
**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, 2010**

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, 2010, was \$2,902,610. As of March 17, 2011, 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 2011 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. Our key strategic growth initiative is our newest marketable product, RenalGuard®.

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 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.

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. Since then, we have expanded our sales efforts for RenalGuard to other countries in the EU and additional countries around the world where we have received the necessary approvals to do so. In the U.S. we must first successfully complete a pivotal clinical study assessing the safety and effectiveness of RenalGuard in reducing the rates of CIN in at-risk patients and obtain U.S. Food and Drug Administration ("FDA") pre-market approval in order to market RenalGuard. We expect to commence this pivotal clinical trial of RenalGuard in 2011.

Recent Developments

Sale of TMR Business to Novadaq

Prior to February 1, 2011, including during all of 2010 and 2009, in addition to advancing our RenalGuard program, we also were engaged in the manufacture and marketing of the *CO₂ Heart Laser System* that cardiac surgeons use to perform carbon dioxide (CO₂) transmyocardial revascularization, or TMR, to alleviate symptoms of severe angina. On February 1, 2011, we completed an asset sale transaction and sold our TMR business to Novadaq Corp. ("Novadaq"), a subsidiary of Novadaq Technologies Inc. [TSX: NDQ]. Novadaq acted as our exclusive distributor in the United States for our TMR business since being appointed to that role in March 2007.

The asset sale transaction, which was announced in November 2010, was approved by our shareholders at a special meeting on January 31, 2011 and the transaction closed on February 1, 2011. Novadaq paid \$1 million in cash and assumed all our TMR service-related obligations, valued at approximately \$614,000, in exchange for acquiring substantially all our TMR-related assets, including all regulatory approvals for the *CO₂ Heart Laser System*, all manufacturing rights, substantially all product inventories and all equipment, intellectual property, clinical data and documentation related to our TMR business. The sale of the TMR business and the resultant gain on the asset sale transaction will be recorded in our first quarter 2011 financial results.

Secured Convertible Debt Financing

On February 22, 2011, we completed a financing agreement with an institutional investor that provides us with up to \$6 million in secured convertible debt financing. We received \$4 million in February as part of a first tranche closing. In addition, under the terms of the financing agreement, we may secure additional secured convertible debt

1

funding of up to \$2 million in the aggregate in two separate \$1 million tranches, based upon meeting certain RenalGuard operational milestones related to sales and U.S. pivotal clinical trial objectives.

Pursuant to the terms of this financing, we issued senior secured convertible notes that mature three years from date of issuance as well as warrants exercisable for a period of five years from the date of issuance for an aggregate number of shares equal to the aggregate number of shares issuable upon conversion of the notes. The notes issued in the February 2011 first tranche funding are convertible at a rate of \$.10 per share. The notes that would be issued in the future for each of the \$1 million tranches would be convertible into our common stock at prices determined by the fair market value of our stock at the time each tranche funds, subject to an agreed-upon minimum and maximum conversion rate price range of \$.06 to \$.15. The notes carry a 5% interest coupon that is required to be paid quarterly and are secured by all of our assets. The warrants can be converted into our common stock as well, at a 50% premium to the conversion price of the notes, which would also vary depending upon the tranche. The conversion price of the notes and the exercise price of the warrants are subject to anti-dilution and other adjustments.

RenalGuard Program

Our near term focus for our RenalGuard program is to (1) establish a broader distribution network in the EU and 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 and use of our technology, (3) continue support of two investigator-sponsored studies utilizing RenalGuard that have been conducted in Italy, as well as any others that may arise, and leverage the positive data from those studies to drive additional RenalGuard sales, as well as help us to raise additional capital in the future and (4) commence our U.S. pivotal clinical trial of RenalGuard.

Italian Clinical Studies

The first of two investigator-sponsored studies in Italy, the MYTHOS trial, is a randomized, open-label controlled clinical trial 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 achieved in January 2010. The study was expanded to enroll additional patients in order to obtain stronger and more meaningful statistical data on the safety and effectiveness of RenalGuard in reducing the incidence rate of CIN.

The most recent data that has been released on the results of the MYTHOS trial is based upon the first 157 patients enrolled in the study. These interim results strongly support both RenalGuard's safety profile and its high degree of efficacy in reducing the rates of CIN in at-risk patients. In the RenalGuard-treated group, the incidence rate of CIN was only 5%, 69% lower than the 16% CIN rate recorded in the control group. The RenalGuard-treated group also experienced a statistically significant fewer number of in-hospital major adverse events.

The MYTHOS investigators are preparing a manuscript summarizing the clinical trial results, which they plan to submit for publication.

The second investigator-sponsored study, the REMEDIAL II trial, is a multi-center, randomized, open-label controlled clinical trial based at the Clinica Mediterranea in Naples, Italy and three other hospitals in Italy. The interim results reported on the first 123 patients also demonstrate strong efficacy, with a 3.2% CIN rate in the RenalGuard treated group, 75% lower than the 13% CIN rate in the control group. The investigators have informed us they have completed patient enrollment and their abstract summarizing the latest study results has been accepted for presentation at the upcoming 60th Annual Scientific Session of the American College of Cardiology in April 2011.

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

U.S. Clinical Trial

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

2

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 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 approval to begin our pivotal study, but we deferred commencing this study until we could raise the necessary additional capital needed to conduct the study. We expect to commence this pivotal U.S. clinical trial of RenalGuard in 2011 with the funds obtained from the recent sale of our TMR business and the \$4 million institutional financing we secured in February 2011.

We have submitted an updated clinical trial protocol to the FDA for the U.S. clinical study of RenalGuard and must obtain FDA approval for this planned study prior to enrolling the first patient in the study.

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, and an estimated 7 million worldwide. 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 — 2011 Update, or 2011 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 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 be considered at-risk for CIN and thus benefit from the use of RenalGuard.

RenalGuard Sales and Marketing

We obtained a CE Mark for RenalGuard in December 2007 and began our initial commercialization efforts in the EU in Italy in April 2008. Since then, we have expanded our sales efforts for RenalGuard to other countries in the EU and additional countries around the world where we have received the necessary approvals to do so.

