
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2009

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)

04-3153858

(I.R.S. Employer Identification No.)

10 Forge Park, Franklin, Massachusetts

(Address of principal executive offices)

02038

(Zip Code)

(508) 541-8800

(Registrant's telephone number, including area code)

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

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

Common stock, no par value

(Title of class)

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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, 2009, was \$8,417,570. As of March 15, 2010, 30,351,092 shares of common stock, no par value per

share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement, which will be issued in connection with the 2010 Annual Meeting of Shareholders, are incorporated by reference in Part III of this annual report on Form 10-K.

Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), 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 considerations described in the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Forward-Looking Statements."

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 *CO₂ Heart Laser System* that cardiac surgeons use to perform carbon dioxide (CO₂) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. Over the past two years, we have begun initial commercialization outside the United States of our newest product, RenalGuard[®], which currently represents our key strategic growth initiative and primary business focus.

RenalGuard is designed to reduce the potentially toxic effects that contrast media can have on the kidneys when it is administered to patients during certain medical imaging procedures. It is believed that allowing contrast media to dwell in the kidneys of certain higher risk patients can lead to contrast-induced nephropathy ("CIN"), a potentially deadly form of acute kidney injury. By inducing and maintaining a high urine flow rate before, during and after these medical imaging procedures, we believe the incidence rates of CIN in at-risk patients can be reduced. RenalGuard facilitates this increased urine clearance automatically, enabling the body to more rapidly void the contrast media, thereby reducing its overall resident time and toxic effects in the kidney.

The RenalGuard System consists of a proprietary, closed loop, software-controlled console and accompanying single-use sets. RenalGuard operates by first collecting and measuring patient urine outputs and then in real-time precisely matching these urine outputs with a prescribed replacement fluid by means of intravenous infusion. With its automated matched fluid replacement capability, RenalGuard is intended to promote and maintain high urine outputs and minimize the risk to patients of over- or under-hydration during image guided catheterization procedures where contrast media are routinely administered.

The U.S. Food and Drug Administration ("FDA") has granted us approval to begin a pivotal clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN; however, we have deferred commencement of this study until we can successfully raise additional capital necessary to start and complete the study. We must successfully complete this study and obtain FDA pre-market approval in order to market RenalGuard in the U.S.

We obtained a CE Mark for RenalGuard in December 2007 and began our initial commercialization efforts in the European Union ("EU") in Italy in April 2008.

Recent Developments

On February 4, 2010, in an effort to lower our expenses, we announced a reduction in our workforce of eight employees, or one-third. In addition, we announced that we have engaged a financial advisor to assist us with our ongoing efforts to raise additional capital and to explore other strategic options for our RenalGuard program. We will need to raise capital in the next few months, whether through asset sales, equity investment or other strategic transaction, in order to continue our operations.

RenalGuard Program

Our near term focus for our RenalGuard program is to (1) establish a broader distribution network in the EU and other select countries outside the EU where we have the approval to market RenalGuard, (2) assist our distributors in their ongoing efforts to sell RenalGuard and increase adoption of our technology and (3) continue support of two investigator-sponsored studies utilizing RenalGuard that are being conducted in Italy and leverage the positive data from those studies to drive additional RenalGuard sales, as well as help us to raise additional needed capital.

Clinical Trials Update

The first of these two investigator-sponsored studies, the MYTHOS trial, is a randomized, open-label controlled clinical trial that is being conducted at the Centro Cardiologico Monzino-University of Milan ("CCM") in Milan, Italy. The MYTHOS trial is designed to determine the safety and effectiveness of RenalGuard in preventing CIN in at-risk patients. The study was originally designed to enroll 120 patients, which was recently achieved in January 2010.

The most recent data that has been released on the results of the MYTHOS trial is based upon the first 114 patients enrolled in the study. These results reinforce RenalGuard's safety profile and its efficacy in reducing the rates of CIN in at-risk patients. In the RenalGuard treated group, the incidence rate of CIN was only 3.7%, 75% lower than the 15% CIN rate recorded in the control group. The RenalGuard treated group also experienced a statistically significant fewer number of in-hospital major adverse events.

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The MYTHOS investigators are currently seeking approval to continue the study, which would expand the enrollment beyond the original 120 patient trial design, in order to obtain even stronger and more meaningful statistical data on the safety and effectiveness of RenalGuard in reducing the incidence rate of CIN.

The second investigator-sponsored study, the REMEDIAL II trial, is a randomized, open-label controlled clinical trial ongoing at the Clinica Mediterranea in Naples, Italy. The interim results reported on the first 123 patients show a similar efficacy level to the MYTHOS trial, with a 3.2% CIN rate in the RenalGuard treated group compared to a 13% CIN rate in the control group (using the same definition for CIN as that which was used and results reported on in the MYTHOS trial). This trial is expected to continue at least through 2010.

We hope that the continued data from the MYTHOS and REMEDIAL II clinical trials will both increase the adoption rate of our RenalGuard technology and enable us to raise the additional capital we need to continue our RenalGuard program.

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.

We believe CIN is a major and growing problem due to the increasing number of older patients, diabetics and patients with pre-existing renal impairment requiring interventional procedures that use radiographic contrast media. CIN is the third most common cause of in-hospital acute renal failure. It 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 who develop CIN may be as high as 35%.

Potential Market Size

Based upon 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 Heart Disease and Stroke Statistics — 2010 Update, or 2010 HSSU, which was published by the American Heart Association, estimates that there were 171 million individuals with diabetes worldwide in 2000 and that number is projected to rise to 366 million by 2030. It is estimated that nearly 26 million people in the U.S. have chronic kidney disease ("CKD") and another 20 million are at increased risk for CKD.

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 Kidney Foundation. A decrease

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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 RenalGuard.

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 automated 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

Our RenalGuard Therapy has now been studied in two randomized, open-label controlled clinical trials. The aim of these studies is to determine if very high urine outputs with precise matching of intravascular volume significantly reduced the risk of CIN.

The results to date reported from these studies have given us confidence that our concept of inducing high urine output with matched fluid replacement to maintain intravascular volume can significantly reduce the incidence of CIN.

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, and because it is automated, it lessens the burden on staff to constantly monitor patients.

U.S. Development Timeline

RenalGuard is currently an investigational device in the U.S. In December 2006, we received 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 November 2008, the FDA granted us full approval to begin our pivotal study which, if we are successful in raising the necessary additional capital in the future to commence it, is currently designed to enroll 406 patients at up to 30 U.S. sites.

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 attractive to hospitals as an automated fluid balancing system which could be used in certain intensive patient monitoring settings within the hospital, such as the intensive care unit, or where fluid management is critical, such as in post-kidney transplant patients where the replacement of fluid losses is necessary to avoid the risk of damage to the transplanted kidney.

Current Treatment Methods for CIN

The only clinically accepted and routinely utilized preventive measure for patients at risk for CIN is pre- and post- procedure overnight hydration, which is inconvenient, expensive and time-consuming for hospital staff. There is currently no FDA-approved device or

drug for CIN prevention. Due to the attractiveness of the potential market, we believe that there are a number of other companies developing or investigating potential new CIN preventive drugs, devices and therapies.

