

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Statutory income tax expense (benefit) . . . . .	\$(805)	\$ 449	\$(431)
Utilization of loss carryforwards . . . . .	—	(465)	(30)
Unbenefited U.S. losses . . . . .	648	—	396
Unbenefited foreign losses . . . . .	<u>143</u>	<u>41</u>	<u>65</u>
Provision for (benefit from) income taxes . . . . .	<u>\$ (14)</u>	<u>\$ 25</u>	<u>\$ —</u>

At December 31, 2007, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$52 million, which expire at various dates through 2027. At December 31, 2007, \$66,000 of federal and state net operating loss carryforwards relate to deductions for stock option compensation for which the associated tax benefit will be credited to additional paid-in capital when realized. At December 31, 2007, the Company had federal and state research and development credit carryforwards of \$760,000 and \$410,000 respectively, which will expire at varying dates through 2027 for federal income tax purposes and through 2022 for state income tax purposes. In addition, the Company had foreign net operating loss carryforwards of approximately \$1,100,000.

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**9. Income Taxes (Continued)**

Under the Internal Revenue Code of 1986, as amended, certain substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards that can be utilized in any one year to offset future taxable income. Any carryforwards that will expire prior to utilization as the result of any limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate.

The Company maintained a reserve of \$70,000 as of December 31, 2007 for any potential tax matters that could arise in the future. The reserve did not change during the year ended December 31, 2007. As of December 31, 2007, the total amount of unrecognized tax benefits was \$0. The Company's policy is to record estimated interest and penalties related to the underpayment of income taxes as a component of its income tax provision. As of January 1, 2007 and December 31, 2007, the Company had no accrued interest or tax penalties recorded.

The Company files income tax returns in the U.S. federal jurisdiction and in several state and foreign jurisdictions. For U.S. federal and state tax purposes, the tax years 2004 through 2006 remain open to examination. In addition, the amount of the Company's federal and state net operating loss carryforwards may be subject to examination and adjustment. The open examination periods for the Company's foreign jurisdictions range from 1997 through 2006.

**10. Segment Information**

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

	<u>North America</u>	<u>Europe</u>	<u>Total</u>
<b>2007</b>			
Net sales .....	\$5,817	\$187	\$6,004
<b>2006</b>			
Net sales .....	\$6,588	\$558	\$7,146
<b>2005</b>			
Net sales .....	\$7,213	\$423	\$7,636

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

**PLC SYSTEMS INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2007**

**11. Selected Quarterly Data (unaudited)**

	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>	<u>Total</u>
	(In thousands, except per share data)				
<b>2007</b>					
Total revenue .....	\$1,493	\$1,932	\$1,331	\$1,248	\$ 6,004
Gross profit .....	699	1,157	863	650	3,369
Loss from operations .....	(805)	(475)	(604)	(923)	(2,807)
Net loss .....	(686)	(363)	(499)	(819)	(2,367)
Loss per share, basic and diluted .....	(0.02)	(0.01)	(0.02)	(0.03)	(0.08)
<b>2006</b>					
Total revenue .....	\$1,889	\$1,943	\$1,567	\$1,747	\$ 7,146
Gross profit .....	1,198	1,221	977	1,018	4,414
Income (loss) from operations .....	1,217	(41)	(203)	(65)	908
Net income (loss) .....	1,291	72	(80)	36	1,319
Earnings (loss) per share, basic and diluted ...	0.04	0.00	(0.00)	0.00	0.04

**PLC SYSTEMS INC.**  
**Valuation and Qualifying Accounts**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Additions Charged (Credited) to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
<b>For the Year Ended December 31, 2007</b>				
Allowance for Doubtful Accounts .....	\$ 51,000	\$(8,000)	\$20,000	\$23,000
<b>For the Year Ended December 31, 2006</b>				
Allowance for Doubtful Accounts .....	\$ 96,000	\$25,000	\$70,000	\$51,000
<b>For the Year Ended December 31, 2005</b>				
Allowance for Doubtful Accounts .....	\$104,000	\$(8,000)	\$ —	\$96,000

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Articles of Continuance, pursuant to the Yukon Business Corporations Act, as amended, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2004, as previously filed with the Securities and Exchange Commission.
3.2	By-Law No. 1, a By-Law relating generally to the transaction of the business and affairs of PLC Systems Inc., incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 1999, as previously filed with the Securities and Exchange Commission.
4.1	Form of Common Stock Certificate, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-48340) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.1#	1993 Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-58258) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.2#	1993 Formula Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-58258) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.3#	1995 Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-8 (SEC File No. 33-95168), as previously filed with the Securities and Exchange Commission.
10.4#	1997 Executive Stock Option Plan, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 1997, as previously filed with the Securities and Exchange Commission.
10.5#	2000 Non-qualified Performance and Retention Equity Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
10.6#	2000 Non-Statutory Stock Option Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.7#	2000 Equity Incentive Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.8#	Form of Stock Option Grant Letter to Employees of the Registrant under the Registrant's 1995 Stock Option Plan, 1997 Executive Stock Option Plan, 2000 Equity Incentive Plan and 2000 Non-Qualified Performance and Retention Plan, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004, as previously filed with the Securities and Exchange Commission.
10.9#	Form of Stock Option Grant Letter to Non-Employee Directors of the Registrant under the Registrant's 1995 Stock Option Plan, 1997 Executive Stock Option Plan and 2000 Equity Incentive Plan, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004, as previously filed with the Securities and Exchange Commission.
10.10#	2005 Stock Incentive Plan, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2005.