To date we have relied exclusively on independent distributors to sell our product into international markets and we expect to continue this sales strategy for the foreseeable future. Distributors who we contract with to market our product typically also represent at least several other company product lines and have demonstrated experience selling their full spectrum of products into cardiovascular centers throughout their territory. Our distribution agreements typically set forth minimum annual purchase requirements over the term of the contract, although these annual minimums may be waived by us in our sole discretion. Typically our distribution agreements provide our distributors the exclusive right to market our products in a specific territory and generally have a duration that ranges between three and five years.

Our international distributors determine the programs, including sale, lease, rental and usage-based offerings, which they believe

will be most effective in selling our products to hospitals in their territory. Our distributors' marketing efforts are directed primarily at interventional cardiologists and nephrologists, whose influence are both believed to be critical in a hospital's decision to acquire our products.

In the U.S., we must first successfully complete a pivotal clinical study assessing the safety and effectiveness of RenalGuard in reducing the rates of CIN in at-risk patients and obtain FDA pre-market approval in order to market 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 upon 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 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 that 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 to address this problem. 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.

4

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 positive 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.

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 that 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

5

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. In January 2001, we received approval from the FDA to market our smaller and lighter second generation CO₂ Heart Laser, the HL2. The FDA 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.

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.

As previously discussed, on February 1, 2011, we sold substantially all of our TMR-related assets to Novadaq, including all regulatory approvals for the Heart Laser System, all manufacturing rights, substantially all product inventories and all equipment, intellectual property, clinical data and documentation related to our TMR business.

TMR Sales and Marketing Strategy

On March 20, 2007, we appointed Novadaq 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 established an independent distributor network to market our TMR products, although in some areas, principally Europe, we continued to sell our TMR products directly to hospitals.

International sales (by origin) accounted for 13% of our total revenue in 2010 and 29% in 2009.

We sold 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 determined the programs, including sale, lease, rental and usage-based offerings, that it believed would be most effective in the U.S. in selling our products to hospitals. Novadaq’s marketing efforts were directed primarily at cardiothoracic surgeons, whose influence is believed to be critical in a hospital’s decision to purchase our products.

TMR Competition

The 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.

Products and Customers

Sales and servicing of our Heart Laser Systems accounted for approximately 85% and 76% of our revenues for

6

the years ended December 31, 2010 and 2009, respectively. RenalGuard sales accounted for approximately 9% and 12% of our revenues for the years ended December 31, 2010 and 2009, respectively.

Our U.S. TMR distributor, Novadaq, was our largest customer the past two years and accounted for 76% and 65% of our total revenues in the years ended December 31, 2010 and 2009, respectively. Our distributor of RenalGuard in Italy, Artech, accounted for 4% and 10% of our total revenues in the years ended December 31, 2010 and 2009, respectively and 48% and 81% of our RenalGuard revenues in the years ended December 31, 2010 and 2009, respectively.

Manufacturing

During 2010 and 2009 we manufactured and tested our Heart Laser System and our RenalGuard console at our facility in Franklin, Massachusetts. Beginning in 2011 we expect both our RenalGuard consoles and sterile disposable kits will be manufactured for us by two separate outside contract manufacturers, both located in New England. We believe that our outside contract manufacturers will have sufficient capacity to meet market demands anticipated in the coming year for our RenalGuard product.

Our facilities and those of our outside contract manufacturers are subject to periodic inspection by regulatory authorities to ensure compliance with FDA and EU quality system regulations.

Government Regulation

RenalGuard and the Heart Laser Systems both 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.

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.

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

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

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.

We have been issued 5 U.S. patents and 1 Canadian patent related to our RenalGuard System and its use in preventing CIN. These patents have terms that expire from 2026 through 2028.

In addition, we currently have eight 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 six 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 approximately \$333,000 and \$780,000 for the years ended December 31, 2010 and 2009, respectively. Our current and near term development efforts will be focused exclusively on advancing our RenalGuard program.

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

Employees

As of March 17, 2011, we had 8 full-time employees worldwide, including our executive officers. Of these, four are in general and administrative positions, two are involved in sales and customer support, one is involved in clinical/research and development and one is involved in manufacturing/regulatory affairs. 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 Systemas 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 conduct our 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 eight months ending August 31, 2011 is approximately \$136,000. 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

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 17, 2011, the last quoted sale price of our common stock was \$0.12 per share.

The following table sets forth the highest and lowest of any bid price for our common stock on the Pink Sheets or the OTCBB. Any bid price listed represents inter-dealer quotations without retail markup, markdown or commission and may not necessarily represent actual transactions.

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
2010	High	Low
First Quarter	\$ 0.30	\$ 0.14
Second Quarter	\$ 0.18	\$ 0.10
Third Quarter	\$ 0.18	\$ 0.05
Fourth Quarter	\$ 0.18	\$ 0.06

As of March 17, 2011, there were 665 record holders of our common stock. We believe that there are approximately 5,542 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. The terms of our secured convertible debt financing prohibits the payment of any cash dividends without the prior written consent of the holders of a majority of the principal amount of the outstanding convertible notes.

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, 2010:

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))
Equity compensation plans approved by security holders(1)	5,529,130	\$ 0.24	1,031,837 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	5,529,130	\$ 0.24	1,031,837

- (1) Consists of the following equity compensation plans: (i) 2000 Employee Stock Purchase Plan, as amended (the "2000 ESPP"); (ii) 2000 Equity Incentive Plan; and (iii) 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, 2011.

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. Our key strategic growth initiative is our newest marketable product, RenalGuard.

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 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.

We obtained a CE Mark for RenalGuard in December 2007 and began our initial commercialization efforts in the EU in Italy in April 2008. We are now marketing RenalGuard in several additional countries around the world. In the U.S. we must first successfully complete a pivotal clinical study assessing the safety and effectiveness of RenalGuard in reducing the rates of CIN in at-risk patients and

obtain FDA pre-market approval in order to market RenalGuard. We intend to begin this U.S. pivotal study in 2011.