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

In January 2009, AngioDynamics Inc. acquired certain assets of FlowMedica, Inc., including its 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.

The CO₂ 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 CO₂ 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 CO₂ 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 on Form 10-K as the Heart Laser System.

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

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 2010 HSSU, an estimated 1,313,000 angioplasty procedures were performed in the U.S. in 2006.

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

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 2010 HSSU, an estimated 448,000 coronary artery bypass procedures were performed on 253,000 patients in the U.S. in 2006 (down from an estimated 469,000 bypass procedures performed on 261,000 patients in the U.S. in 2005). 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 upon 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 upon 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 coronary artery disease.

TMR Sales and Marketing Strategy

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. Its 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 the 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.

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

International sales (by origin) accounted for 29% of our total revenue in 2009 and 15% in 2008.

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.

TMR 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.

TMR Competition

Our only direct competitor in the TMR market at this time is CardioGenesis Corporation. 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 its TMR system, which allows it to sell its product commercially in the EU. CardioGenesis promotes the advantages it believes its 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 its TMR products will have in terms of competing with our present Heart Laser System design.

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. No assurance can be given that our competitors or others will not succeed in developing technologies, products or procedures that are more effective than our TMR products or that would render our technology and products obsolete or noncompetitive. 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.

Products and Customers

We currently sell and service the Heart Laser Systems, which accounted for approximately 76% and 85% of our revenues for the years ended December 31, 2009 and 2008, respectively.

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Our U.S. TMR distributor, Novadaq, is our largest customer and accounted for 65% and 74% of our total revenues in the years ended December 31, 2009 and 2008, respectively. Our distributor of RenalGuard in Italy, Artech, accounted for 10% of our total revenues and 81% of our RenalGuard revenues in the year ended December 31, 2009. We expect these sales concentrations with Novadaq for TMR sales and Artech for RenalGuard sales to continue in 2010.

Manufacturing

We currently manufacture and test our Heart Laser System and our RenalGuard console at our facility in Franklin, Massachusetts. Our RenalGuard sterile disposable kit is manufactured for us by an outside contract manufacturer. We expect to move the manufacturing of our RenalGuard console to a contract manufacturer beginning in the third quarter of 2010. We believe that our own manufacturing capacity as well as that which is available to us through our outside contract manufacturers will be sufficient to meet market demands anticipated in the coming year for all our products.

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. We filed this postapproval study report with the FDA on February 28, 2007. On August 18, 2008, we received a letter from the FDA informing us that we had satisfied our postapproval study requirements with the submission of our final report.

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

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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.

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 35 U.S. patents, of which 29 are still in force. These patents have terms that expire from 2010 through 2024 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. In addition, we have two applications filed in the field of percutaneous valves.

In addition, we currently have one issued patent in Canada and ten patent applications pending at the U.S. patent office in connection with the prevention of CIN related to RenalGuard. We have international patent applications pending on eight of these RenalGuard patents, including individual patent applications pending in the EU and Japan.

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.

Research and Development

Research and development expenses were \$780,000 and \$2,075,000 for the years ended December 31, 2009 and 2008, respectively. Our current and near term development efforts will be focused on advancing our RenalGuard program.

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 15, 2010, we had 16 full-time employees worldwide, including our executive officers. Of these, six are in general and administrative positions, two are involved in sales, one is involved in research and development, three are involved in manufacturing, and four are involved in service. We also employ one part-time employee in research and development. 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. 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

Pursuant to the instructions to Item 1A. of Form 10-K, we are not required to provide this information because we are a smaller reporting company.

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, 2011. The total base rental payments for the year-ending December 31, 2010 and for the eight months ending August 31, 2011 total approximately \$204,000 and \$136,000, 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. (Removed and Reserved)**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

From September 17, 1992 to November 7, 2008, our common stock traded on the NYSE Alternext Market (formerly the American Stock Exchange) ("AMEX") under the symbol "PLC"; from November 10, 2008 to November 14, 2008, our common stock was quoted on the Pink Sheets under the symbol "PLCSF"; and since November 17, 2008, our common stock has been quoted on both the Pink Sheets and the OTC Bulletin Board (the "OTCBB") under the symbol "PLCSF". On March 15, 2010, the last sale price of our common stock was \$0.16 per share.

From the first quarter of 2008 through the third quarter of 2008, the following table sets forth the range of high and low sales prices for our common stock on AMEX. From the fourth quarter of 2008 through the fourth quarter of 2009, the following table sets forth the highest and lowest of (1) any sales price for our common stock on AMEX through November 7, 2008 or (2) any bid price for our common stock on the Pink Sheets or the OTCBB on and after November 10, 2008. Any bid price listed represents inter-dealer quotations without retail markup, markdown or commission and may not necessarily represent actual transactions.

2008	High	Low
First Quarter	\$ 0.49	\$ 0.35
Second Quarter	\$ 0.45	\$ 0.32
Third Quarter	\$ 0.43	\$ 0.06
Fourth Quarter	\$ 0.15	\$ 0.025
2009	High	Low
First Quarter	\$ 0.27	\$ 0.05
Second Quarter	\$ 0.50	\$ 0.06
Third Quarter	\$ 0.40	\$ 0.21
Fourth Quarter	\$ 0.32	\$ 0.12

As of March 15, 2010, there were 674 record holders of our common stock. We believe that there are approximately 6,200 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.

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, 2009:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
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Equity compensation plans approved by security holders(1)	5,309,954	\$	0.25	2,275,795 (2)
Equity compensation plans not approved by security holders	—		—	—
Total	5,309,954	\$	0.25	2,275,795

- (1) Consists of the following equity compensation plans: (i) 1995 Stock Option Plan; (ii) 2000 Employee Stock Purchase Plan, as amended (the “2000 ESPP”); (iii) 2000 Equity Incentive Plan; and (iv) 2005 Stock Incentive Plan.
- (2) Includes 294,461 shares issuable under the 2000 ESPP, including shares issuable in connection with the current offering period, which ends on May 31, 2010.

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, but not the OTCBB, 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 advisors 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

Pursuant to Item 301(c) of Regulation S-K, we are not required to provide this information because we are a smaller reporting company.

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. Over the past two years, we have begun initial commercialization outside the United States of our newest product, RenalGuard®, which currently represents our key strategic growth initiative and primary business focus.

RenalGuard is designed to reduce the potentially toxic effects that contrast media can have on the kidneys when it is administered to patients during certain medical imaging procedures. It is believed that allowing contrast media to dwell in the kidneys of certain higher risk patients can lead to CIN, a potentially deadly form of acute kidney injury. By inducing and maintaining a high urine flow rate before, during and after these medical imaging procedures, we believe the incidence rates of CIN in at-risk patients can be reduced. RenalGuard facilitates this increased urine clearance automatically, enabling the body to more rapidly void the contrast media, thereby reducing its overall resident time and toxic effects in the kidney.

