Zacks Small-Cap Research

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# PLC Systems Inc (PLCSF-OTC)

## PLCSF: Consumables Sales Up 300% in 1H 2013

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | Neutral |
| Date of Last Change | 08/22/2012 |
| Current Price (08/15/13) | $0.07 |
| **Target Price** | **$0.30** |

## OUTLOOK

RenalGuard, PLC's flagship product for reducing the risk of dangerous acute kidney injury, specifically contrast induced nephropathy, in at-risk patients undergoing image-guided cardiology and radiology procedures has demonstrated superior efficacy compared to standard of care in clinical trials to date. Commercialization in international markets recently began ramping up following compelling clinical trial data from European studies which were published in prestigious peer-reviewed journals. RenalGuard is currently in a large, multi-site pivotal U.S. clinical trial, results of which expect to be used to support a PMA filing for FDA approval. If all goes to plan, we think RenalGuard could launch in the U.S. market sometime in mid-to-late 2015. Risks include the need to secure a significant amount of additional capital to sustain them until PLC can reach the point of self-sustainable cash flow generation. Despite risks, we believe the shares trade cheaper than warranted and are maintaining our Outperform rating.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.30** |
| **52-Week Low** | **$0.07** |
| **One-Year Return (%)** | **-53.75** |
| **Beta** | **1.52** |
| **Average Daily Volume (sh)** | **230,975** |
| **Shares Outstanding (mil)** | **64** |
| **Market Capitalization ($mil)** | **$5** |
| **Short Interest Ratio (days)** | **1.07** |
| **Institutional Ownership (%)** | **40** |
| **Insider Ownership (%)** | **5** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **-39.0** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2013 Estimate** | **N/A** |
| **P/E using 2014 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med Products** |

## ZACKS ESTIMATES

**Revenue**
(in 000s $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | 20 A | 363 A | 212 A | 485 A | 1080 A |
| 2013 | 348 A | 372 A | 393 E | 470 E | 1583 E |
| 2014 | | | | | 2944 E |
| 2015 | | | | | 5675 E |

**Earnings per Share**
(EPS is operating earnings before non recurring items)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | -$0.22 A | -$0.05 A | -$0.10 A | $0.09 A | -$0.27 A |
| 2013 | -$0.19 A | $0.06 A | -$0.02 E | -$0.02 E | -$0.03 E |
| 2014 | | | | | -$0.02 E |
| 2015 | | | | | -$0.01 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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## WHAT'S NEW…

### Q2 Results: *Consumables Revenue Increases Almost 300% Through 1H 2013…*

PLC reported financial results for the second quarter ending June 30, 2013 on August 14th. For the fourth straight quarter PLC beat our revenue estimate. While consoles revenue fell significantly, this was more than offset by continued strong sales of single-use disposables. Sales of single-use disposables, which also have the benefit of being relatively high margin, have been on a tear in 2013, with sales up 299% through the first six months of the year. And while we still expect there may be some quarterly gyrations from things such as stocking orders, the recent growth in consumables, which should be the long-term driver of total revenue, is clearly a positive sign.

**Financials**
Q2 revenue of $372k was an increase of 3% from Q2 2012 and was up 7% sequentially. Through the first six months of 2013, revenue is up 88% from the same period in 2012. Q2 revenue was about 5% better than our $354k estimate and marked the fourth straight quarter that revenue beat our number. PLC does not specifically disclose the number of consoles and consumables sold but did note that consoles sales fell $229k and consumables sales increased $237k from Q2 2012. Console sales, which we estimate were probably in the low single-digits (or zero), fell due to lower sales to international distributors. As noted, however, we expected and continue to expect some quarterly variability. Meanwhile, consumables sales tracked significantly better than our expectations in Q2.

We continue to project revenue from consoles to be roughly equal to that from consumables through the end of 2013 but then sales from consumables, which should be feeding an ever larger installed base, to begin to outpace that of consoles beginning in 2014.

Q2 gross margin at 64% was significantly better than our 51% estimate and benefitted from the bulk of revenue coming from consumables, which we estimate are higher margin than consoles. Operating expenses of $1.5 million were meaningfully higher than out $1.1 million number - the 10-Q notes that additional investor relations expense was recorded in the quarter. Net income and EPS, which benefitted from non-cash gain of change in fair value of derivatives, were $7.9 million and $0.06 compared to our $1.4 million and $0.02 estimates.

Cash balance stood at $1.1 million at Q2 quarter end, down from $1.9 million at the end of Q1. PLC also has $500k in restricted cash that was part of the recent $4MM capital raise and is escrowed for investor relations purposes. Cash used in operations was $712k in Q2. Excluding changes in working capital, cash used in operations was $1.3 million. We continue to expect that PLC will look to raise additional operating capital in the near term to fund operations including their U.S. clinical trial.

**Operations**
On the operational front, PLC continues to make progress with patient enrollment for their pivotal U.S. RenalGuard trial, expanding their international presence including entry into new territories (most recently in Brazil where PLC gained regulatory approval), capital raising (including $4.0MM raised during Q1 2013) and building greater awareness of RenalGuard and CIN through attendance / presentations at key industry conferences throughout the world. PLC also recently noted that they are now exploring potential opportunities outside of CID with RenalGuard to expand their target markets - PLC has not provided any details but we would expect to hear more on this front in the future.

