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, 2011

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	**04-3153858**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
459 Fortune Boulevard, Milford, Massachusetts	**01757**
(Address of principal executive offices)	(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 ☐ (Do not check if a smaller reporting company)	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, 2011, was $4,216,795. As of March 17, 2012, 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 2012 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, patented 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. The first patient was enrolled in the U.S. pivotal study in January 2012.

Prior to February 1, 2011, including during all of 2010, in addition to advancing our RenalGuard program, we also were engaged in the manufacture and marketing of the *CO_2 Heart Laser System* that cardiac surgeons use to perform carbon dioxide (CO_2) 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 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 *CO_2 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 transaction was recorded in our first quarter 2011 financial results.

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 to move our US clinical trial forward by qualifying and signing up more sites and

continuing to drive enrollment, (4) leverage the positive data from the two Italian studies that have been published to drive additional RenalGuard sales, and (5) focus on raising additional capital.

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 was designed to determine the safety and effectiveness of RenalGuard in preventing CIN in at-risk patients. The trial results were published in the *Journal of the American College of Cardiology JACC — Cardiovascular Interventions* in January 2012.

The trial data presented is on 170 enrolled patients with chronic kidney disease ("CKD") who underwent elective or urgent percutaneous coronary interventions (PCI). The results indicate that patients who were at higher risk for renal failure and who were treated with RenalGuard while undergoing imaging procedures developed CIN at a rate 74% lower than those who were treated with overnight hydration. Developing CIN has been found to lead to a range of serious and potentially deadly outcomes in patients who already have compromised kidney function. The trial also found that patients treated with RenalGuard had significantly fewer in-hospital adverse events than those treated with overnight hydration.

The second investigator-sponsored study, the REMEDIAL II trial, was a multi-center, randomized, open-label controlled clinical trial based at the Clinica Mediterranea in Naples, Italy and three other hospitals in Italy.

The results of REMEDIAL II were presented at the American College of Cardiology's annual Conference in April 2011 and published in September 2011 in *Circulation,* a peer-reviewed journal of the American Heart Association. In this trial, the investigators reported that patients treated with RenalGuard and N-acetylcysteine (NAC) developed CIN at a much lower rate than patients in the control group who were treated with an infusion of sodium bicarbonate and NAC. A combination of sodium bicarbonate and NAC remains the current standard of care for the prevention of CIN in many healthcare institutions worldwide. The results provided strong scientific data that RenalGuard Therapy® is more effective than sodium bicarbonate and N-acetylcysteine in preventing contrast-induced acute kidney injury (CI-AKI) in high-risk patients.

The lead author, Dr. Carlo Briguori, reported on data from 294 patients with CKD who underwent elective catheterization procedures. The primary end point for the study used a definition of CIN as a rise in serum creatinine (SCr) of 0.3mg/dl over the patient's baseline reading. The RenalGuard-treated group had a CIN incidence rate 46% lower than the control group using this definition of CIN. In secondary endpoints, Dr. Briguori also reported a 60% reduction in CIN in the RenalGuard-treated group compared to the control group when defining CIN as a 0.5mg/dl absolute rise in SCr and an 80% reduction of CIN in the RenalGuard-treated group over the control group when defining CIN as a 25% rise over baseline SCr. Notably, the trial also found that RenalGuard Therapy significantly reduced the need for in-hospital dialysis in high risk patients. In the control group, seven patients (4.8%) required some level of dialysis, compared to only one patient (0.7%), or 85% fewer, in the RenalGuard-treated group required dialysis.

We hope that the strong scientific data from these published papers regarding MYTHOS and REMEDIAL II, 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 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 stopped 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.

With the funds obtained from the recent sale of our TMR business and the $4 million institutional financing we secured in February 2011, we reestablished our effort to start our US clinical study.

We modified the pivotal trial protocol based upon insights learned from the clinical trials of RenalGuard in Europe as well as other clinical developments since 2008. In October 2011, we received final approval from the U.S. Food and Drug Administration (FDA) to commence the U.S. pivotal trial to study the efficacy of the Company's RenalGuard Therapy® and RenalGuard System(TM) in the prevention of CIN using the modified protocol.

Our U.S. trial, the CIN-RG trial is a pivotal study under the supervision of principal investigators at Northwestern University

Medical School, University of Vermont College of Medicine and Mount Sinai School of Medicine. It is designed as an adaptive, randomized controlled trial at up to 30 sites in the U.S. Enrollment in the trial will include at least 326 patients and potentially up to 652 patients, depending upon the outcome of a sample size re-estimation after 163 patients. The sample size re-estimation, often used in adaptive trials, enables investigators to ensure that the trial is sufficiently powered so that the final results are statistically meaningful. The first patient was enrolled in the CIN-RG trial at Mount Sinai Hospital in New York in January 2012. On the trial's listing on ClinicalTrials.gov (http://www.clinicaltrials.gov/ct2/show/NCT01456013), we currently list 6 sites that are enrolling patients and two additional sites that are active but not yet enrolling patients.

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 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 the patients in 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.

Evidence-based Therapy

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

The positive results published 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 many physicians due to an extremely low risk profile and cost. A team of Brazilian researchers recently published data on the largest trial of Mucomyst to date, the ACT Trial. They reported that after studying Mucomyst in 2,308 patients, the rate of CIN was identical between the group of patients who received the drug and those who did not. While additional research is continuing into this therapy, the

results of the ACT trial have reduced the use of Mucomyst as a preventative therapy at many centers.

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. Meta-analysis of these studies is inconclusive and point to

the wide variability of results between different studies. 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

Benephit Catheter

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 the lack of clear supporting clinical data, concerns regarding complications of direct renal intervention and the cost of the catheter.

CINCOR System

Osprey Medical Systems has announced that it has received CE Mark for its CINCOR system and is seeking to raise funds to begin their Pivotal US Trial in 2012. CINCOR is a catheter based system that is designed to be placed in the coronary sinus. The system attempts to reduce the incidence of CIN by removing a fraction of the contrast from the patient's blood as it flows through the coronary sinus. Osprey's public statements list the CINCOR price as between $1500-$2000. We believe market challenges for this approach may include concerns regarding complications of placing a catheter in the coronary sinus, lack of clear supporting clinical data, and the significant cost of the system. Additionally, published reports to date only indicate that CINCOR removes on average 32% of the contrast injected, which still allows a significant volume of potentially dangerous contrast to pass to the patient's kidney. While RenalGuard should work for any procedure where iodinated contrast is used, CINCOR only works for coronary interventions, so the technology cannot be used in patients undergoing peripheral catheterizations, transcatheter aortic-valve implantation (TAVI), or contrast enhanced CT.

Products and Customers

RenalGuard sales accounted for approximately 82% and 58% of our revenues for the years ended December 31, 2011 and 2010, respectively.