The RenalGuard System consists of a proprietary, closed loop, software-controlled console and accompanying single-use sets. RenalGuard operates by first collecting and measuring patient urine outputs and then in real-time precisely matching these urine outputs with a prescribed replacement fluid by means of intravenous infusion. With its automated matched fluid replacement capability, RenalGuard is intended to promote and maintain high urine outputs and minimize the risk to patients of over- or under-hydration during image guided catheterization procedures where contrast media are routinely administered.

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In the U.S., we have received FDA approval to conduct a pivotal human clinical trial of RenalGuard evaluating its safety and effectiveness in preventing CIN. This trial is required to support a pre-market approval application, which must be approved by the FDA before we can market RenalGuard in the U.S. We do not intend to commence this pivotal study until we are able to secure sufficient additional capital to complete the study.

We obtained a CE Mark for RenalGuard in December 2007 and began our initial commercialization efforts in the EU in Italy in April 2008.

Novadaq, our U.S. distributor for the Heart Laser System, is our largest customer, accounting for 65% and 74% of our total revenues in the years ended December 31, 2009 and 2008, respectively. Our distributor of RenalGuard in Italy, Artech, accounted for 10% of our total revenues and 81% of our RenalGuard revenues in the year ended December 31, 2009. We expect these sales concentrations with Novadaq for TMR sales and Artech for RenalGuard sales to continue in 2010.

Approximately 76% and 85% of our revenues in the years ended December 31, 2009 and 2008, respectively, came from the sale and service of TMR lasers and related disposable kits. We did not sell any HL2 lasers to Novadaq in 2009 and they have placed no demand on us to manufacture additional HL2 lasers for them in 2010. We believe that the number of opportunities for new TMR laser sales to U.S. hospital customers, and specifically sales opportunities for our HL2 laser, will continue to be limited 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 do so in the future and (2) continuing financial pressures that hospitals face, in particular for the funding of new capital equipment purchases, in light of the ongoing trend of cutbacks in both Medicare and private insurance reimbursement rates for a majority of medical procedures. As such, we expect that our U.S. TMR revenues in future quarters will be entirely dependent upon the sale of TMR kits and service revenues.

As a result, while we do not expect that our TMR-related kit and service revenues will change significantly in the near term, we do believe it is more likely they will decline over time. Therefore we will be largely dependent upon our ability to increase our revenues through higher sales of our RenalGuard product into international markets. On February 4, 2010, we announced that we have engaged a financial advisor to assist us with our ongoing efforts to raise additional capital and to explore other strategic options for our RenalGuard program. We will need to raise capital in the next few months, whether through asset sales, equity investment or other strategic transaction, in order to continue our operations.

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 U.S. TMR laser and kit sales for the next four quarters, as provided by Novadaq in a rolling 12 month sales forecast, (3) projected future sales of original equipment manufactured ("OEM") surgical tubes and laser assembly services, (4) projected future sales of RenalGuard consoles and single-use sets, (5) research and development progress as measured against internal project plan objectives, (6) budget to actual financial expenditure results, (7) inventory levels (both our own and our distributors'), and (8) short term and long term projected cash flows of the business.

Critical Accounting Policies and Estimates

Our financial statements are based upon 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 upon our best estimate of the net realizable value of inventory on hand, taking into consideration factors such as (1) actual trailing 12 month sales, (2) expected future product line demand, based in part upon sales forecast input received from Novadaq and our other customers, 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 are stated at the amount we expect to collect from the outstanding balances. 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. 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 might 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 and RenalGuard consoles and single-use sets 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 from Edwards, our previous exclusive U.S. TMR distributor, 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). We determined that a seven year timeframe was the most appropriate amortization period based upon 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 \$785,000 and \$763,000 in the years ended December 31, 2009 and 2008, 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, sales of RenalGuard consoles and single-use sets 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.

Results of Operations

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

	2009		2008	
	(dollars in thousands)			
Total revenues	\$ 4,711	100%	\$ 5,330	100%
Total cost of revenues	2,098	45	2,200	41
Gross profit	2,613	55	3,130	59
Selling, general and administrative expenses	3,462	73	3,164	59
Research and development expenses	780	17	2,075	39
Loss from operations	(1,629)	(35)	(2,109)	(39)
Other income	3	—	99	2
Loss before income taxes	(1,626)	(35)	(2,010)	(37)
Benefit from income taxes	—	—	70	1
Net Loss	\$ (1,626)	(35)%	\$ (1,940)	(36)%

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	2009		Increase (decrease) over 2008		2008	
	(dollars in thousands)					
Product sales	\$ 3,452	\$ (466)	(12)%	\$ 3,918		
Service fees	1,259	(153)	(11)	1,412		
Total revenues	4,711	(619)	(12)	5,330		
Product cost of revenues	1,454	(72)	(5)	1,526		
Service fees cost of revenues	644	(30)	(4)	674		
Total cost of revenues	2,098	(102)	(5)	2,200		
Gross profit	2,613	(517)	(17)	3,130		
Selling, general and administrative expenses	3,462	298	9	3,164		
Research and development expenses	780	(1,295)	(62)	2,075		
Total operating expenses	4,242	(997)	(19)	5,239		
Other income	3	(96)	(97)	99		
Loss before income taxes	(1,626)	384	(19)	(2,010)		
Benefit from income taxes	—	70	(100)	70		
Net Loss	\$ (1,626)	\$ 314	(16)%	\$ (1,940)		

Product Sales

Disposable TMR kit revenues, the largest component of product sales in 2009, decreased by \$352,000, or 15%, in 2009 as compared to 2008. The decrease was due to a (1) a \$327,000 decrease in domestic TMR kit revenues as a result of a lower volume of kits shipped and (2) a \$48,000 decrease in international TMR kit revenues, also stemming primarily from a lower volume of TMR kit shipments to international customers. These decreases were offset in part by a \$23,000 increase in disposable kit revenue amortization.

TMR laser revenues decreased \$456,000, or 62%, in 2009 as compared to 2008. Domestic TMR laser revenues decreased \$406,000 due to the absence of any HL2 shipments in 2009. International TMR laser revenues decreased \$50,000 due to a lower average selling price on lasers sold and a decrease in other international TMR laser revenues in 2009 compared to 2008.

International RenalGuard revenues increased \$370,000, or 172%, in 2009 as compared to 2008 due to an increase in the number of RenalGuard consoles and single-use sets shipped to international customers.

Other product sales decreased \$28,000, or 5%, in 2009 as compared to 2008. We provide OEM manufacturing contract assembly services to a single customer. These product revenues decreased \$330,000, as end user customer orders for new general purpose CO2 lasers declined significantly in 2009. International other product sales increased \$302,000 as a result of the one-time sale of certain third party equipment we were required to supply along with an international HL2 sale that we recorded as revenue in 2009.

Service Fee Revenues

Service fees decreased \$153,000, or 11%, in 2009 as compared to 2008. Domestic service fees decreased \$172,000 as a result of fewer billable service calls to domestic customers. International service fees increased \$19,000 due to increased service billings to international customers.