Novadaq, our U.S. distributor for the Heart Laser System, accounted for 76% and 65% of our total revenues in the years ended December 31, 2010 and 2009, respectively. Our distributor of RenalGuard in Italy, Artech, accounted for 4% and 10% of our total revenues in the years ended December 31, 2010 and 2009, respectively and 48% and 81% of our RenalGuard revenues in the years ended December 31, 2010 and 2009, respectively.

Approximately 85% and 76% of our revenues in the years ended December 31, 2010 and 2009, respectively, came from the sale and service of TMR lasers and related disposable kits. We did not sell any HL2 lasers to Novadaq in either of the years ended December 31, 2010 and 2009. With the sale of our TMR business to Novadaq, we will, commencing in February 2011, be solely dependent upon our ability to increase our future revenues through higher sales of our RenalGuard products into international markets. This dependency on international RenalGuard revenue growth will continue until such time, if ever, that we may obtain FDA pre-market approval and are permitted to begin selling RenalGuard in the U.S.

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 sales for the next four quarters, (3) research and development progress as measured against internal project plan objectives, (4) budget to actual financial expenditure results, (5) inventory levels (both our own and our distributors'), and (6) 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. We regularly review 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.

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.

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 recognize revenue when the following basic revenue recognition criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the price to the buyer charged for products delivered or services rendered and collectability of the sales price. We assess credit worthiness of customers based upon prior history with the customer and assessment of financial condition. Our shipping terms are customarily Free On Board ("FOB") shipping point.

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 sales price we receive upon a sale of the kits. We amortized this payment into our consolidated statements of operations as revenue on a monthly basis commencing in February 2004 and culminating in December 2010. We determined that this 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 this amortization period resulting from the reduction in the prospective sales 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 recorded amortization of deferred revenue of \$1,156,000 and \$785,000 in the years ended December 31, 2010 and 2009 respectively which is included in revenues in our consolidated statements of operations. All amortization related to this transaction has been recorded as of December 31, 2010.

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. Included in other current assets was \$351,000 and deferred revenue of \$400,000 at both December 31, 2010 and 2009.

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, if all other revenue recognition criteria have been met.

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.

As discussed in Note 10 to the consolidated financial statements, we entered into an agreement in November 2010 to sell our TMR business to Novadaq and this sale transaction closed on February 1, 2011.

Results of Operations

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

13

	2010		2009	
	(dollars in thousands)			
Total revenues	\$ 3,910	100%	\$ 4,711	100%
Total cost of revenues	1,375	35	2,098	45
Gross profit	2,535	65	2,613	55
Selling, general and administrative expenses	2,805	72	3,462	73
Research and development expenses	333	9	780	17
Gain on the sale of assets	(98)	3	—	—
Loss from operations	(505)	(13)	(1,629)	(35)
Other income	—	—	3	—
Net Loss	\$ (505)	(13)%	\$ (1,626)	(35)%

	2010		2009	
	Increase (decrease) over 2009 (dollars in thousands)			
Product sales	\$ 2,807	\$ (645)	(19)%	\$ 3,452
Service fees	1,103	(156)	(12)	1,259
Total revenues	3,910	(801)	(17)	4,711
Product cost of revenues	809	(645)	(44)	1,454
Service fees cost of revenues	566	(78)	(12)	644
Total cost of revenues	1,375	(723)	(34)	2,098
Gross profit	2,535	(78)	(3)	2,613
Selling, general and administrative expenses	2,805	(657)	(19)	3,462
Research and development expenses	333	(447)	(57)	780
Total operating expenses	3,138	(1,104)	(26)	4,242
Gain on the Sale of Assets	(98)	(98)	100	—
Loss from Operations	(505)	1,124	69	(1,629)
Other income	—	(3)	(100)	3
Net Loss	\$ (505)	\$ 1,121	69%	\$ (1,626)

Product Sales

Disposable TMR kit revenues, the largest component of product sales in 2010, decreased by \$13,000, or 1%, in 2010 as compared

to 2009. The decrease was due to (1) a \$368,000 decrease in domestic TMR kit revenues primarily as a result of a lower volume of kits shipped, and (2) a \$16,000 decrease in international TMR kit revenues, primarily stemming from a lower average selling price of TMR kit shipments to international customers. These decreases were offset in part by a \$371,000 increase in disposable kit revenue amortization.

TMR laser revenues decreased \$261,000, or 93%, in 2010 as compared to 2009 due to fewer laser transactions in 2010 than in 2009.

RenalGuard revenues decreased \$248,000, or 42%, in 2010 as compared to 2009 due to a lower volume of RenalGuard consoles and single-use sets sold to international distributors.

Other product sales decreased \$123,000, or 47%, in 2010 as compared to 2009. International other product sales decreased \$302,000 as a result of a one-time sale of certain third party equipment required to be supplied along with an international Heart Laser System that we recorded as revenue in 2009. As discussed in Note 8 to the Consolidated Financial Statements, we sold our OEM surgical tube business in May 2010. Domestic other product sales decreased in 2010 by \$9,000 as a result of this sale of the OEM business. These decreases were offset in part by other product sales of \$188,000 for a non-refundable customer deposit that was never utilized and that became earned revenue at the expiration of an international TMR distribution agreement in December 2010.

As discussed in Note 10 to the Consolidated Financial Statements, we sold our TMR business to Novadaq in February 2011. Accordingly we will not have Disposable TMR kit revenue or Service Fee Revenues after the transaction closing in February 2011. We did retain one HL2 TMR laser that, by the terms of our asset sale agreement with Novadaq, we have the right to sell to one of two international hospitals in the future.

Service Fee Revenues

Service fees decreased \$156,000, or 12%, in 2010 as compared to 2009. Domestic service fees decreased \$119,000 as a result of lower overall service activities to domestic customers. International service fees decreased \$37,000 due to decreased service billings to international customers.