Our distributor of RenalGuard in Italy, Artech, accounted for 46% and 27% of our total revenues in the years ended December 31, 2011 and 2010, respectively and 56% and 48% of our RenalGuard revenues in the years ended December 31, 2011 and 2010, respectively. ACIST, our distributor in France and Germany, accounted for 12% of our total revenues in the year ended December 31, 2011 and 14% of our RenalGuard revenues in the year ended December 31, 2011.

Manufacturing

During 2010, we manufactured and tested our RenalGuard console at our facility in Franklin, Massachusetts. In 2011 we began manufacturing our RenalGuard consoles by a contract manufacturer located in New England. Our RenalGuard sterile disposable kit continues to be manufactured for us by a separate outside contract manufacturer also 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 is 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. 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 8 U.S. patents, 1 Canadian patent and 1 Japanese patent related to our RenalGuard System and its use in preventing CIN. These patents have terms that expire from 2026 through 2029.

In addition, we currently have four 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 $1,212,000 and $333,000 for the years ended December 31, 2011 and 2010, respectively. Our current and near term development efforts will be focused exclusively on advancing our RenalGuard program. In November 2010, we received a grant in the amount of $244,000 from the Internal Revenue Service under the Qualifying Therapeutic Discovery Project (QTDP) 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 16, 2012, 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 are located at 459 Fortune Boulevard, Milford, Massachusetts 01757. 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 6,000 square feet of leased space in Milford, Massachusetts. The lease on this space expires on August 31, 2014. The total base rental payments for the years ending December 31, 2012, 2013, and 2014 are $38,000, $41,000, and $30,000, respectively. We are also responsible for certain operating and maintenance costs and real estate taxes.

Item 3. ***Legal Proceedings***

We are not presently involved in any material litigation proceedings.

Item 4. ***(Removed and Reserved)***

PART II

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

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 5, 2012, the last quoted sale price of our common stock was $0.33 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.

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

2011	High	Low
First Quarter	$ 0.17	$ 0.06
Second Quarter	$ 0.24	$ 0.12
Third Quarter	$ 0.16	$ 0.07
Fourth Quarter	$ 0.20	$ 0.08

As of March 5, 2012, there were 640 record holders of our common stock. We believe that there are approximately 5,160 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, 2011:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, and other rights	(b) Weighted-average exercise price of outstanding options, and other 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)	5,602,458	$ 0.21	2,238,467 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	5,602,458	$ 0.21	2,238,467

(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, 2012.

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. The first patient was enrolled in the U.S. pivotal study in January 2012.

Our distributor of RenalGuard in Italy, Artech, accounted for 46% and 27% of our total revenues in the years ended December 31, 2011 and 2010, respectively and 56% and 48% of our RenalGuard revenues in the years ended December 31, 2011 and 2010, respectively.

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 write

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.

We evaluate the estimated future unrecoverable costs of warranty and preventative maintenance services for our installed base of 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.

Valuation of Convertible Notes and Warrant Liabilities

The valuation of our convertible notes and our warrant liabilities as derivative instruments utilizes certain estimates and judgments that affect the fair value of the instruments. Fair values are estimated by utilizing valuation models that consider current and expected stock prices, volatility, dividends, forward yield curves and discount rates. Such amounts and the recognition of such amounts are subject to significant estimates that may change in the future.

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 all other product revenue, including sales of RenalGuard consoles and single-use sets at the time of shipment, if all other revenue recognition criteria have been met.

Results of Operations

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

	2011	2010	Increase/(decrease) over 2010	
	$	$	$	%
	(dollars in thousands)			
Total revenues	$ 671	$ 587	$ 84	14%
Total cost of revenues	426	656	(230)	(35)
Gross profit (loss)	245	(69)	314	(455)
Selling, general and administrative expenses	2,445	2,805	(360)	(13)
Research and development expenses	1,212	333	879	264
Total operating expenses	3,657	3,138	519	17
Gain on the sale of assets	(40)	(98)	58	(59)
Loss from continuing operations	(3,372)	(3,109)	(263)	8
Interest expense	(396)	—	(396)	100
Interest income	10	—	10	100
Financing costs associated with convertible notes	(530)	—	(530)	100
Change in fair value of warrant liabilities	(808)	—	(808)	100
Change in fair value of convertible notes	(1,894)	—	(1,894)	100
Total other expense	(3,618)	—	(3,618)	100
Net loss from continuing operations before income taxes	(6,990)	(3,109)	(3,881)	125
Benefit for income taxes from continuing operations	492	—	(492)	100
Net loss from continuing operations, net of income taxes	(6,498)	—	(6,498)	100
Income from discontinued operations	53	2,604	(2,551)	(98)
Gain on sale of discontinued operations, net of income taxes	687	—	687	100
Net income from discontinued operations, net of income taxes	740	2,604	(1,864)	(72)
Net Loss	$ (5,758)	$ (505)	$ (5,253)	1,040%

Product Sales

Revenues increased $84,000, or 14% in 2011 as compared to 2010. RenalGuard Console sales increased $153,000 or 133% in 2011 as compared to 2010 due to a higher volume of RenalGuard consoles sold to international distributors. RenalGuard single use set revenues increased $61,000 or 28% in 2011 as compared to 2010 due to a higher volume of RenalGuard single-use sets sold to international distributors. During the fourth quarter of 2011, we deferred $277,000 of revenue related to shipments to our distributor in Italy, Artech because not all revenue recognition criteria were met. We expect this revenue to be recognized in 2012.

Gross Profit/(Loss)

Gross profit was $245,000 or 37% of total revenues, in 2011, as compared with gross loss of $69,000, or 12% of total revenues, in 2010. Gross margin generated from the low volume of OEM and RenalGuard revenues was not sufficient to offset the fixed manufacturing costs incurred during 2010.

Selling, General and Administrative Expenses

Selling, general and administrative expenditures decreased 13% in 2011 as compared to 2010. The decrease was due to lower compensation-related costs, reflecting the decrease in headcount associated with our 2010 workforce reductions.

Research and Development Expenses

Research and development expenditures increased 264% in 2011 as compared to 2010 due to RenalGuard U.S. clinical trial costs.

As we continue our U.S clinical trial for our RenalGuard program, we expect our Research and development expenses to significantly increase in 2012.

Gain on Sale of Assets

We recorded a gain on the sale of assets of $40,000 in 2011 and $98,000 in 2010 related to our OEM surgical tube business.

Other Expense

In February 2011, the Company entered into a Securities Purchase Agreement and a 5% Senior Secured Convertible Debenture Agreement as described in Note 10 of the Consolidated Financial Statements. As a result of this transaction, interest expense on the Convertible Notes of $396,000 was recorded in 2011. In addition, financing costs associated with convertible note of $530,000 was recorded during 2011.

The Company recorded other expense of $808,000 during 2011 as a result of a fair value adjustment related to the Warrant Liabilities. The Company recorded other expense of $1,895,000 during 2011 as a result of a fair value adjustment related to the Convertible Notes.