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Gross Profit

Gross profit was \$2,613,000, or 55% of total revenues, in 2009 as compared with gross profit of \$3,130,000, or 59% of total revenues, in 2008. The decrease in gross profit dollars is due to (1) lower OEM manufacturing contract assembly revenues and (2) lower TMR revenues and service fees. These decreases were offset in part by (1) the international sale of an HL2 and other third party equipment in 2009 and (2) the absence of an inventory reserve charge recognized in 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenditures increased 9% in 2009 as compared to 2008. The increase was due to (1) higher sales expenses associated with the sale of an international HL2 and third party equipment we supplied in 2009 and (2) higher international travel expenses related to RenalGuard activities. These increases were offset in part by (1) lower compensation related costs due to workforce reductions and lower incentive compensation expense and (2) lower legal expenses.

Research and Development Expenses

Research and development expenditures decreased 62% in 2009 as compared to 2008. The decrease was due to lower RenalGuard clinical trial costs resulting from the deferral of the U.S. pivotal trial.

Other Income

Other income decreased \$96,000, or 97%, in 2009 due to lower average investable balances and lower interest rates on those investable balances as compared to 2008.

Benefit from Income Taxes

In 2008, we recorded a \$70,000 benefit from income taxes due to the reversal of an income tax accrual originally recorded for a specific tax exposure, which was no longer required. There was no activity in 2009.

Net Loss

In 2009, our net loss decreased \$314,000, or 16%, as compared to 2008. This decrease is a result of lower operating expenses offset in part by lower gross margin dollars, lower interest income and the absence of a benefit from income taxes.

TMR Kit Shipments

We generally view disposable TMR kit shipments to end users as an important metric in evaluating our TMR business, although we believe that specific short-term factors not indicative of long-term trends can sometimes affect shipments of disposable kits in any given quarter. Domestic TMR kit shipments referenced in the table below relate to sales by Novadaq to hospital end users. International TMR kit shipments relate to sales by us directly to our international distributors or hospital end users.

	2009	% Decrease Over 2008	2008
Domestic (U.S. Distributor)	970	(39)	1,586
International	67	(1)	68
Total	1,037	(37)	1,654

Liquidity and Capital Resources

We compete in the highly regulated and competitive medical device market place where products can take significant time to develop, gain regulatory approval and then introduce to distributors and end users. We have historically funded our working capital requirements through cash received from public and private offerings of our common stock and to a lesser extent through our sales of products and services. We have incurred recurring quarterly operating losses over the past few years as we have worked to bring our RenalGuard System through development and begin our initial commercialization efforts outside the United States. We expect such operating losses will continue until such time, if ever, that RenalGuard product sales increase sufficiently to generate profitable results.

We believe that the recently announced positive clinical data from the MYTHOS and REMEDIAL II clinical trials, which show RenalGuard to be both a safe and effective product for the prevention of CIN in at-risk patients, presents a substantial opportunity for us to increase our sales and achieve profitable results in the next few years, provided we are able to raise the capital we need in the near term to sustain our operations until such time as we can reach this level of commercial success.

Absent any such additional outside financing in the next few months, whether through asset sales, equity investment or other strategic transaction, we believe that our existing available cash resources will be insufficient to sustain our ongoing operations. As a result, a substantial doubt exists about our ability to continue as a going concern without such additional financing, and our independent registered public accounting firms' report on our 2009 financial statements, which is included in this annual report on Form 10-K, contains a going concern opinion to this effect.

Although we are continuing to explore all available options to us to raise the additional capital we need to continue our operations and implement our business plan, there can be no assurance that such capital will be available on terms and conditions acceptable to us. Should additional financing not be available on terms and conditions acceptable to us, we will need to take actions that will adversely impact our ability to continue to realize assets and satisfy liabilities in the normal course of business. The consolidated financial statements set forth in this annual report on Form 10-K do not include any adjustments to reflect the possible future effects of these uncertainties.

Cash and cash equivalents totaled \$2,686,000 as of December 31, 2009, a decrease of \$2,340,000 from \$5,026,000 as of December 31, 2008. We have no debt obligations.

Cash used for operating activities in the year ended December 31, 2009 was \$2,373,000 due to our net loss, partially offset by non-cash depreciation and amortization expense and non-cash compensation expense related to stock options. The effect of exchange rate changes was a \$33,000 increase in cash.

Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of 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:

- We will need to, and we may be unable to, raise capital to continue our operations, including to implement our RenalGuard business plan, and any such financing will likely be highly dilutive to existing shareholders given our current market capitalization;

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- Our independent registered public accounting firm’s report on our 2009 financial statements included in this annual report on Form 10-K contains a going concern opinion, the effect of which is uncertain, but which could be detrimental to our efforts to raise the additional capital we need on terms that are acceptable to us;
- We expect to incur significant net losses in future quarters;
- We have a concentration of revenues and credit risk with a single customer, Novadaq, our exclusive U.S. distributor for our TMR products;
- We believe it is likely that our TMR revenues will decline over time, making our future prospects highly dependent upon the successful commercialization of RenalGuard;
- If we are unable to raise substantial additional capital, we will not be able to commence our U.S. pivotal clinical trial to study RenalGuard, which is necessary to obtain FDA pre-market approval to market RenalGuard in the U.S. We therefore may never be successful in our goal of demonstrating the value of RenalGuard in the U.S. which would have an impact on the overall valuation of the Company;
- Our ability to effectively market RenalGuard outside the U.S. is largely dependent on the results of the MYTHOS and REMEDIAL II investigator-sponsored clinical trials, which we do not control; however, we have no assurance that the results from these two trials will be viewed as clinically meaningful or that they will lead to increased sales of RenalGuard;
- We may never be successful in establishing a broad distribution channel for RenalGuard outside the U.S., and any distribution channel we may establish may never generate sufficient sales for us to attain profitability;
- Our RenalGuard System has only had limited testing in a clinical setting and we may need to modify it substantially in the future for it to be commercially acceptable in the broader market; and
- Any potential future modifications required to make RenalGuard commercially acceptable for the broader market may result in substantial additional costs and/or market introduction delays.

Off-Balance Sheet Arrangements

None.

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

Pursuant to Item 305(e) of Regulation S-K, we are not required to provide this information because we are a smaller reporting company.

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(T). *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, 2009. 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’s”) 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 upon the evaluation of our disclosure controls and procedures as of December 31, 2009, 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, 2009 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, 2009. 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, 2009, our internal control over financial reporting was effective based on those criteria.

This annual report on Form 10-K 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 on Form 10-K.

Item 9B. Other Information

On January 20, 2010, our board of directors adopted a new severance policy for our employees. Under the new policy, Kenneth J. Luppi, our Vice President of Operations, and Vincent C. Puglisi, our Managing Director, International, are entitled to receive payments equal to 26 weeks of base salary in the event that we terminate them for any reason without cause on or before July 20, 2011. Mark R. Tauscher, our President and Chief Executive Officer, and James G. Thomasch, our Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer, will continue to be entitled to receive the severance payments provided for pursuant to the terms of their

respective employment agreements with us.