Gross Profit

Gross profit was \$2,535,000, or 65% of total revenues, in 2010, as compared with gross profit of \$2,613,000, or 55% of total revenues, in 2009. Gross margin dollars decreased due to lower overall revenues, most notably from the absence of any Heart Laser System sales in 2010 as compared to the one international sale of a Heart Laser System and other third party equipment in the first quarter of 2009. The overall decrease was offset in part by (1) higher TMR disposable kit amortization, (2) the sale of our OEM surgical tube business in May 2010 which was a lower margin business, and (3) the non-refundable customer deposit realized upon the expiration of an international distribution agreement.

Selling, General and Administrative Expenses

Selling, general and administrative expenditures decreased 19% in 2010 as compared to 2009. The decrease was due to (1) lower sales expenses in 2010 as compared to 2009 when we incurred \$269,000 of sales costs associated with the sale of a Heart Laser System and third party equipment we supplied during the first quarter of 2009 and (2) lower compensation-related costs, reflecting the decrease in headcount associated with our February 2010 workforce reduction and other terminations. These decreases were offset in part by higher corporate legal expenses and proxy filing costs in connection with the sale of our TMR business to Novadaq.

Research and Development Expenses

Research and development expenditures decreased 57% in 2010 as compared to 2009. The decrease is a result of (1) lower compensation-related costs as a result of our February 2010 workforce reduction and other terminations and (2) a governmental research and development grant of \$244,000 that was received in November 2010 and recorded as a reduction in our fourth quarter research and development expense. In 2011, we expect research and development expenses to increase as we commence our U.S. pivotal clinical trial of RenalGuard.

Gain on Sale of Assets

In 2010, we recorded a gain on the sale of assets of \$98,000 related to our OEM surgical tube business. We had no gain on sale of assets in 2009.

Other Income

Other income consists of interest income earned on our invested cash balances and decreased \$3,000 in 2010 as compared to 2009 due to lower average cash balances.

Net Loss

In 2010, our net loss decreased \$1,121,000, or 69%, compared to 2009, due to lower operating expenses and a gain on sale of assets, offset, in part, by a lower overall gross profit on our sales.

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 incurred recurring quarterly operating losses over the past few years as we have worked to bring our RenalGuard System through development and 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.

Cash and cash equivalents totaled \$1,324,000 as of December 31, 2010, a decrease of \$1,362,000 from \$2,686,000 as of December 31, 2009. We had no debt obligations as of December 31, 2010. 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. In May 2010, we sold certain of our OEM surgical tube assets and received approximately \$154,000 in cash at the time of closing. Most recently, in February 2011, we sold our TMR business for \$1 million in cash plus the relief of approximately \$614,000 in service contract obligations, and we issued \$4 million in senior secured convertible notes to an institutional investor. We believe our existing cash resources will meet our working capital requirements through at least December 31, 2011.

Cash used for operating activities in the year ended December 31, 2010 was \$1,346,000 due to our net loss and unfavorable working capital changes, partially offset by non-cash depreciation and amortization expense and non-cash stock based compensation expense. The effect of exchange rate changes was a \$16,000 decrease 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 expect to incur significant net losses in future quarters;
- Our quarterly operating results have varied in the past and will continue to vary significantly in the future, causing volatility in our stock price;
- With the sale of our TMR business in February 2011, our future prospects are solely dependent upon the successful commercialization of RenalGuard. To date we have recorded only a limited amount of sales of RenalGuard, principally to a single customer in one country, Italy. Sales of RenalGuard alone are currently insufficient, and may never grow to be sufficient, to sustain our ongoing operations;
- 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. 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;
- If we are required to change our pricing models to compete successfully, our margins and operating results may be adversely affected;
- We plan to commence our U.S. pivotal clinical trial in 2011 to study RenalGuard, which is necessary to obtain FDA pre-market approval to market RenalGuard in the U.S. This study will take us a significant amount of time and money to complete and will require us to raise additional capital in the future. We can provide no assurance that we will be able to complete this study or, if we are able to complete it, that RenalGuard will be shown to be safe or effective in preventing CIN, or that the degree of any positive safety and efficacy results will be sufficient to either obtain FDA approval or otherwise successfully market our product. Furthermore, the completion of a U.S. pivotal clinical trial is dependent upon many factors, some of which are not entirely within our control, including, but not limited to, our ability to successfully recruit investigators, the availability of patients meeting the inclusion criteria of our clinical study, the competition for these particular study patients amongst other clinical trials being conducted by other companies at these same study sites, the ability of the sites participating in our study to successfully enroll patients in our trial, and proper data gathering on the part of the investigating sites. Should a U.S. pivotal clinical trial take longer than we expect, our competitive position relative to existing preventative measures, or relative to new devices, drugs or therapies that may be developed could be seriously harmed and our ability to successfully fund the completion of the trial and bring RenalGuard to market may be adversely affected;
- 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;
- 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;
- Rapid technological change in the medical device industry could make our products obsolete and requires substantial research and

development expenditures and responsiveness to customer needs. We expect to continue to face substantial competition from different treatment modalities and if we do not compete effectively with these alternatives our market share may never grow and could decline;

- An inability to obtain third party reimbursement for RenalGuard could materially affect future demand for our product. We know of no existing Medicare coverage or other third party reimbursement that currently would be available in the U.S. to either hospitals or physicians that would help defray the additional cost that would result from the future purchase and/or use of our RenalGuard System. We also can provide no assurance that we will ever be able to obtain Medicare coverage or other third party reimbursement for the use of RenalGuard, which could materially and adversely affect the potential future demand for our product;
- Securing patent protection over our intellectual property ideas in the field of CIN prevention is, we believe, critical to our plans to successfully differentiate and market our RenalGuard System and grow our future revenues. However, we can provide no assurance as to how strong our issued patents will prove to be. Furthermore we can provide no assurance that we will be successful in securing any additional patent protection for our intellectual property ideas in this field or that our efforts to obtain patent protection will not prove more difficult, and therefore more costly, than we are otherwise expecting. Finally, even if we are successful in securing patent protection for some of our pending patent applications, or for additional intellectual property ideas in this field, we cannot predict when in the future any such potential patents may be issued, how strong such additional patent protection will prove to be, or whether these patents will be issued in a timely enough fashion to afford us any commercially meaningful advantage in marketing our RenalGuard System against other potentially competitive devices;
- We are exposed to risks associated with outsourcing activities, which could result in supply shortages that could affect our ability to meet customer needs;
- If we deliver systems with defects, our credibility may be harmed, sales and market and regulatory approvals acceptance of our systems may decrease and we may incur liabilities associated with those defects;
- If we require additional capital in the future, it may not be available, or if available, may not be on terms acceptable to us;
- We are exposed to various risks related to the regulatory environment for medical devices. Compliance with medical device health and safety regulations may be very costly, and the failure to comply could result in liabilities, fines and cessation of our business;
- Our share price will fluctuate based upon a number of factors including, but not limited to:
 - actual or anticipated fluctuations in our results of operations;