Net Loss

In 2011, our net loss increased to $5,758,000 due to increased clinical trial costs and other expense related to the fair value adjustments of our Convertible Notes and Warrant Liabilities..

Discontinued Operations

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

As discussed in Note 9 to our consolidated financial statements, the operating results of these operations, including those related to prior periods, have been reclassified from continuing operations to discontinued operations in our condensed consolidated financial statements for both 2010 and 2011.

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 $2,585,000 as of December 31, 2011, an increase of $1,261,000 from $1,324,000 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 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 that our existing resources, based on our currently projected financial results, are sufficient to fund operations through the second quarter of 2012. Based upon current and anticipated revenue projections from foreign sales of our RenalGuard product, and the anticipated costs of our U.S. patient trials, we will need to raise additional capital during the second quarter of 2012. Under the terms of the Securities Purchase Agreement, we had the opportunity to raise up to an additional $2 million from the Holders of the Convertible Notes in two separate $1 million tranches, based upon meeting certain operational milestones within certain periods of time. The deadline for achieving the operational milestones for the first $1 million tranche expired February 2012 without achieving such milestones. The second $1 million tranche is due to us upon achievement of the applicable operational milestones at any time prior to February 22, 2014.

Our plan is to seek additional capital through the sale of equity and/or debt securities to fund operations. However, there can be no assurance that such capital will be available at all, or if available, that the terms of such financing will not be dilutive to our existing stockholders. The Holders of the Convertible Notes have a right to participate in up to 50% of any subsequent financing. If we raise, additional funds through the issuance of equity or convertible debt securities, the percentage ownership of the company by our stockholders would be diluted. In addition, any debt securities would have rights, preferences and privileges senior to our common stock and we may sell equity or other convertible debt financing securities which would have rights, preferences and privileges senior to our common stock.

If we are unable to generate adequate cash flows or obtain sufficient additional funding when needed, we may have to take certain actions including, but not limited to, cutting back our operations, selling some or all of our assets, licensing potentially valuable technologies to third parties, and/or ceasing some or all of our operations.

Cash flows used in operating activities in the twelve months ended December 31, 2011 were $3,603,000 due to our net loss and unfavorable working capital changes, partially offset by non cash activity including 1) the change in fair value of convertible notes and warrant liabilities 2) non-cash interest expense; 3) depreciation expense; 4) stock-based compensation expense; and 5) financing costs associated with convertible notes. Cash flows from financing activities in the twelve months ended December 31, 2011 were $3,605,000 from the issuance of $4 million in senior secured convertible notes to an institutional investor, net of financing costs. Cash provided by discontinued operations was $1,210,000. The effect of exchange rate changes was a $67,000 increase in cash.

Forward-Looking Statements

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

- We expect to incur significant net losses in future quarters;
- We have received a ‘going concern’ opinion in our consolidated financial statements indicating that our cash balance as of December 31, 2011, combined with recurring net losses and negative cash flows from operations, raises substantial doubt about our ability to continue as a going concern for the next 12 months. As noted above, we are investigating ways to raise additional capital to continue our operations.
- 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 reception of the results of the MYTHOS and REMEDIAL II investigator-sponsored clinical trials. 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 commenced our U.S. pivotal clinical trial in 2012 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 in the United States 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, 2011. 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, 2011, 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, 2011 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, 2011. 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, 2011, 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(b) of Regulation S-K, we are not required to provide such an attestation report because we are a smaller reporting company.

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, 459 Fortune Boulevard, Milford, Massachusetts 01757. 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 hereto and are included as part of this annual report on Form 10-K.

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 30, 2012

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
/s/ Mark R. Tauscher Mark R. Tauscher	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2012
/s/ Gregory W. Mann Gregory W. Mann	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 30, 2012
/s/ Edward H. Pendergast Edward H. Pendergast	Chairman of the Board	March 30, 2012
/s/ Kevin J. Dunn Kevin J. Dunn	Director	March 30, 2012
/s/ Benjamin L. Holmes Benjamin L. Holmes	Director	March 30, 2012
/s/ Brent Norton, M.D. Brent Norton, M.D.	Director	March 30, 2012

PLC SYSTEMS INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 sheets of PLC Systems Inc. and subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of PLC Systems Inc. and subsidiaries as of December 31, 2011 and 2010, and the results of their operations and their cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

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 continuing 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/ McGladrey & Pullen, LLP

Boston, Massachusetts
March 30, 2011

PLC SYSTEMS INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2011 and 2010
(In thousands)

	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,585	$ 1,324
Accounts receivable, net of allowance of $2 and $10 at December 31, 2011 and 2010, respectively	453	121
Inventories	238	310
Prepaid expenses and other current assets	233	252
Assets from discontinued operations	—	1,095
Total current assets	3,509	3,102
Equipment, furniture and leasehold improvements, net	36	27
Other assets	4	186
Total assets	3,549	$ 3,315
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 149	$ 343
Accrued compensation	63	91
Accrued other	221	232
Deferred revenue	277	98

Liabilities from discontinued operations	—	1,117
Total current liabilities	710	1,881
Convertible notes	5,327	—
Warrant liabilities	1,600	—
Commitments and Contingencies (Note 7)		
Stockholders' equity (deficit):		
Common stock, no par value, unlimited shares authorized, 30,351 shares issued and outstanding at December 31, 2011 and 2010	93,893	93,893
Additional paid in capital	996	848
Accumulated deficit	(98,727)	(92,969)
Accumulated other comprehensive loss	(250)	(338)
Total stockholders' equity (deficit)	(4,088)	1,434
Total liabilities and stockholders' equity (deficit)	$ 3,549	$ 3,315

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

PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For The Years Ended December 31, 2011 and 2010
(In thousands, except per share data)

	2011	2010
Revenues	$ 671	$ 587
Cost of revenues	426	656
Gross profit (loss)	245	(69)
Operating expenses:		
Selling, general and administrative	2,445	2,805
Research and development	1,212	333
Total operating expenses	3,657	3,138
Gain on the sale of assets	(40)	(98)
Loss from continuing operations	(3,372)	(3,109)
Other income (expense):		
Interest expense	(396)	—
Interest income	10	—
Financing costs associated with convertible notes	(530)	—
Change in fair value of warrant liabilities	(808)	—
Change in fair value of convertible notes	(1,894)	—
Total other expense	(3,618)	—
Net loss from continuing operations before income taxes	(6,990)	(3,109)
Benefit for income taxes from continuing operations	492	—
Net loss from continuing operations, net of income taxes	(6,498)	—
Discontinued operations:		
Income from discontinued operations, net of income taxes	53	2,604
Gain on sale of discontinued operations, net of provision for income taxes of $492	687	—
Net income from discontinued operations	740	2,604
Net loss	$ (5,758)	$ (505)
Net loss per weighted average share, basic and diluted:		
From loss on continuing operations attributable to common stockholders	$ (0.21)	$ (0.10)
From income on discontinued operations	0.00	0.08
From gain on sale of discontinued operations	0.02	0.00
Net loss attributable to common stockholders per weighted average share, basic and diluted	$ (0.19)	$ (0.02)
Weighted average shares outstanding:		
Basic and diluted	30,351	30,351