PART III

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

The information required by this item is incorporated herein by reference to our definitive proxy statement to be filed with the SEC in connection with our 2010 Annual Meeting of Shareholders (referred to as our Definitive Proxy Statement) under the captions "Proposal 1 - Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance".

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 undertake to 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 relate to any element of the code of ethics definition enumerated in applicable SEC rules by posting such information, if any, on our Internet website, www.plcmed.com.

Item 11. *Executive Compensation*

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "Proposal 1 - Election of Directors".

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

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the captions "Securities Authorized for Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management".

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

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the captions "Certain Relationships and Related Transactions" and "Corporate Governance".

Item 14. *Principal Accountant Fees and Services*

The information required by this item is incorporated herein by reference to our Definitive Proxy Statement under the caption "Principal Accountant Fees and Services".

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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.

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Consolidated Balance Sheets as of December 31, 2009 and 2008	F-3
Consolidated Statements of Operations for the years ended December 31, 2009 and 2008	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2009 and 2008	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2009 and 2008	F-6
Notes to Consolidated Financial Statements	F-7

All 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.

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SIGNATURES

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

PLC SYSTEMS INC.

Date: March 30, 2010

By: /s/ Mark R. Tauscher

Mark R. Tauscher

President and Chief Executive Officer

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

Name	Capacity	Date
<u>/s/ Mark R. Tauscher</u> Mark R. Tauscher	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2010
<u>/s/ James G. Thomasch</u> James G. Thomasch	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 30, 2010
<u>/s/ Edward H. Pendergast</u> Edward H. Pendergast	Chairman of the Board	March 30, 2010
<u>/s/ Louis Brenner, M.D.</u> Louis Brenner, M.D.	Director	March 30, 2010
<u>/s/ Kevin J. Dunn</u> Kevin J. Dunn	Director	March 30, 2010
<u>/s/ Benjamin L. Holmes</u> Benjamin L. Holmes	Director	March 30, 2010
<u>/s/ Brent Norton, M.D.</u> Brent Norton, M.D.	Director	March 30, 2010
<u>/s/ Robert I. Rudko, Ph.D.</u> Robert I. Rudko, Ph.D.	Director	March 30, 2010

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APPENDIX A

PLC SYSTEMS INC.
CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2009 and 2008

PLC SYSTEMS INC.
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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. and subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two year period ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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. and subsidiaries as of December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the two year period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has sustained recurring net losses and negative cash flows from operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are described in Note 1. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Caturano and Company, P.C.
Boston, Massachusetts
March 30, 2010

**PLC SYSTEMS INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2009 and 2008
(In thousands)**

	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,686	\$ 5,026
Accounts receivable, net of allowance of \$24 and \$20 at December 31, 2009 and 2008, respectively	720	802
Inventories	876	1,136
Prepaid expenses and other current assets	505	598
Total current assets	4,787	7,562
Equipment, furniture and leasehold improvements, net	69	160
Other assets	186	191
Total assets	\$ 5,042	\$ 7,913
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 336	\$ 296
Accrued compensation	224	525

Accrued other	279	138
Deferred revenue	2,084	2,405
Total current liabilities	2,923	3,364
Deferred revenue, net of current portion	390	1,358
Commitments (note 7)		
Stockholders' equity:		
Preferred stock, no par value, unlimited shares authorized, none issued and outstanding	—	—
Common stock, no par value, unlimited shares authorized, 30,351 shares issued and outstanding at		
December 31, 2009 and 2008	93,893	93,893
Additional paid in capital	627	474
Accumulated deficit	(92,464)	(90,838)
Accumulated other comprehensive loss	(327)	(338)
Total stockholders' equity	1,729	3,191
Total liabilities and stockholders' equity	\$ 5,042	\$ 7,913

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

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PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For The Years Ended December 31, 2009 and 2008
(In thousands, except per share data)

	2009	2008
Revenues:		
Product sales	\$ 3,452	\$ 3,918
Service fees	1,259	1,412
Total revenues	4,711	5,330
Cost of revenues:		
Product sales	1,454	1,526
Service fees	644	674
Total cost of revenues	2,098	2,200
Gross profit	2,613	3,130
Operating expenses:		
Selling, general and administrative	3,462	3,164
Research and development	780	2,075
Total operating expenses	4,242	5,239
Loss from operations	(1,629)	(2,109)
Other income	3	99
Loss before income taxes	(1,626)	(2,010)
Benefit from income taxes	—	70
Net loss	\$ (1,626)	\$ (1,940)
Basic and diluted loss per share	\$ (0.05)	\$ (0.06)
Average shares outstanding:		
Basic and diluted	30,351	30,333

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

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PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For The Years Ended December 31, 2009 and 2008
(In thousands)

Accumulated
Other

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance, December 31, 2007	30,329	\$ 93,891	\$ 270	\$ (88,898)	\$ (313)	\$ 4,950
Issuance of common stock	22	2	—	—	—	2
Stock based compensation	—	—	204	—	—	204
Comprehensive income:						
Net loss	—	—	—	(1,940)	—	(1,940)
Foreign currency translation, net	—	—	—	—	(25)	(25)
Total comprehensive loss						(1,965)
Balance, December 31, 2008	30,351	93,893	474	(90,838)	(338)	3,191
Stock based compensation	—	—	153	—	—	153
Comprehensive income:						
Net loss	—	—	—	(1,626)	—	(1,626)
Foreign currency translation, net	—	—	—	—	11	11
Total comprehensive loss						(1,615)
Balance, December 31, 2009	<u>30,351</u>	<u>\$ 93,893</u>	<u>\$ 627</u>	<u>\$ (92,464)</u>	<u>\$ (327)</u>	<u>\$ 1,729</u>

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

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PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For The Years Ended December 31, 2009 and 2008
(In thousands)

	2009	2008
Operating activities:		
Net loss	\$ (1,626)	\$ (1,940)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	96	111
Compensation expense from stock options	153	204
Loss on retirement of equipment	—	34
Change in assets and liabilities:		
Accounts receivable	63	206
Inventory	260	(284)
Prepaid expenses and other assets	93	225
Accounts payable	39	(327)
Deferred revenue	(1,291)	(769)
Accrued liabilities	(160)	(428)
Net cash used for operating activities	<u>(2,373)</u>	<u>(2,968)</u>
Investing activities:		
Purchase of equipment	—	(29)
Net cash used for investing activities	<u>—</u>	<u>(29)</u>
Financing activities:		
Net proceeds from issuance of common stock	—	2
Net cash provided by financing activities	<u>—</u>	<u>2</u>
Effect of exchange rate changes on cash and cash equivalents	33	(39)
Net decrease in cash and cash equivalents	(2,340)	(3,034)
Cash and cash equivalents at beginning of year	5,026	8,060
Cash and cash equivalents at end of year	<u>\$ 2,686</u>	<u>\$ 5,026</u>

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

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2009

1. Nature of Business and Liquidity

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 *CO₂ Heart Laser System* (the "Heart Laser System") that cardiac surgeons use to perform carbon dioxide (CO₂) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. Over the past two years, the Company has begun initial commercialization outside the United States of its newest product, RenalGuard®, which currently represents the Company's key strategic growth initiative and primary business focus.