- changes in estimates of our future results of operations by us or securities analysts;
 - announcements of technological innovations or new products or services by us or our competitors;
 - changes affecting the medical device industry;
 - announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
 - additions or departures of key technical or management personnel;
 - issuances of debt or equity securities;
 - significant lawsuits, including patent or stockholder litigation;
 - changes in the market valuations of similar companies;
 - sales of our common stock by us or our stockholders in the future;
 - dilution caused by the conversion of convertible debt currently outstanding or which may be issued to our current secured lender and its assignees as well as the exercise of warrants issued to this lender, as well as by the exercise of employee stock options or the issuance of shares on the vesting of restricted stock units;
 - trading volume of our common stock; and
 - other events or factors that may directly or indirectly affect the value or perceived value of our business and/or prospects, including the risk factors identified in this prospectus.
- We have pledged all of our assets to our secured debtholders. We are not currently permitted, nor do we currently intend, to pay any cash dividends on our common stock in the foreseeable future and therefore our shareholders may not be able to receive a return on their shares unless they sell them at an amount greater than the price paid for such shares;
 - Our secured debtholders may be able to exert significant control over the company through restrictive covenants contained in such debt agreements or through the conversion to our equity securities of the convertible debt and warrants issued and/or issuable to these debtholders;
 - Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our stock plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall;
 - U.S. broker-dealers may be discouraged from effecting transactions in shares of our common stock because they may be considered penny stocks and thus be subject to the penny stock rules; and
 - Our ability to recruit and retain management and other qualified personnel is crucial to our ability to develop, market, sell and support our products.

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. *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, 2010. 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, 2010, 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, 2010 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, 2010. 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, 2010, 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. Pursuant to Item 308(c) of Regulation S-K, we are not required to provide such an attestation report because we are a smaller reporting company.

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 2011 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".

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

	<u>Page</u>
Reports of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets as of December 31, 2010 and 2009	F-4
Consolidated Statements of Operations for the years ended December 31, 2010 and 2009	F-5
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010 and 2009	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009	F-7

All schedules for which provision is made in the applicable accounting regulation of the SEC that are not required under the related instructions or are inapplicable 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.

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 29, 2011

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 29, 2011
<u>/s/ James G. Thomasch</u> James G. Thomasch	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 29, 2011
<u>/s/ Edward H. Pendergast</u> Edward H. Pendergast	Chairman of the Board	March 29, 2011
<u>Kevin J. Dunn</u>	Director	March 29, 2011
<u>/s/ Benjamin L. Holmes</u> Benjamin L. Holmes	Director	March 29, 2011
<u>/s/ Brent Norton, M.D.</u> Brent Norton, M.D.	Director	March 29, 2011

APPENDIX A

PLC SYSTEMS INC.
CONSOLIDATED FINANCIAL STATEMENTS
For the years ended December 31, 2010 and 2009

PLC SYSTEMS INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<u>Reports of Independent Registered Public Accounting Firms</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2010 and 2009</u>	F-4
<u>Consolidated Statements of Operations for the years ended December 31, 2010 and 2009</u>	F-5
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010 and 2009</u>	F-6
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
PLC Systems Inc.:

We have audited the accompanying consolidated balance sheet of PLC Systems Inc. and subsidiaries as of December 31, 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit 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 that our audit provides 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, 2010, and the results of their operations and their cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

/s/ McGladrey & Pullen, LLP

McGladrey & Pullen, LLP
Boston, Massachusetts
March 29, 2011

F-2

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of
PLC Systems Inc.

We have audited the accompanying consolidated balance sheet of PLC Systems Inc. and subsidiaries as of December 31, 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for the year 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 audit.

We conducted our audit 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 audit 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 audit provides 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 the results of their operations and their cash flows for the year 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

F-3

PLC SYSTEMS INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2010 and 2009
(In thousands)

	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,324	\$ 2,686
Accounts receivable, net of allowance of \$10 and \$24 at December 31, 2010 and 2009, respectively	338	720
Inventories	836	876
Prepaid expenses and other current assets	604	505
Total current assets	3,102	4,787
Equipment, furniture and leasehold improvements, net	27	69
Other assets	186	186
Total assets	\$ 3,315	\$ 5,042
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 373	\$ 336
Accrued compensation	118	224
Accrued other	281	279
Deferred revenue	1,109	2,084
Total current liabilities	1,881	2,923
Deferred revenue, net of current portion	—	390
Commitments and contingencies (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, 2010 and 2009	93,893	93,893
Additional paid in capital	848	627
Accumulated deficit	(92,969)	(92,464)
Accumulated other comprehensive loss	(338)	(327)
Total stockholders' equity	1,434	1,729
Total liabilities and stockholders' equity	\$ 3,315	\$ 5,042

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

F-4

PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

For The Years Ended December 31, 2010 and 2009
(In thousands, except per share data)

	<u>2010</u>	<u>2009</u>
Revenues:		
Product sales	\$ 2,807	\$ 3,452
Service fees	1,103	1,259
Total revenues	<u>3,910</u>	<u>4,711</u>
Cost of revenues:		
Product sales	809	1,454
Service fees	566	644
Total cost of revenues	<u>1,375</u>	<u>2,098</u>
Gross profit	<u>2,535</u>	<u>2,613</u>
Operating expenses:		
Selling, general and administrative	2,805	3,462
Research and development	333	780
Total operating expenses	<u>3,138</u>	<u>4,242</u>
Gain on the sale of assets	(98)	—
Loss from operations	<u>(505)</u>	<u>(1,629)</u>
Other income	—	3
Net loss	<u>\$ (505)</u>	<u>\$ (1,626)</u>
Basic and diluted loss per share	\$ (0.02)	\$ (0.05)
Weighted average shares outstanding:		
Basic and diluted	30,351	30,351