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

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For The Years Ended December 31, 2011 and 2010
(In thousands)

	Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Paid in Capital	Deficit	Income (Loss)	Total
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						(516)
Balance, December 31, 2010	30,351	$ 93,893	$ 848	$ (92,969)	$ (338)	$ 1,434
Stock based compensation	—	—	148	—	—	148
Comprehensive income:						
Net loss	—	—	—	(5,758)	—	(5,758)
Foreign currency translation, net	—	—	—	—	88	88
Total comprehensive loss						(5,670)
Balance, December 31, 2011	30,351	$ 93,893	$ 996	$ (98,727)	$ (250)	$ (4,088)

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

PLC SYSTEMS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For The Years Ended December 31, 2011 and 2010
(In thousands)

	2011	2010
Cash flows from operating activities:		
Net loss	$ (5,758)	$ (505)
Income from discontinued operations	(53)	(2,604)
Gain on sale of discontinued operations, net of taxes	(687)	—
Depreciation and amortization	9	42
Stock-based compensation expense	148	221
Change in fair value of warrant liabilities	808	—
Change in fair value of convertible notes	1,894	—
Financing costs associated with convertible notes	530	—
Non-cash interest expense	225	—
Deferred income taxes	(492)	—
Change in assets and liabilities:		
Accounts receivable	(321)	235
Inventory	72	(4)
Prepaid expenses and other assets	(116)	(102)
Other assets	182	—
Accounts payable	(194)	8
Deferred revenue	186	98
Accrued liabilities	(36)	(166)
Net cash flows used in operating activities	(3,603)	(2,777)
Cash flows from investing activities:		
Purchase of property and equipment	(18)	—
Net cash used for investing activities	(18)	—
Cash flows from financing activities:		
Net proceeds from issuance of convertible notes and warrants	3,605	—
Net cash provided by financing activities	3,605	—
Discontinued Operations:		
Net cash provided by operating activities	210	1,429
Net cash provided by investing activities	1,000	—
Net cash provided by discontinued operations	1,210	1,429

Effect of exchange rate changes on cash and cash equivalents	67	(14)
Net increase (decrease) in cash and cash equivalents	1,261	(1,362)
Cash and cash equivalents at beginning of period	1,324	2,686
Cash and cash equivalents at end of period	$ 2,585	$ 1,324
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 171	$ —
Supplemental disclosure of noncash investing and financing activities:		
Warrant liabilities	$ 792	$ —
Convertible Notes	$ 3,208	

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

PLC SYSTEMS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2011

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. Over the past four years, the Company has begun initial commercialization outside the United States of its 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.

For the year ended December 31, 2011, the Company incurred a net loss from continuing operations before taxes of approximately $6,990,000 and used cash in operations of approximately $3,603,000. As of December 31, 2011, cash and cash equivalents were $2,585,000. Management expects that quarterly losses and negative cash flows will continue during 2012. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Based upon the current financial condition of the Company and the expectation of continued quarterly losses during 2012, management is currently investigating ways to raise additional capital that can be completed in the next few months. Subsequent to December 31, 2011, the Company reported that it had engaged a financial advisor to assist the Company in this effort. The Company will continue to review its other expense areas to determine whether additional reductions in discretionary spending can be achieved.

The Company also believes that the recent publication of positive clinical results from two independent investigator-sponsored clinical trials in Italy, which show RenalGuard to be both a safe and effective product for the prevention of CIN in at-risk patients, presents a substantial opportunity for it to increase its sales and achieve profitable results in the next few years, provided the Company is able to raise the additional capital it needs in the near term to sustain its operations and expand its RenalGuard sales and marketing programs.

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.

In the first quarter of 2011, the Company sold the assets related to its TMR business to Novadaq Corp., a subsidiary of Novadaq Technologies Inc., the Company's then exclusive distributor of TMR in the U.S., for $1,000,000 plus the relief of approximately $614,000 in service contract obligations (see Note 9), and issued $4,000,000 in secured convertible debt (see Note 10).

As a result of its sale in the first quarter of 2011, the operating results of the Company's TMR business, including those related to the prior periods, have been reclassified from continuing operations to discontinued operations in the accompanying consolidated financial statements (see Note 9).

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, accounts receivable, and convertible notes and warrant liabilities. 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, 2011 and 2010, respectively, consisted 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 high-quality financial instruments. At December 31, 2011 and 2010, the majority of the cash and cash equivalents balance was invested with a single financial institution.

Artech accounted for 46% and 27% of the Company's revenues for the years ended December 31, 2011and 2010, respectively. ACIST, the Company's distributor in France and Germany, accounted for 12% of the Company's revenues for the year ended December 31, 2011. At December 31, 2011, Artech and ACIST accounted for 85% and 13%, respectively of gross accounts receivable.

Concentration of Revenues

Approximately 82% and 57% of the Company's revenues for the years ended December 31, 2011 and 2010, respectively, were derived from the sales of RenalGuard.

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

	North America	Europe	Total
2011			
Net sales	$ 124	$ 547	$ 671
2010			
Net sales	$ 252	$ 335	$ 587

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 and maintains a provision for estimated credit losses based upon historical experience and any specific customer collection issues that the Company has identified. Historically, the Company has not experienced significant losses related to its accounts receivable. Collateral is generally not required. If the financial condition of its customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.

Inventories

Inventories are stated at the lower of cost (computed on a first-in, first-out method) or market value and include allocations of labor and overhead. The Company regularly reviews slow-moving and excess inventories, and writes down inventories to net realizable value if the ultimate expected proceeds from the disposals of excess inventory are less than the carrying cost of the inventory.

Equipment, Furniture, Leasehold Improvements and Long-Lived Assets

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

Depreciation and amortization are based on the following useful lives:

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

The 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, 2011 and 2010, the Company did not recognize any asset impairment charges.

Warranty and Preventative Maintenance Costs

The Company evaluates the estimated future unrecoverable costs of warranty and preventative maintenance services for its installed base products 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. There was no reserve for warranty and preventative maintenance costs recorded at December 31, 2011 and 2010.

Valuation of Convertible Notes and Warrant Liabilities

The valuation of our convertible notes and our warrant liabilities as derivative instruments utilizes certain estimates and judgments that affect the fair value of the instruments. Fair values are estimated by utilizing valuation models that consider current and expected stock prices, volatility, dividends, forward yield curves and discount rates. Such amounts and the recognition of such amounts are subject to significant estimates that may change in the future.

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. The Company's shipping terms are customarily Free On Board ("FOB") shipping point.

The Company typically records all product revenue at the time of shipment if all other revenue recognition criteria are met.

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. The Company records the impact from foreign currency transactions as a component of other income (expense).

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 2010.