RenalGuard is designed to reduce the potentially toxic effects that contrast media can have on the kidneys when it is administered to patients during certain medical imaging procedures. It is believed that allowing contrast media to dwell in the kidneys of certain high risk patients can lead to contrast-induced nephropathy ("CIN"), a potentially deadly form of acute kidney injury. By inducing and maintaining a high urine flow rate before, during and after these medical imaging procedures, the Company believes the incidence rates of CIN in at-risk patients can be reduced. RenalGuard facilitates this increased urine clearance automatically, enabling the body to more rapidly void the contrast media, thereby reducing its overall resident time and toxic effects in the kidney.

The RenalGuard System consists of a proprietary, closed loop, software-controlled console and accompanying single-use sets. RenalGuard operates by first collecting and measuring patient urine outputs and then in real-time precisely matching these urine outputs with a prescribed replacement fluid by means of intravenous infusion. With its automated matched fluid replacement capability, RenalGuard is intended to promote and maintain high urine outputs and minimize the risk to patients of over- or under-hydration during image guided catheterization procedures where contrast media are routinely administered.

The U.S. Food and Drug Administration ("FDA") has granted the Company approval to begin clinical trial to study the safety and effectiveness of RenalGuard in the prevention of CIN; however, the Company has deferred commencement of this study until it can successfully raise additional capital necessary to start and complete the study. The Company must successfully complete this study and obtain FDA pre-market approval in order to market RenalGuard in the U.S.

The Company obtained a CE Mark for RenalGuard in December 2007 and began its initial commercialization efforts in the European Union in Italy in April 2008.

The Company has sustained recurring net losses and negative cash flows from operations for several years. During the year ended December 31, 2009, the Company incurred a net loss of \$1,626,000 and used cash in operations of \$2,373,000. As of December 31, 2009, cash and cash equivalents were \$2,686,000. Management expects that quarterly losses and negative cash flows will continue during 2010. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Based upon the current financial condition of the Company and the expectation of continued quarterly losses during 2010, management is currently investigating ways to raise additional capital that can be completed in the next few months. Subsequent to December 31, 2009, the Company announced that it had engaged a financial advisor to assist the Company in this effort. In addition, the Company announced a one-third reduction in its workforce during the first quarter of 2010, which it estimates will save the Company approximately \$750,000 annually starting in the third quarter of 2010. See Note 10 for further discussion. The Company will continue to review its other expense areas to determine whether additional reductions in discretionary spending can be achieved.

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2009

The Company also believes that the recent announcements of interim positive clinical data from two independent investigator-sponsored clinical trials in Italy, which show RenalGuard to be both a safe and effective product for the prevention of CIN in at-risk patients, presents a substantial opportunity for it to increase its sales and achieve profitable results in the next few years, provided the Company is able to raise the additional capital it needs in the near term to sustain its operations and expand its RenalGuard sales and marketing programs. There can be no assurance however that the Company's plans will be successful or that the Company will be successful in obtaining the capital necessary to continue its ongoing operations.

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 (Deutschland) GmbH. All intercompany accounts and transactions have been eliminated.

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 and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents at December 31, 2009 and 2008 consist of an overnight sweep to repurchase agreements.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents and accounts receivable. At times, the Company possesses cash balances above federally-insured limits. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing its cash equivalents in high-quality financial instruments. At December 31, 2009 and 2008, the majority of the cash and cash equivalents balance was invested with a single financial institution.

The Company has a concentration of credit risk due to its exclusive U.S. TMR distribution arrangement with Novadaq. Novadaq accounted for 49% and 69% of the Company's net accounts receivable at December 31, 2009 and 2008, respectively. Novadaq also accounted for 65% and 74% of the Company's revenues for the years ended December 31, 2009 and 2008, respectively. Collateral is not required on sales to Novadaq.

Artech accounted for 10% and 8% of the Company's revenues for the years ended December 31, 2009 and 2008, respectively.

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2009

Concentration of Revenues

Approximately 76% and 85% of the Company's revenues for the years ended December 31, 2009 and 2008, respectively, were derived from the sales and service of its 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. If the financial condition of its customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could 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. The Company regularly reviews slow-moving and excess inventories, and writes down inventories to net realizable value if the ultimate expected proceeds from the disposals of excess inventory are less than the carrying cost of the inventory.

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. The accrued warranty liability was \$7,000 and \$10,000 at December 31, 2009 and 2008, respectively. During the year ended December 31, 2009, the warranty liability related to potential pre-existing warranties was

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2009

increased by \$20,000. Prior to December 31, 2009, the liability was then decreased by \$23,000 for actual warranty costs incurred. During the year ended December 31, 2008, the warranty liability related to potential pre-existing warranties was reduced by \$50,000.

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 orders received, as well as an amortized portion of deferred revenue related to a payment of \$4,533,333 from Edwards, the Company's previous exclusive U.S. TMR distributor, 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). 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 \$785,000 and \$763,000 in the years ended December 31, 2009 and 2008, respectively, which is included in revenues in the Consolidated Statements of Operations. Included in deferred revenue is \$1,157,000 related to this amortization, which will be recognized in 2010.

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, sales of RenalGuard consoles and single-use sets 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 of the Company's foreign subsidiary 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.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income Taxes

The Company uses an asset and liability based approach in accounting for income taxes. Deferred income tax assets and liabilities are recognized for the future tax consequences attributed to differences between the financial statement and tax basis of existing assets and liabilities using enacted rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount estimated by us to be realizable.

Research and Development

Research and development costs are expensed as incurred.

Loss Per Share

In 2009 and 2008, 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.

For the years ended December 31, 2009 and 2008, 5,310,000 and 5,499,000 shares, respectively, attributable to outstanding stock options and warrants were excluded from the calculation of diluted loss per share because the effect would have been antidilutive.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board ("FASB") issued *FASB Accounting Standards Codification*TM (the "ASC" or "Codification"). The ASC is effective for interim and annual periods ending after September 15, 2009. Upon the effective date, the ASC became the single source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with U.S. generally accepted accounting principals ("U.S. GAAP"). Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. The Codification does not replace or affect guidance issued by the Securities and Exchange Commission ("SEC") or its staff for public companies in their filings with the SEC. Effective July 1, 2009, changes to the ASC are communicated through an Accounting Standards Update ("ASU"). The Company adopted the ASC during the third quarter of 2009, and as a result, all references to prior accounting and reporting standards which have been superseded by the ASC have been changed to reflect the new reference within the ASC. The ASC does not change or alter existing U.S. GAAP and, therefore, it did not impact the Company's financial position, results of operations or cash flows.

PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2009

3. Inventories

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

	2009	2008
Raw materials	\$ 404	\$ 573
Work in process	14	154
Finished goods	458	409
	<u>\$ 876</u>	<u>\$ 1,136</u>

4. Equipment, Furniture and Leasehold Improvements

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

	2009	2008
Equipment	\$ 1,203	\$ 1,203
Office furniture and fixtures	218	218
Leasehold improvements	349	349
	<u>1,770</u>	<u>1,770</u>
Less accumulated depreciation and amortization	<u>1,701</u>	<u>1,610</u>
	<u>\$ 69</u>	<u>\$ 160</u>

Depreciation expense was \$91,000 and \$104,000 for the years ended December 31, 2009 and 2008, respectively.

5. Stockholders' Equity

At December 31, 2009, there were 6,583,000 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.

6. *Stock Based Compensation*

Stock Option Plans

In May 2005, the Company's shareholders approved the 2005 Stock Incentive Plan (the "2005 Plan"). Incentive stock options are issuable only to employees of the Company, while non-qualified stock options may be issued to non-employee directors, consultants and others, as well as to employees. Under the 2005 Plan, the per share exercise price of incentive stock options may not be less than the fair 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 stock options at an exercise price less than 85% of the fair market value of the Company's common stock.

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2009

The Company grants stock options to its non-employee directors. New non-employee directors receive an initial grant of an option to purchase 45,000 shares of the Company's common stock that generally vests in quarterly 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.

On April 21, 2009, the Board of Directors approved an option exchange program pursuant to which employees and directors at the time were offered the opportunity to exchange outstanding options to purchase shares of common stock of the Company that had an exercise price of \$0.30 or greater per share for new options to purchase shares of common stock. The exchange offer commenced on April 22, 2009 and expired on May 19, 2009.

Pursuant to the exchange offer, options to purchase a total of 5,175,000 shares of common stock with exercise prices ranging from \$0.37 to \$2.78 per share were canceled in exchange for options to purchase 5,175,000 shares of common stock at an exercise price of \$0.24 per share. The exchange offer resulted in an incremental compensation charge of \$170,000 which is recognized over the vesting period of the new option grants. All options tendered under the exchange program, which were previously granted to employees and directors under the Company's 1993 Stock Option Plan, 1995 Stock Option Plan, 1997 Executive Stock Option Plan, 2000 Equity Incentive Plan, 2000 Non-Statutory Stock Option Plan, 2000 Non-Qualified Performance and Retention Equity Plan and the 2005 Plan, were replaced with new options granted under the 2005 Plan. Options granted to employees pursuant to the option exchange program vest one-third on the one-year anniversary of the new option grant and an additional one-twelfth for each successive three month period following the one-year anniversary of the new option grant and expire five years from the date of grant. Options granted to non-employee directors pursuant to the option exchange program vest ratably quarterly over a one year period and expire five years from the date of grant. In addition, other options to purchase a total of 75,000 shares were granted to certain directors in 2009. These options vest ratably quarterly over a one year period and expire five years from the date of grant or they vest ratably quarterly over a three year period and expire ten years from the date of grant. As of December 31, 2009, there were 979,000 shares of common stock available to be granted under the 2005 Plan.

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

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PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2009

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2007	5,298	\$ 0.96		
Granted	549	0.37		
Exercised	—	—		
Forfeited	(70)	0.58		
Expired	(278)	5.22		

Outstanding, December 31, 2008	5,499	\$	0.69		
Granted	5,250		0.24		
Exercised	—		—		
Forfeited	(163)		0.60		
Expired	(101)		2.50		
Cancelled	(5,175)		0.65		
Outstanding, December 31, 2009	5,310	\$	0.25	4.46	—
Exercisable, December 31, 2009	448	\$	0.33	4.26	—

Stock-Based Compensation Expense

The Company recorded compensation expense of \$153,000 and \$204,000 in the years ended December 31, 2009 and 2008, respectively. As of December 31, 2009, the Company had \$209,000 of total unrecognized compensation cost related to its unvested options, which is expected to be recognized over a weighted average period of 2.0 years.

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2009

The weighted average fair value of options issued during the years ended December 31, 2009 and 2008 were estimated using the Black-Scholes model.

	Year Ended December 31,	
	2009	2008
Expected life (years)	1.00 – 5.50	5.50-6.00
Interest rate	0.47 – 2.75%	2.92-3.55%
Volatility	103.1 – 205.2%	63.9-73.6%
Expected dividend yield	None	None
Value of option granted	\$0.15 – 0.23	\$0.22-0.27

The expected life was calculated in 2009 and 2008 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.

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 average of the closing bid and ask prices 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 21,612 shares of common stock in 2008 at an average price of \$0.08. There was no activity in 2009. At December 31, 2009, 294,461 shares were reserved for future issuance under the Purchase Plan.

7. *Commitments*

Lease Commitments

The Company leases its corporate office under an operating lease agreement that expires in August 2011. 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, 2009, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments
2010	\$ 204
2011	136
Total	\$ 340

Total rent expense was \$237,000 and \$253,000 in 2009 and 2008, respectively.

Bonus Commitment

The Company has a bonus plan for substantially 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, 2008, \$16,000 of bonuses were accrued on the accompanying Consolidated Balance

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2009

Sheets. There were no bonuses accrued at December 31, 2009.

8. Income Taxes

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

	2009	2008
Net U.S. operating loss carryforwards	\$ 23,279	\$ 21,333
Net foreign operating loss carryforwards	435	417
Accrued expenses and reserves	684	774
Tax credits	1,330	1,273
Other	1,069	1,561
Total deferred tax assets	26,797	25,358
Valuation allowance	(26,797)	(25,358)
Net deferred tax assets	\$ —	\$ —

The valuation allowance increased by approximately \$1,439,000 in 2009 primarily due to a net loss and the reversal of temporary differences associated with deferred revenue in 2009. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset of \$26,797,000.

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

	2009	2008
Domestic	\$ (1,415)	\$ (1,789)
Foreign	(211)	(151)
	\$ (1,626)	\$ (1,940)

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

	2009	2008
Statutory income tax benefit	\$ 553	\$ 660
Unbenefited U.S. losses	(481)	(539)
Unbenefited foreign losses	(72)	(51)
Benefit from income taxes	\$ 0	\$ 70

At December 31, 2009, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$58 million, which expire at various dates through 2029. At December 31, 2009, \$123,000 of federal and state net operating loss carryforwards related 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, 2009, the Company had federal and state research and development credit carryforwards of \$811,000 and \$519,000, respectively, which will expire at various dates through 2029 for federal income tax purposes and through 2024 for state income tax purposes. In addition, the Company had foreign net operating loss carryforwards of approximately \$1,090,000.

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

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PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2009

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 recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities. At December 31, 2007, the Company maintained a reserve of \$70,000 for certain identified income tax exposure. During the year ended December 31, 2008, the reserve was reversed, as it was no longer required for the specific tax exposure. As of December 31, 2009 and 2008, 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 December 31, 2009 and 2008, 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 2006 through 2008 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 1999 through 2008.