Exhibit Number	Description of Document
10.11#	Form of Stock Option Grant Letter for Employees of the Registrant under the Registrant's 2005 Stock Incentive Plan, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2005.
10.12#	Form of Stock Option Grant Letter for Non-Employee Directors of the Registrant under the Registrant's 2005 Stock Incentive Plan, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2005.
10.13#	Employment Agreement of James G. Thomasch, dated November 4, 1999, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
10.14#	Employment Agreement of Mark R. Tauscher, dated December 22, 1999, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2000, as previously filed with the Securities and Exchange Commission.
10.15#	Terms of Employment dated October 28, 2003 between the Registrant and Dr. Robert I. Rudko, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2003, as previously filed with the Securities and Exchange Commission.
10.16#	Amendment dated March 15, 2005 to Terms of Employment between PLC Medical Systems, Inc. and Dr. Robert I. Rudko, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on March 17, 2005.
10.17+	Distribution Agreement, dated January 9, 2001, by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2005, as previously filed with the Securities and Exchange Commission.
10.18	Shareholders Agreement, dated January 9, 2001, by and between the Registrant and Edwards Lifesciences Corporation, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2001, as previously filed with the Securities and Exchange Commission.
10.19+	Distribution Agreement by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC dated February 24, 2004, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.20+	Contribution, Development and Manufacturing Agreement by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC dated as of February 24, 2004, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.21	First Amendment to Distribution Agreement entered into as of February 24, 2004 by and among Edwards Lifesciences LLC, the Registrant and PLC Medical Systems, Inc., incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.
10.22	First Amendment to Shareholders Agreement entered into as of February 24, 2004 by and between Edwards Lifesciences Corporation and the Registrant, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2004, as previously filed with the Securities and Exchange Commission.

Exhibit Number	Description of Document
10.23+	Supply Agreement, dated March 9, 2006, by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006, as previously filed with the Securities and Exchange Commission.
10.24+	Letter Agreement, dated March 9, 2006, between the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006, as previously filed with the Securities and Exchange Commission.
10.25	Second Amendment to Shareholders Agreement, dated April 6, 2006, by and among the Registrant and Edwards Lifesciences Corporation, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006, as previously filed with the Securities and Exchange Commission.
10.26+	Distribution Agreement, dated March 20, 2007, by and among the Registrant, PLC Medical Systems, Inc., Novadaq Technologies Inc. and Novadaq Corp., incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2007, as previously filed with the Securities and Exchange Commission.
10.27	Letter Agreement, dated March 20, 2007, by and among the Registrant, PLC Medical Systems, Inc. and Edwards Lifesciences LLC, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2007, as previously filed with the Securities and Exchange Commission.
10.28*#	Compensatory Arrangements with Executive Officers.
10.29*#	Compensatory Arrangements with Non-Employee Directors.
10.30*#	Severance Arrangements with Executive Officers.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Vitale, Caturano & Company Ltd.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed with this annual report on Form 10-K for the year ended December 31, 2007.

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

# Management contract or compensatory plan or arrangement.

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**BOARD OF DIRECTORS**

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

**Kevin J. Dunn**  
President and Chief Executive Officer  
US Operations  
Canaccord Adams Inc.

**Benjamin L. Holmes**  
President, The Holmes Company  
Formerly General Manager  
and Vice President  
Hewlett-Packard  
Medical Products Group

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

**Brent Norton, M.D.**  
President and Chief Executive Officer  
PreMD Inc.

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

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

**CORPORATE OFFICERS**

**Mark R. Tauscher**  
President and Chief Executive Officer

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

**Kenneth J. Luppi**  
Vice President, Operations

**Robert I. Rudko**  
Founder and Chief Scientific Officer

**Vincent C. Puglisi**  
Managing Director - International

**COMMON STOCK**

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

**ANNUAL MEETING**

The Annual Meeting of Shareholders  
of PLC Systems Inc. will be held on  
Wednesday, June 18, 2008, at 10 a.m.  
at the offices of WilmerHale LLP,  
60 State Street, Boston, Massachusetts.

**STOCK TRANSFER AGENT AND REGISTRAR**

Please contact Computershare Trust Company  
N.A. with inquiries about address or name  
changes, lost stock certificates or stock  
transfers.

**Computershare Trust Company, N.A.**  
250 Royall Street  
Canton, MA 02021  
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**Investor Relations**

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