Loss Per Share

In 2011 and 2010, 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, 2011 and 2010, 46,162,000 and 5,529,000 shares, respectively, attributable to outstanding warrants, convertible notes, and stock options 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):

	2011	2010
Raw materials	$ 157	$ 130
Finished goods	81	180
	$ 238	$ 310

4. *Equipment, Furniture and Leasehold Improvements*

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

	2011	2010
Equipment	$ 414	$ 399
Office furniture and fixtures	218	218
Leasehold improvements	4	349
	636	966
Less accumulated depreciation and amortization	600	939
	$ 36	$ 27

Depreciation expense was $9,400 and $42,000 for the years ended December 31, 2011 and 2010, respectively.

5. *Stockholders' Equity*

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 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 additional 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.

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.

As a result of employee terminations in 2011, options held by terminated employees to purchase a total of 173,000 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 were immediately vested, to purchase 173,000 shares of common stock at an exercise price of $0.24 per share. The Company recorded an additional $2,000 in stock compensation expense related to these grants during the year ended December 31, 2011

During year ended December 31, 2011, the Company granted options to purchase 300,000 shares of the Company's common stock to non-employees that vested immediately, and granted options to purchase 350,000 shares of the Company's common stock to employees that vest ratably over a three year period.

During the year ended December 31, 2011, the Company granted options to purchase 565,000 shares of the Company's common stock to employees with performance-based vesting, and granted options to purchase 112,500 shares of the Company's common stock to non-employee directors which vest quarterly over one year. Management has determined that as of December 31, 2011 it is probable that the performance conditions associated with the performance based vesting will be met, however not within the one year vesting term as originally estimated. Therefore, the related expense is being recognized over the estimated extended service period.

As of December 31, 2011, there were 664,068 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, 2010	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			
Granted	1,500	0.15		
Exercised	—	—		
Forfeited	(1,254)	0.23		
Expired	—	—		
Cancelled	(173)	0.24		
Outstanding, December 31, 2011	5,602	$ 0.21	3.37	—
Exercisable, December 31, 2011	3,975	$ 0.22	2.06	—

Stock-Based Compensation Expense

The Company recorded compensation expense of $148,000 and $221,000 in the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011, the Company had $72,150 of total unrecognized compensation cost related to its unvested options, which is expected to be recognized over a weighted average period of 1.02 years.

The weighted average fair value of options issued during the years ended December 31, 2011 and 2010 was estimated using the Black-Scholes model and was $0.10 and $0.08 respectively.

	Year Ended December 31,	
	2011	2010
Expected life (years)	1.00 – 6.00	1.00 – 6.00
Interest rate	0.27 – 2.65%	0.26 – 2.27%
Volatility	107.2 – 169.0%	85.6 – 292.8%
Expected dividend yield	None	None
Value of option granted	$0.01 – 0.13	$0.02 – 0.14

The expected life was calculated in 2011 and 2010 using the simplified method. The risk-free interest rate is based upon 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, 2011 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 2011 or 2010. At December 31, 2011, 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 2014. 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, 2011, future minimum lease payments are estimated to be as follows (in thousands):

Year	Future Minimum Lease Payments
2012	$ 38
2013	41
2014	30
Total	$ 109

Total rent expense was $148,000 and $204,000 in 2011 and 2010, respectively.

The Company manufactures its RenalGuard consoles and sterile disposable kits using two separate outside contract manufacturers. The contracts with these manufacturers do not contain minimum purchase requirements or any future commitments. Purchases are made upon request to the manufacturer.

During the year ended December 31, 2011, the Company hired a clinical research organization ("CRO") to assist with managing its clinical trial. The contract with the CRO does not contain minimum purchase requirements or any future commitments, and payments are made once services are provided.

8. Sale of Assets

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 totaling $71,000. 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. Also in March 2011, the Company reached an agreement with the acquiring company to settle the note receivable at a reduced amount of $40,000. This amount was collected in April 2011, and was recorded as a gain when the cash was received.

9. Discontinued Operations

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 totaling $614,000. The total carrying value of the assets sold as of the transaction date was $385,000. In addition, the Company incurred transaction costs of $50,000. The Company has recorded a gain on sale of discontinued operations before income taxes of $1,179,000 in the statement of operations.

The operating results of these operations, including those related to the prior periods, have been reclassified from continuing operations to discontinued operations in the accompanying consolidated financial statements.

Revenues and net income attributable to discontinued operations for the years ended December 31, 2011 and 2010 are as follows:

	Year ended December 31 (In thousands)	
	2011	2010
Revenues:		
Product sales	$ 455	$ 2,219
Service fees	68	1,104
Total	523	3,323
Income from discontinued operations	$ 53	$ 2,604

A summary of discontinued operations on the consolidated balance sheets at December 31, 2011 and 2010 are as follows:

	December 31, 2011	December 31, 2010
	(In thousands)	
Current assets:		
Accounts receivable, net	$ —	$ 217
Inventory	—	526
Prepaid expenses and other current assets	—	352
	$ —	$ 1,095
Current liabilities:		
Accounts payable	—	$ 30
Accrued compensation	—	27
Accrued expenses	—	50
Deferred revenue	—	1,010
	$ —	$ 1,117

10. ***Convertible Notes and Warrant Liabilities***

Features of the Convertible Notes and Investor Warrants

On February 22, 2011 (the "Original Issue Date"), the Company entered into a Securities Purchase Agreement ("Purchase Agreement") and a 5% Senior Secured Convertible Debenture Agreement (the "Note Agreement") with GCP IV LLC (the "Investors" or "Holders") pursuant to which the Company agreed to issue and sell in a private placement to the Investors an aggregate principal amount of $4,000,000 of convertible notes due February 22, 2014 (the "Convertible Notes") and 40,000,000 warrants, which expire February 22, 2016 (the "Investor Warrants"). Under the terms of the Securities Purchase Agreement, the Company had the opportunity to raise up to an additional $2 million from the Holders of the Convertible Notes in two separate $1 million tranches, based upon meeting certain operational milestones within certain periods of time. The deadline for achieving the operational milestones for the first $1 million tranche expired in February 2012 without our achieving such milestones. The second $1 million tranche remains available to the Company upon achievement of the applicable operational milestones at any time prior to February 22, 2014.

Convertible Notes

The Convertible Notes require payment of interest on the outstanding principal amount, in cash, at the rate of 5% per annum, payable quarterly on January 1, April 1, July 1, and October 1, beginning on the first such date following the Original Issue Date, on each conversion date (for the principal amount then being converted), on each optional redemption date (for the principal amount then being redeemed) and on the maturity date. Interest is calculated on the basis of a 360-day year and accrues daily commencing on the Original Issue Date until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts that may become due in connection with the Convertible Notes, has been made.

The Holders may convert the outstanding principal amount of the Convertible Notes into shares of the Company's common stock at the conversion price of $0.10 per share ("Conversion Price"). The Conversion Price is subject to adjustment in the event of (a) stock splits, stock dividends, combinations, reclassifications, mergers, consolidations, distributions of assets or evidence of indebtedness, sales or

transfers of substantially all assets, share exchanges or similar events, and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the then Conversion Price.