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

F-5

PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For The Years Ended December 31, 2010 and 2009
(In thousands)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
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						<u>(1,615)</u>
Balance, December 31, 2009	30,351	\$ 93,893	\$ 627	\$ (92,464)	\$ (327)	\$ 1,729
Stock based compensation	—	—	221	—	—	221
Comprehensive income:						
Net loss	—	—	—	(505)	—	(505)
Foreign currency translation, net	—	—	—	—	(11)	(11)
Total comprehensive loss						<u>(516)</u>
Balance, December 31, 2010	<u>30,351</u>	<u>\$ 93,893</u>	<u>\$ 848</u>	<u>\$ (92,969)</u>	<u>\$ (338)</u>	<u>\$ 1,434</u>

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

F-6

CONSOLIDATED STATEMENTS OF CASH FLOWS
For The Years Ended December 31, 2010 and 2009
(In thousands)

	2010	2009
Operating activities:		
Net loss	\$ (505)	\$ (1,626)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	42	96
Stock-based compensation	221	153
Change in assets and liabilities:		
Accounts receivable	385	63
Inventory	40	260
Prepaid expenses and other assets	(99)	93
Accounts payable	37	39
Deferred revenue	(1,365)	(1,291)
Accrued liabilities	(104)	(160)
Net cash used for operating activities	<u>(1,346)</u>	<u>(2,373)</u>
Effect of exchange rate changes on cash and cash equivalents	(16)	33
Net decrease in cash and cash equivalents	<u>(1,362)</u>	<u>(2,340)</u>
Cash and cash equivalents at beginning of year	2,686	5,026
Cash and cash equivalents at end of year	<u>\$ 1,324</u>	<u>\$ 2,686</u>

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

F-7

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2010

1. 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 three 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. The RenalGuard System consists of a proprietary console and accompanying single-use sets and 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. The Company conducts business operations as one operating segment.

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, which is effective through February 11, 2019, reflects substantially the same roles, responsibilities and financial terms as the previous agreement with Edwards.

For the years ended December 31, 2010 and 2009, the Company incurred a net loss of approximately \$505,000 and \$1,626,000, respectively, and negative cash flows from operations of \$1,346,000 and \$2,373,000, respectively. At December 31, 2010, the Company had an accumulated deficit of \$92,969,000. In the first quarter of 2011, the Company sold the assets related to its TMR business to Novadaq for \$1,000,000 plus the relief of approximately \$614,000 in service contract obligations, and issued \$4,000,000 in secured convertible debt (see Note 11). Management projects that its existing resources will be sufficient to fund operations through at least December 31, 2011.

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 Systemas 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. Significant estimates include revenue recognition, warranty, inventory valuation, and accounts receivable. 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 at December 31, 2010 consist of deposits held in bank checking accounts and at December 31, 2009 consist of deposits held in bank checking accounts and 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

F-8

PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2010

high-quality financial instruments. At December 31, 2010 and 2009, 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 62% and 49% of the Company's net accounts receivable at December 31, 2010 and 2009, respectively. Novadaq also accounted for 76% and 65% of the Company's revenues for the years ended December 31, 2010 and 2009, respectively. Collateral is not required on sales to Novadaq.

Artech accounted for 4% and 10% of the Company's revenues for the years ended December 31, 2010 and 2009, respectively.

Concentration of Revenues

Approximately 85% and 76% of the Company's revenues for the years ended December 31, 2010 and 2009, respectively, were derived from the sales and service of TMR.

Net sales to unaffiliated customers (by origin) are summarized below (in thousands):

	<u>North America</u>	<u>Europe</u>	<u>Total</u>
2010			
Net sales	\$ 3,403	\$ 507	\$ 3,910
2009			
Net sales	\$ 3,338	\$ 1,373	\$ 4,711

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

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

The carrying amount of long-lived assets is reviewed whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. When required, recoverability of these assets is measured by comparing the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. During the years ended December 31, 2010 and 2009, the Company did not recognize any asset impairment charges.

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 TMR 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 and RenalGuard consoles and single-use sets 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 \$0 and \$7,000 at December 31, 2010 and 2009, respectively. During the year ended December 31, 2010, the warranty liability was increased by \$35,000 related to potential pre-existing warranties and decreased by \$42,000 for actual warranty costs incurred. During the year ended December 31, 2009, the warranty liability was increased by \$20,000 related to potential pre-existing warranties and then decreased by \$23,000 for actual warranty costs incurred.

Revenue Recognition

The Company recognizes revenue when the following basic revenue recognition criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the price to the buyer charged for products delivered or services rendered and collectability of the sales price. The Company assesses credit worthiness of customers based upon prior history with the customer and assessment of financial condition. Our shipping terms are customarily Free On Board ("FOB") shipping point.

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 sales price the Company receives upon a sale of the kits. The Company amortized this payment into its consolidated statements of operations as revenue on a monthly basis commencing in February 2004 and culminating in December 2010. The Company determined that this 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 the amortization period resulting from the reduction in the prospective sales 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 recorded amortization of \$1,156,000 and \$785,000 in the years ended December 31, 2010 and 2009, respectively, which is included in revenues in the consolidated statements of operations. All amortization related to this transaction has been recorded as of December 31, 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. Included in other current assets was \$351,000 and deferred revenue of \$400,000 at both December 31, 2010 and 2009.

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

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.

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. In November 2010, the Company received a grant in the amount of \$244,000 from the Internal Revenue Service under the Qualifying Therapeutic Discovery Project (QTDP) Program. The Company recorded this grant amount as a reduction to research and development expenses in the accompanying consolidated statement of operations during the fourth quarter of 2010.

Loss Per Share

In 2010 and 2009, 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, 2010 and 2009, 5,529,000 and 5,310,000 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.