9. 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):

	North America	Europe	Total
2009			
Net sales	\$ 3,338	\$ 1,373	\$ 4,711
2008			
Net sales	\$ 4,550	\$ 780	\$ 5,330

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

10. Subsequent Event

On February 4, 2010, the Company announced a reduction in its workforce of eight employees, or one-third of its staff. This step is expected to provide annualized cost savings of approximately \$750,000, beginning in the third quarter of 2010. It will also require a special charge of approximately \$214,000 for severance pay and stock option compensation expense, which will be reflected in the Company's consolidated statement of operations during the first quarter of 2010.

EXHIBIT INDEX

Exhibit Number	Description of Document
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#	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.
10.2#	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.
10.3#	Form of Stock Option Grant Letter to Employees of the Registrant under the Registrant's 1995 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 June 30, 2004, as previously filed with the Securities and Exchange Commission.
10.4#	Form of Stock Option Grant Letter to Non-Employee Directors of the Registrant under the Registrant's 1995 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.
10.5#	2005 Stock Incentive Plan, as amended, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2008.

- 10.6# Form of Stock Option Grant Letter for Employees of the Registrant under the Registrant's 2005 Stock Incentive Plan used prior to June 18, 2008, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2005.
- 10.7# Form of Stock Option Grant Letter for Employees of the Registrant under the Registrant's 2005 Stock Incentive Plan used beginning June 18, 2008 and prior to June 3, 2009, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2008.
- 10.8# Form of Stock Option Grant Letter for Employees of the Registrant under the Registrant's 2005 Stock Incentive Plan used beginning June 3, 2009, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009, as previously filed with the Securities and Exchange Commission.
- 10.9# Form of Stock Option Grant Letter for Non-Employee Directors of the Registrant under the Registrant's 2005 Stock Incentive Plan used prior to June 18, 2008, 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
10.10#	Form of Stock Option Grant Letter for Non-Employee Directors of the Registrant under the Registrant's 2005 Stock Incentive Plan used beginning June 18, 2008 and prior to June 3, 2009, incorporated by reference to the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2008.
10.11#	Form of Stock Option Grant Letter for Non-Employee Directors of the Registrant under the Registrant's 2005 Stock Incentive Plan used beginning June 3, 2009, incorporated by reference to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009, as previously filed with the Securities and Exchange Commission.
10.12#	Employment Agreement dated November 4, 1999 between PLC Medical Systems, Inc. and James G. Thomasch, 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.
10.13#	Amendment dated June 18, 2008 to Employment Agreement between PLC Medical Systems, Inc. and James G. Thomasch, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission.
10.14#	Employment Agreement dated December 22, 1999 between PLC Medical Systems, Inc. and Mark R. Tauscher, 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#	Amendment dated June 18, 2008 to Employment Agreement between PLC Medical Systems, Inc. and Mark R. Tauscher, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission.
10.16#	Terms of Employment dated October 28, 2003 between PLC Medical Systems, Inc. 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.
10.17#	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.
10.18#	Modifications effective as of April 1, 2008 to Terms of Employment between PLC Medical Systems, Inc. and Dr. Robert I. Rudko, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission.
10.19#	Amendment dated June 18, 2008 to Terms of Employment between PLC Medical Systems, Inc. and Dr. Robert I. Rudko, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission.
10.20+	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.
10.21*#	Compensatory Arrangements with Executive Officers.
10.22*#	Compensatory Arrangements with Non-Employee Directors.
10.23*#	Severance Arrangements with Executive Officers.

Exhibit Number	Description of Document
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Caturano and Company, P.C.
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, 2009.

+ 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.

Compensatory Arrangements with Executive Officers*Base Salary*

The current annual base salaries of each of the executive officers of PLC Systems Inc. (the “Company”) are as follows:

Mark R. Tauscher, President and Chief Executive Officer	\$	310,247
James G. Thomasch, Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer	\$	194,776
Kenneth J. Luppi, Vice President of Operations	\$	164,625
Vincent C. Puglisi, Managing Director, International	\$	161,537

Other Compensation

Mr. Tauscher and Mr. Thomasch each currently receive an annual car allowance of \$12,000. Mr. Luppi and Mr. Puglisi each currently receive an annual car allowance of \$6,000.

The Compensation Committee may also, from time to time, award each of the executive officers compensation in the form of stock options granted under the Company’s 2005 Stock Incentive Plan, as amended.

Compensatory Arrangements with Non-Employee Directors

Each non-employee director (other than the chairman of the board) of PLC Systems Inc. (the "Company") 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. At a meeting held on March 2, 2010, the board of directors voted unanimously to suspend all director fees that they otherwise would be entitled to receive until such time as the board of directors votes at a subsequent meeting to reinstate them. The Company reimburses its directors for reasonable out-of-pocket expenses incurred in attending meetings of the board of directors and committees of the board of directors.

The Company also grants stock options to its 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 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. The annual grants are generally made on the date of the Company's annual meeting of shareholders. All such options have an exercise price equal to the fair market value of the Company's common stock on the date of grant.

Severance Arrangements with Executive Officers

Pursuant to resolutions adopted by the Board of Directors of PLC Systems Inc. (the "Company") on January 20, 2010, Kenneth J. Luppi, the Company's Vice President of Operations, and Vincent C. Puglisi, the Company's Managing Director, International, are entitled to receive payments equal to 26 weeks of base salary in the event that they are terminated for any reason without cause on or before July 20, 2011.

Mark R. Tauscher, the Company's President and Chief Executive Officer, and James G. Thomasch, the Company's Senior Vice President of Finance and Administration, Chief Financial Officer and Treasurer, are separately entitled to receive severance payments pursuant to the terms of their respective employment agreements with the Company.

SUBSIDIARIES OF THE REGISTRANT

- 1) PLC Medical Systems, Inc., a Delaware corporation
 - 2) PLC Sistemas Medicos Internacionais (Deutschland) GmbH, a German corporation
-

Consent of Independent Registered Public Accounting Firm

As independent registered public accountants, we hereby consent to the incorporation of our report dated March 30, 2010, relating to the consolidated financial statements of PLC Systems Inc. and subsidiaries for each of the years in the two year period ended December 31, 2009, included in this Form 10-K, into the Company's previously filed Registration Statements on Form S-8 (File Nos. 33-95168, 333-51547, 333-37814, 333-48706, 333-51136, 333-57752, 333-91430, 333-106100, 333-127770 and 333-153535).

/s/ Caturano and Company, P.C.
Boston, Massachusetts
March 30, 2010

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

I, Mark R. Tauscher, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 30, 2010

/s/ Mark R. Tauscher

Mark R. Tauscher
President and Chief Executive Officer
(Principal Executive Officer)

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

I, James G. Thomasch, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 30, 2010

/s/ James G. Thomasch
James G. Thomasch
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of PLC Systems Inc. (the "Company") for the period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark R. Tauscher, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2010

By: /s/ Mark R. Tauscher
Mark R. Tauscher
President and Chief Executive Officer
(Principal Executive Officer)

In connection with the annual report on Form 10-K of PLC Systems Inc. (the "Company") for the period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, James G. Thomasch, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2010

By: /s/ James G. Thomasch
James G. Thomasch
Chief Financial Officer
(Principal Financial Officer)