At any time after February 2012, and upon entering into a change of control transaction or Fundamental Transaction, as defined in the Debenture Agreement, the Company may deliver a notice to the Holders of its irrevocable election to redeem all of the then outstanding principal of the Convertible Notes for cash in an amount equal to the sum of (a) the greater of (i) the outstanding amount of the Convertible Notes divided by the Conversion Price on the date of the mandatory default amount, as defined in the Purchase Agreement, is either (A) demanded or (B) paid in full, whichever has a lower conversion price, multiplied by the Volume Weighted Average Price ("VWAP") of the date of the mandatory default amount is either (x) demanded or otherwise due or (y) paid in full, whichever has higher VWAP, plus all accrued and unpaid interest, or (ii) 130% of the outstanding principal amount of the Notes, plus 100% of accrued and unpaid interest, and (b) all other amounts, costs, expenses and liquidated damages due under the various agreements covering issuance of the Convertible Notes. Such amount would include the liquidated damages due under the default provision of the Purchase Agreement.

The Company is required to repay, in cash, any outstanding principal amount of the Convertible Notes on February 22, 2014 and is not permitted, except upon entering into a change of control transaction or fundamental transaction as noted above, to prepay any portion of the principal amount without prior written consent of the Holders.

Investor Warrants

On February 22, 2011, in connection with the issuance of the Convertible Notes, the Company issued warrants for the purchase of up to 40,000,000 shares of common stock at the exercise price of $0.15 per share and with an expiration date of February 22, 2016 (the "Warrants"). The following is a summary of the Warrants outstanding as of December 31, 2011:

	Warrants	Exercise Price
Beginning balance - February 22, 2011	40,000,000	$ 0.15
Add: Adjustments (pursuant to warrants agreement)	0	n/a
Less: Exercised	0	n/a
Ending balance	40,000,000	$ 0.15

The Warrants are exercisable in cash to purchase shares of the Company's common stock (the "Warrant Shares"). The Exercise Price may be paid pursuant to a cashless exercise provision if the Warrant Shares have not been registered within six months after the Warrants are issued. The Exercise Price of the Warrants shall be adjusted in the event of (a) stock splits, stock dividends, combinations, reclassifications, mergers, consolidations, distributions of assets or evidence of indebtedness, sales or transfers of substantially all assets, share exchanges or similar events, and (b) dilutive issuances of (i) common stock or (ii) common stock equivalents at an effective price per share that is lower than the then Exercise Price.

In connection with a Fundamental Transaction, as defined in the Purchase Agreement, that is an all-cash transaction, the Company shall have the right to purchase from the Holders all, but not less than all, of the unexercised portion of the Warrants by paying in cash to the Holders an amount equal to 30% of the Exercise Price multiplied by the number of shares of Common Stock for which the Warrants are exercisable immediately prior to such change of control transaction.

Fair Value Measurements

The Company measures and reports fair value in accordance with Accounting Standards Codifications ("ASC") 820 — *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value investments.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value of an asset should reflect its highest and best use by market participants, principal (or most advantageous) markets, and an in-use or an in-exchange valuation premise. The fair value of a liability should reflect the risk of nonperformance, which includes, among other things, the Company's credit risk.

Valuation techniques are generally classified into three categories: the market approach; the income approach; and the cost approach. The selection and application of one or more of the techniques may require significant judgment and are primarily dependent upon the characteristics of the asset or liability, and the quality and availability of inputs. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820 also provides fair value hierarchy for inputs and resulting measurement as follows:

Level 1

Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2

Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3

Unobservable inputs for the asset or liability that are supported by little or no market activity and that are significant to the fair values.

Fair value measurements are required to be disclosed by the Level within the fair value hierarchy in which the fair value measurements in their entirety fall. Fair value measurements using significant unobservable inputs (in Level 3 measurements) are subject to expanded disclosure requirements including a reconciliation of the beginning and ending balances, separately presenting changes during the period attributable to the following: (i) total gains or losses for the period (realized and unrealized), segregating those gains or losses included in earnings, and a description of where those gains or losses included in earning are reported in the statement of income.

The following summarizes the Company's assets and liabilities measured at fair value as of December 31, 2011:

		Fair Value Measurements at Reporting Date Using:		
Description	**Balance as of December 31, 2011**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Liabilities				
Convertible notes	$ 5,327,000	$ —	$ —	$ 5,327,000
Warrant liabilities	$ 1,600,000	$ —	$ —	$ 1,600,000
Total Liabilities	$ 6,927,000	$ —	$ —	$ 6,927,000

Accounting for the Convertible Notes and Investor Warrants

Investor Warrants

In June 2008, the FASB issued ASC 815-40-15 (formerly EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*), which was effective for the Company in 2009. This issued guidance requires that derivative instruments be evaluated for certain contingencies and anti-dilution provisions that would affect their equity classification as a derivative under ASC 815, *Derivatives and Hedging* (ASC 815) and requires the instruments to be classified as liabilities and reported at fair value.

Upon issuance, the Investor Warrants were not considered indexed to the Company's own stock and therefore are required to be accounted for as freestanding derivative instruments and classified as a liability. As a result, the Investor Warrants are recorded as a liability at fair value as of February 22, 2011 and December 31, 2011 with subsequent changes in fair value recorded in the consolidated statement of operations.

Convertible Notes

The Company has determined that the Convertible Notes constitute a hybrid instrument that has the characteristics of a debt host contract containing several embedded derivative features that would require bifurcation and separate accounting as a derivative instrument pursuant to the provisions of ASC 815. The Company has identified all of the derivatives associated with the February 22, 2011 financing. As permitted under ASC 825-10-10 — *Financial Instruments*, as it relates to the fair value option, the Company has elected, as of February 22, 2011, to measure the Convertible Notes in their entirety at fair value with changes in fair value recognized in the Consolidated Statement of Operations as either a gain or loss until the notes are settled. As such, the Company has appropriately valued the embedded derivatives as a single hybrid contract together with the Convertible Notes. This election was made by the Company after determining the aggregate fair value of the Convertible Notes to be more meaningful in the context of the Company's financial statements than if separate fair values were assigned to each of the multiple embedded instruments contained in the Convertible Notes.

Upon issuance of the Convertible Notes, the Company allocated the proceeds received to the Convertible Notes and Investor Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Notes to be $3,208,000. The Notes were immediately marked to fair value, resulting in a derivative liability in the amount of $3,677,000 million. As of December 31, 2011, the Convertible Notes have been marked to fair value resulting in a derivative liability of $5,327,000. The net charge to other income (expense) was expense of $1,895,000 in the year ended December 31, 2011. The debt discount in the amount of $792,000

(resulting from the allocation of proceeds) is being amortized to interest expense using the effective interest method over the expected term of the Convertible Notes. The Company amortized $225,000 in the year ended December 31, 2011, which is a component of interest expense.