3. *Inventories*

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

	<u>2010</u>	<u>2009</u>
Raw materials	\$ 290	\$ 404
Work in process	—	14
Finished goods	546	458
	<u>\$ 836</u>	<u>\$ 876</u>

F-11

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

4. *Equipment, Furniture and Leasehold Improvements*

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

	<u>2010</u>	<u>2009</u>
Equipment	\$ 1,175	\$ 1,203
Office furniture and fixtures	218	218
Leasehold improvements	349	349
	1,742	1,770
Less accumulated depreciation and amortization	1,715	1,701
	<u>\$ 27</u>	<u>\$ 69</u>

Depreciation expense was \$42,000 and \$91,000 for the years ended December 31, 2010 and 2009, respectively.

5. *Stockholders' Equity*

At December 31, 2010, there were 6,561,000 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.

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 vest 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 22,500 shares of the Company's common stock that generally will vest in four equal quarterly installments. The Chairman of the Board receives an annual grant of an option to purchase 45,000 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

F-12

PLC SYSTEMS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2010

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 a result of employee terminations in 2010, options held by terminated employees to purchase a total of 1,233,000 shares of common stock with an exercise price of \$0.24 per share were cancelled, but were replaced by the Company with new options, all of which immediately vested, to purchase 1,233,000 shares of common stock at an exercise price of \$0.24 per share. The Company recorded an additional \$72,000 in stock compensation expense related to these grants during the year ended December 31, 2010.

During the year ended December 31, 2010, the Company granted options to purchase 200,000 shares of the Company's common stock to non-employees that vested immediately, and granted options to purchase 112,500 shares of the Company's common stock to non-employee directors which vest in four equal quarterly installments.

As of December 31, 2010, there were 737,000 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):

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
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		
Granted	1,545	0.22		
Exercised	—	—		
Forfeited	(71)	0.26		
Expired	(22)	1.66		
Cancelled	(1,233)	0.24		
Outstanding, December 31, 2010	5,529	\$ 0.24	2.86	—
Exercisable, December 31, 2010	3,889	\$ 0.24	2.59	—

Stock-Based Compensation Expense

The Company recorded compensation expense of \$221,000 and \$153,000 in the years ended December 31, 2010 and 2009, respectively. As of December 31, 2010, the Company had \$75,000 of total unrecognized compensation

F-13

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

cost related to its unvested options, which is expected to be recognized over a weighted average period of 1.20 years.

The weighted average fair value of options issued during the years ended December 31, 2010 and 2009 were estimated using the Black-Scholes model and was \$0.08 and \$0.18 respectively.

	Year Ended December 31,	
	2010	2009
Expected life (years)	1.00 – 6.00	1.00 – 5.50
Interest rate	0.26 – 2.27%	0.47 – 2.75%
Volatility	85.6 – 292.8%	103.1 – 205.2%
Expected dividend yield	None	None
Value of option granted	\$0.02 – 0.14	\$0.15 – 0.23

The expected life was calculated in 2010 and 2009 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. Expected volatility is based exclusively on historical volatility data of the Company's common stock. The Company estimates an expected forfeiture rate by analyzing historical forfeiture activity and considering how future forfeitures are expected to differ from historical forfeitures. The Company expects that all outstanding options at December 31, 2010 will fully vest over their requisite service period. 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. There was no activity in 2010 or 2009. At December 31, 2010, 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, 2010, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments
2011	136

Total rent expense was \$204,000 and \$237,000 in 2010 and 2009, respectively.

Bonus Commitment

The Company has a bonus plan for substantially all employees calculated based upon predetermined Company milestones and targets. The Board of Directors has the discretion to adjust the bonus amounts prior to approval and payment. There were no bonuses accrued at December 31, 2010 or 2009.

F-14

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

8. Asset Purchase Agreement

In May 2010, the Company sold to a newly-formed corporation affiliated with its principal OEM customer certain of its OEM surgical tube assets, comprised principally of inventory, equipment, intellectual property and certain other intangible assets, as well as all necessary manufacturing documentation needed to perform contract assembly services for general purpose CO2 lasers. The total sale price for these assets was \$225,000, of which approximately \$154,000 was paid at the time of closing, with the balance in a note receivable. At the closing of the transaction and as of December 31, 2010, the note receivable was fully reserved. Following the sale, Dr. Robert I. Rudko, who was a director and a stockholder of the Company at the time, acquired a minority interest in the corporation that purchased the OEM assets. In conjunction with this transaction, in the year ended December 31, 2010, the Company recorded an initial gain on sale of assets of \$98,000. In March 2011, Dr. Rudko resigned from the Company's board of directors and the Company reached an agreement with the acquiring company to settle the note receivable at a reduced amount of \$40,000. The portion of the gain related to the note receivable will be recorded when cash is received.

9. Income Taxes

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

	2010	2009
Net U.S. operating loss carryforwards	\$ 23,848	\$ 23,279
Net foreign operating loss carryforwards	486	435
Accrued expenses and reserves	592	684
Tax credits	1,245	1,330
Other	566	1,069
Total deferred tax assets	26,737	26,797
Valuation allowance	(26,737)	(26,797)
Net deferred tax assets	\$ —	\$ —

The valuation allowance decreased by \$60,000 in 2010 primarily due to a reversal of temporary differences associated with deferred revenue in 2010, offset in part by the Company's net loss. The Company recorded the valuation allowance due to the uncertainty of the realizability of the related net deferred tax asset.

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

	2010	2009
Domestic	\$ (133)	\$ (1,415)
Foreign	(372)	(211)
	\$ (505)	\$ (1,626)

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

	2010	2009
Tax benefit at statutory rate	\$ (172)	\$ (553)
State income taxes, net of U.S. federal income tax benefit	(30)	(97)
Permanent differences	57	41
Change in valuation allowance	145	609
Total expense	\$ 0	\$ 0

F-15

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

At December 31, 2010, the Company had U.S. net operating loss carryforwards available to reduce future taxable income of approximately \$60 million, which expire at various dates through 2030. At December 31, 2010, \$175,000 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, 2010, the Company had federal and state research and development credit carryforwards of \$773,000 and \$472,000, respectively, which will expire at various dates through 2030 for federal income tax purposes and through 2025 for state income tax purposes. In addition, at December 31, 2010 the Company had foreign net operating loss carryforwards of approximately \$1,217,000.