Upon issuance, the Company allocated $792,000 of the initial proceeds to the Investor Warrants and immediately marked them to fair value resulting in a derivative liability of $908,000. As of December 31, 2011, the Investor Warrants have been marked to fair value resulting in a derivative liability of $1,600,000. The charge to other income (expense) for the year ended December 31, 2011 was expense of $808,000.

A summary of changes in the Convertible Notes and Investor Warrants is as follows:

	Fair Value of Convertible Notes	Fair Value of Warrant Liabilities	Total
Allocation of initial proceeds	$ 3,208,000	$ 792,000	$ 4,000,000
Initial fair value adjustment	$ 469,000	$ 116,000	$ 585,000
February 22, 2011	$ 3,677,000	$ 908,000	$ 4,585,000
Amortization of debt discount	$ 225,000	$ —	$ 225,000
Fair value adjustment	$ 1,425,000	$ 692,000	$ 2,117,000
Balance December 31, 2011	$ 5,327,000	$ 1,600,000	$ 6,927,000

The Company records the fair value of Convertible Notes and Investor Warrants as a long term liability.

Financing Costs

Financing costs include costs associated with obtaining the February 22, 2011 financing. Financing costs totaling $530,000 have been recorded in other income (expense) in the year ended December 31, 2011, $135,000 of which were recorded in prepaid expenses and other current assets at December 31, 2010 and expensed upon closing of the transaction in February 2011.

Valuation — Methodology and Significant Inputs Assumptions

Fair values for the Company's derivatives and financial instruments are estimated by utilizing valuation models that consider current and expected stock prices, volatility, dividends, market interest rates, forward yield curves and discount rates. Such amounts and the recognition of such amounts are subject to significant estimates that may change in the future. The methods and significant inputs and assumptions utilized in estimating the fair value of the Warrant Liabilities and Convertible Notes are discussed below. Each of the measurements is considered a Level 3 measurement as a result of at least one significant unobservable input.

Warrant Liabilities

A Black-Scholes-Merton option-pricing model, with dilution effects, was utilized to estimate the fair value of the Warrant Liabilities as of February 22, 2011 and December 31, 2011. This model is widely used in estimating value of European options dependent upon a non-paying dividend stock and fixed inputs. This model is subject to the significant assumptions discussed below and requires the following key inputs with respect to the Company and/or instrument:

Input	February 22, 2011	December 31, 2011
Stock Price	$ 0.0755	$ 0.1075
Exercise Price	$ 0.15	$ 0.15
Expected Life (in years)	5.00	4.15
Stock Volatility	90%	95%
Risk-Free Rate	2.16%	0.63%
Dividend Rate	0%	0%
Outstanding Shares of Common Stock	30,351,092	30,351,092

Convertible Notes

A binomial lattice model was utilized to estimate the fair value of the Convertible Notes as of February 22, 2011 and December 31, 2011. The binomial model considers the key features of the Convertible Notes, as noted above, and is subject to the significant assumptions discussed below. First, a discrete simulation of the Company's stock price, without effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Second, a discrete simulation of the Company's stock price, with effects of dilution due to the conversion feature, was conducted at each node and throughout the expected life of the instrument. Third, based upon the simulated stock price with dilution effect, an analysis of the higher position of a conversion position, redemption position, or holding position (i.e. fair value of the respective future nodes value discounted using the applicable discount rate) was conducted relative to each node until a final fair value of the instrument is conducted at the node representing the measurement date. This model requires the following key inputs with respect to the Company and/or instrument:

Input	February 22, 2011	December 31, 2011
Stock Price	$ 0.0755	$ 0.1075
Strike Price	$ 0.10	$ 0.10
Expected remaining term (in years)	3.00	2.15
Stock Volatility	95%	100%
Risk-Free Rate	1.22%	0.27%
Dividend Rate	0%	0%
Outstanding Shares of Common Stock	30,351,092	30,351,092
Effective discount rate	20.3%	13.2%
Probability of forced redemption	20%	20%

The following are significant assumptions utilized in developing the inputs:

- The Company's common stock shares are traded on the OTC Bulletin Board and, accordingly, the stock price input is based upon bid prices as of the valuation dates due to the extremely thin trading volume, broker-driven market (vs. exchange market) and the wide bid/ask spread as of the valuation date;

- The expected future stock prices of the Company's stock were modeled to include the effect of dilution upon conversion of the instruments to shares of common stock;

- Stock volatility was estimated by considering (i) the annualized monthly volatility of the Company's stock price during the historical period preceding the respective valuation dates and measured over a period corresponding to the remaining life of the instruments (monthly data set is more relevant given the extremely thin trading volume of the Company's common stock) and (ii) the annualized daily volatility of comparable companies' stock price during the historical period preceding the respective valuation dates and measured over a period corresponding to the remaining life of the instrument. Historic prices of the Company and comparable companies' common stock were used to estimate volatility as the Company did not have traded options as of the valuation dates;

- Based upon the Company's historical operations and management's expectations for the foreseeable future, the Company's stock was assumed to be a non-dividend-paying stock;

- The risk-free interest rate is based on the U.S. Treasury Yield curve in effect as of the valuation date for the expected term;

- With respect to the Convertible Notes, the Company is expected to pay all accrued interest due to the Holders on each Interest Payment Date;

- With respect to the Convertible Notes, based upon management's expectations for a change of control or fundamental transaction to occur prior to the maturity date of the Convertible Notes, a low

probability of a forced redemption;

- Upon a change of control redemption, the change of control redemption amount shall equal to the sum of:

  I. the greater of:

  (i) the outstanding amount of the debt divided by the Conversion Price on the date of the mandatory default amount is either (A) demanded or (B) paid in full, whichever has a lower conversion price, multiplied by the VWAP of the date of the mandatory default amount is either (x) demanded or otherwise due or (y) paid in full, whichever has higher VWAP, plus all accrued and unpaid interest, or

  (ii) 130% of the outstanding principal amount of the debt, plus 100% of accrued and unpaid interest, and

  II. all other amounts, costs, expenses and liquidated damages due under the various agreements covering issuance of the debt.

Additionally, it is assumed that no amounts are due pursuant to clause (II) above in any period and that the stock price at each respective node represents a reasonable approximation of the VWAP requirements.

The changes in fair value between reporting periods are related to the changes in the price of the Company's common stock as of the measurement dates, the volatility of the Company's common stock during the remaining term of the instrument, changes in the conversion price and effective discount rate.

11. Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2011	2010
Loss before income taxes:		
Continuing operations		
United States	$ (6,859)	$ (2,656)
Foreign	(131)	(453)
	$ (6,990)	(3,109)
Current income tax benefit from continuing operations:		
Federal	$ 492	$ —
Foreign	—	—
State	—	—
	$ 492	$ —
Deferred income tax benefit/(provision) from continuing operations:		
Federal	$ 3,335	(58)
Foreign	(2)	50
State	(4,415)	(52)
	(1,082)	(60)
Change in valuation allowance	1,082	60
	$ 0	$ 0
Benefit for income taxes from continuing operations	$ 492	$ —
Provision for income taxes from gain on sale of discontinued operations	(492)	—
Total provision for 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):

	2011	2010
Net federal and state operating loss carryforwards	$ 23,611	$ 23,848
Net foreign operating loss carryforwards	484	486
Accrued expenses and reserves	10	592
Tax credits	1,202	1,245
Other	348	566
Total deferred tax assets	25,655	26,737
Valuation allowance	(25,655)	(26,737)
Net deferred tax assets	$ —	$ —

The valuation allowance decreased by $1,082,000 in 2011 primarily due to the use of the Company's net operating loss carryforwards against the gain on sale of discontinued operations, 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.

Total provision for income taxes computed at the federal statutory rate differs from amounts provided as follows (in thousands):

	2011	2010
Tax benefit at federal statutory rate	$ (1,893)	$ (172)
State income taxes, net of U.S. federal income tax benefit	(331)	(30)
Permanent differences	44	57

Other	3,262	—
Change in valuation allowance	(1,082)	145
Total expense	$ —	$ —

At December 31, 2011, the Company had federal net operating loss carryforwards available to reduce future taxable income of approximately $66,200,000, which expire at various dates through 2030. At December 31, 2011, the Company had federal and state research and development credit carryforwards of $718,000 and $483,000, 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, 2011 the Company had foreign net operating loss carryforwards of approximately $1,213,000

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, 2011 and 2010, 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, 2011 and 2010, 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 2011 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.

12. Subsequent Events

The Company has evaluated all events or transactions through the date of this filing. During this period the Company did not have any material subsequent events that impacted its consolidated financial statements or disclosures.

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Articles of Continuance, pursuant to the Yukon Business Corporations Act, as amended, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2004, as previously filed with the Securities and Exchange Commission.
3.2	By-Law No. 1, a By-Law relating generally to the transaction of the business and affairs of PLC Systems Inc., incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 1999, as previously filed with the Securities and Exchange Commission.
4.1	Form of Common Stock Certificate, incorporated by reference to the Registrant's registration statement on Form S-1 (SEC File No. 33-48340) and amendments thereto, as previously filed with the Securities and Exchange Commission.
10.1#	1995 Stock Option Plan, incorporated by reference to the Registrant's registration statement on Form S-8 (SEC File No. 33-95168), as previously filed with the Securities and Exchange Commission.
10.2#	2000 Equity Incentive Plan, incorporated by reference to the Registrant's annual report on Form 10-K for the year ended December 31, 2001, as previously filed with the Securities and Exchange Commission.
10.3#	Form of Stock Option Grant Letter to Employees of the Registrant under the Registrant's 1995 Stock Option Plan and2000 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 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.
10.13#	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.
10.14*#	Employment letter dated September 2, 2011 between PLC Medical Systems, Inc. and Gregory W. Mann.
10.15	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.
10.16	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.
10.17	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.
10.18*#	Compensatory Arrangements with Executive Officers.
10.19*#	Compensatory Arrangements with Non-Employee Directors.
10.20*#	Severance Arrangements with Executive Officers.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of McGladrey & Pullen, LLP
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.
101*	The following materials from PLC Systems Inc. Yearly Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

* Filed with this annual report on Form 10-K for the year ended December 31, 2011.

+ 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.

EXHIBIT 10.14

Sept 2, 2011

Gregory Mann

Dear Gregory,

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

1) Title and Position: Chief Financial Officer (CFO)

2) Base Salary: $4615.38 biweekly.

3) Fringe Benefits: 20 days of annual flexible time off (FTO) earned on a monthly basis and to be taken at mutually satisfactory times. You will also be eligible for medical, dental, short and long-term disability and life insurance benefits starting on your first day of employment and, all in accordance with PLC's standard benefit package. In addition, you may elect to participate in the Company's 401(k) plan and Employee Stock Purchase Plan after completing one full calendar quarter. Upon your acceptance of the position, I will forward copies of our benefits enrollment materials.

4) Stock Options: You will be granted a stock option to purchase 150,000 shares of PLC Systems Inc. common stock upon the close of business of your first day of employment. This stock option will vest according to the Company's standard three year vesting schedule. The exercise price of the stock option will be the fair market value of our common stock on the day of grant.

5) At Will Employment: PLC is an "at will" employer and it is important to understand that either of us can terminate our employment arrangement at any time with or without cause.

6) Non-Disclosure: Upon hire, you agree to enter into the non-disclosure agreement with the Company which is attached to this letter.

7) Form I-9: Your employment with PLC is contingent upon your ability to provide the necessary documents authorizing you to work in the United States as required on the Form I-9.

8) Smoking: PLC Medical Systems is a smoke free facility.

I would like you to start on Oct 3 2011, or sooner. If these terms are agreeable to you, please sign and return a copy of this letter, the non-disclosure agreement and Form I-9. This offer will remain open for one (1) week.

Greg, I sincerely hope that you will accept this offer. I look forward to your response.

Sincerely,

/s/ Mark Tauscher

Mark Tauscher
President and Chief Executive Officer

Enclosures

Agreed:

/s/ Gregory Mann
Gregory Mann

Date: _____

Start Date: 10/03/2011

EXHIBIT 10.18

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
Gregory W. Mann, Chief Financial Officer	$	120,000
Kenneth J. Luppi, Vice President of Operations	$	164,625
Vincent C. Puglisi, Managing Director, International	$	161,537

Other Compensation

Mr. Tauscher currently receives 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.

EXHIBIT 10.19

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.

EXHIBIT 10.20

Severance Arrangements with Executive Officers

Mark R. Tauscher, the Company's President and Chief Executive Officer, is entitled to receive severance payments pursuant to the terms of his employment agreement with the Company.

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

1) PLC Medical Systems, Inc., a Delaware corporation

2) PLC Systemas Medicos Internacionais (Deutschland) GmbH, a German corporation

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 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 (which includes an emphasis paragraph relating to an uncertainty as to the Company's ability to continue as a going concern) dated March 30, 2012, relating to our audits of the consolidated financial statements as of and for the years ending December 31, 2011 and 2010, which appear in this Annual Report on Form 10-K of PLC Systems Inc. and subsidiaries for the year ended December 31, 2011.

/s/ McGladrey & Pullen, LLP

Boston, Massachusetts
March 30, 2012

EXHIBIT 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

I, Mark R. Tauscher, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 30, 2012

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

EXHIBIT 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

I, Gregory W. Mann, certify that:

1. I have reviewed this annual report on Form 10-K of PLC Systems Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 30, 2012

/s/ Gregory W. Mann
Gregory W. Mann
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark R. Tauscher, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2012

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, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gregory W. Mann, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2012

By: /s/ Gregory W. Mann
Gregory W. Mann
Chief Financial Officer
(Principal Financial Officer)