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 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. As of December 31, 2010 and 2009, there were no unrecognized tax benefits. 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, 2010 and 2009, 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 2007 through 2010 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 2000 through 2009.

10. Subsequent Events

Sale of TMR Business to Novadaq

On November 5, 2010 the Company entered into an agreement to sell its TMR business to Novadaq. This transaction was approved by the Company's shareholders at a special meeting on January 31, 2011 and the transaction closed on February 1, 2011.

Under terms of the agreement, Novadaq acquired substantially all of the Company's assets that were used in the TMR business including all manufacturing rights, substantially all product inventories, and all equipment, intellectual property, regulatory approvals, clinical data and documentation related to TMR, for a purchase price of \$1 million in cash and the assumption of all the Company's obligations under service contracts as of the closing date, which was valued at approximately \$614,000 and a total value of assets sold of \$435,000. The sale of the TMR business and the resultant gain on the asset sale transaction will be recorded in the Company's first quarter 2011 financial results.

Secured Convertible Debt Financing

On February 22, 2011, the Company completed a financing agreement with an institutional investor that provides up to \$6 million in secured convertible debt financing. We received \$4 million in February as part of a first tranche closing. In addition, under the terms of the financing agreement, the Company may secure additional secured convertible debt funding of up to \$2 million in the aggregate in two separate \$1 million tranches, based upon meeting certain RenalGuard operational milestones related to sales and U.S. pivotal clinical trial objectives.

Pursuant to the terms of this financing, the Company issued senior secured convertible notes that mature three years from date of issuance as well as warrants offering 100% coverage that can be exercised within five years from issuance. The notes issued in the February 2011 first tranche funding are convertible at a rate of \$.10 per share. The notes that would be issued in the future for each of the \$1 million tranches would be convertible into the Company's common stock at prices determined by the fair market value of the Company's stock at the time each tranche funds, subject to an agreed upon minimum and maximum conversion rate price range of \$.06 to \$.15. The notes carry a 5%

F-16

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2010

interest coupon that is required to be paid quarterly and are secured by all of the Company's assets. The warrants can be converted into the Company's common stock as well, at a 50% premium to the conversion price of the notes, which would also vary depending upon the tranche. The conversion price of the notes and the exercise price of the warrants are subject to anti-dilution and other adjustments.

F-17

EXHIBIT INDEX

**Exhibit
Number**

Description of Document

2.1	Asset Purchase Agreement dated November 5, 2010 by and among the Registrant, PLC Medical Systems, Inc., PLC Systemas Medicos Internacionais (Deutschland) GmbH, Novadaq Corp. and Novadaq Technologies Inc., incorporated by reference to the Registrant's current report on Form 8-K dated November 5, 2010, as previously filed with the Securities and Exchange Commission.
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.
- 10.20.1 Addendum to Amended and Restated Distribution Agreement dated November 5, 2010 by and among the Registrant, PLC Medical Systems, Inc., Novadaq Technologies Inc. and Novadaq Corp., incorporated by reference to the Registrant's current report on Form 8-K dated November 5, 2010, as previously filed with the Securities and Exchange Commission.

Exhibit Number	Description of Document
10.21	Securities Purchase Agreement dated February 22, 2011 by and between the Registrant and GCP IV LLC, incorporated by reference to the Registrant's current report on Form 8-K dated February 22, 2011, as previously filed with the Securities and Exchange Commission.
10.22	Form of 5% Senior Secured Convertible Debenture issued by the Registrant, incorporated by reference to the Registrant's current report on Form 8-K dated February 22, 2011, as previously filed with the Securities and Exchange Commission.
10.23	Form of Common Stock Purchase Warrant issued by the Registrant, incorporated by reference to the Registrant's current report on Form 8-K dated February 22, 2011, as previously filed with the Securities and Exchange Commission.
10.24*#	Compensatory Arrangements with Executive Officers.
10.25*#	Compensatory Arrangements with Non-Employee Directors.
10.26*#	Severance Arrangements with Executive Officers.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of McGladrey & Pullen, LLP
23.2*	Consent of Caturano and Company, Inc. (formerly 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, 2010.

+ 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

At a meeting held on June 16, 2010, the board of directors voted unanimously to reinstate director fees. Each non-employee director (other than the chairman of the board) of PLC Systems Inc. (the "Company") receives \$1,000 for each board meeting he attends in person and \$500 for each board meeting he participates by means of teleconference. The chairman of the board receives \$1,500 for each board meeting that he attends in person and \$750 for each board meeting he participates by teleconference. 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.

At the board meeting held on June 16, 2010, the board of directors voted unanimously to revise the policy regarding the annual grant of stock options to non-employee directors. Non-employee directors (other than the chairman of the board) will now receive an annual grant of an option to purchase 22,500 shares of the Company's common stock, such option to vest in four equal quarterly installments. The chairman of the board will receive an annual grant of an option to purchase 45,000 shares of the Company's common stock, such option to vest in four equal quarterly installments. The annual grants to non-employee directors are generally made on the date of the Company's annual meeting of shareholders. All such options will 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 Systemas Medicos Internacionais (Deutschland) GmbH, a German corporation
-

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the 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) of PLC Systems Inc. and subsidiaries of our report dated March 29, 2011, relating to our audit of the consolidated financial statements, which appear in this Annual Report on Form 10-K of PLC Systems Inc. and subsidiaries for the year ended December 31, 2010.

/s/ McGladrey & Pullen, LLP

McGladrey & Pullen, LLP
Boston, Massachusetts
March 29, 2011

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 the year 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, Inc.
Caturano and Company, Inc. (formerly Caturano and Company, P.C.)
Boston, Massachusetts
March 29, 2011

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 29, 2011

/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 29, 2011

/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 29, 2011

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 29, 2011

By: /s/ James G. Thomasch

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