PLC also further beefed up its IP and strengthened its patent protection. In May the company announced it was granted its first European patent for RenalGuard. The patent covers the core RenalGuard device and its redundant infusion rate monitoring which allows RenalGuard to safely infuse saline at very high and accurate rates. The patent has a term extending to April 2027. Then in June the company received a new U.S. method patent covering the use of RenalGuard to protect the kidneys from potentially toxic therapeutic agents - which expands their existing patent portfolio to now include additional toxic agents and in more therapeutic settings.

Specifically related to recent awareness-building efforts, RenalGuard data was presented at the International Conference of the Israel Heart Society in early May. Two researchers from Israeli hospitals presented clinical results using RenalGuard which indicated lower incidence of CIN than what would be expected without use of RenalGuard. One of the investigators, Fr. Eyal Ben-Assa of Tel Aviv Medical Center noted, Based on these results, RenalGuard has become the standard of care for at-risk patients at our center." The other presentation at ICIHS

was by Dr. Eyal Nacum of Sheeba Hospital in Petah Tikvah, titled "Incidence of Acute Kidney Injury in the Patients Undergoing Surgical TAVI".

Then in late May data from RenalGuard therapy was presented at EuroPCR. The presentation, titled, "Minimizing Acute Kidney Injury During TAVI (transcatheter aortic valve implantation) Procedures", detailed how RenalGuard can be safely used during a TAVI procedure, which oftentimes results in the development of acute kidney injury from contrast agents. Dr. Vaikom Mahadevan, who is a Consultant Cardiologist at Manchester Royal Infirmary and made the presentation noted that, "RenalGuard has performed very nicely in this difficult patient population. My experiences so far lead me to believe that RenalGuard can be used effectively as a treatment for TAVI patients with renal impairment to reduce the risk of renal function deterioration."

Awareness-building, through event attendance / presentations as well as via investigator sponsored trials is expected to continue to be a key part of PLC's early marketing-related efforts.

**Maintaining Outlook / Recommendation / Price Target**
We have made only minor changes to our model following Q2 results and are maintaining our outlook and Outperform rating. Our price target has moved from $0.35 to $0.30 per share.

## BACKGROUND

PLC Systems Inc. (OTC: PLCSF) is a medical device company focused on commercialization of its RenalGuard product which is designed to reduce the risk of adverse exposure to toxic contrast media which can accumulate in the kidneys of patients undergoing angiographic medical imaging procedures. PLC went public through an IPO in 1992 and until recently was also involved in the manufacture and sale of a carbon dioxide laser used in transmyocardial revascularization procedures, called $CO_2$ Heart Laser System. In February 2011 PLC sold its heart laser to Novadaq Technologies for $1 million in cash in order to focus all of their resources and efforts on RenalGuard. PLC's scientific advisory board and trial investigators are counted among the world-renowned experts in the field of contrast induced nephropathy and have helped guide the science and clinical development of RenalGuard.

Angiographic imaging is used to view blood vessels and organs of the body and incorporates the use of a contrast agent injected into the blood stream to enhance the visibility of these structures in an X-ray. Data from completed and ongoing clinical trials indicate a strong safety profile and effectiveness of RenalGuard in reducing the risk of dangerous acute kidney injury, specifically contrast induced nephropathy (CIN), in at-risk patients undergoing image-guided cardiology and radiology procedures. Current standard of care to address the risk of CIN, a worldwide market PLC estimates at approximately 1 million patients and worth $500 million/year, are relatively unsophisticated, antiquated and (based on clinical data to-date) less effective than RenalGuard.

PLC obtained CE Mark in late 2007 allowing them to sell RenalGuard in Europe and also allowed them to initiate clinical studies of RenalGuard in Europe, which commenced shortly after CE Mark was granted. The company initiated commercialization in Italy in 2008 but only recently began ramping up their international sales efforts after their compelling clinical trial data from European studies was published in prestigious peer-reviewed journals and presented at the American College of Cardiology conference. PLC expects this, along with ongoing presentations and awareness-building efforts, to support their recently commenced roll-out into larger territories including France, Germany, Brazil, Israel and other regions where they just signed distribution agreements. This includes a deal signed in October 2011 with a subsidiary of the Bracco Group, a worldwide leader in diagnostic imaging equipment and agents, to be the exclusive distributor of RenalGuard in France and Germany. International expansion plans also include selling into China, other parts of Europe and, eventually into Japan.

RenalGuard is currently in a large (300 - 600 patient), multi-site (~30) pivotal U.S. clinical trial comparing it to standard of care in reducing the rates of CIN. Patient enrollment and clinical site recruitment is ongoing. Results of the study, which we think could wrap up in 2014, will be used (assuming positive) to support a PMA filing for FDA approval. If all goes to plan, we think RenalGuard could launch in the U.S. market sometime in mid-to-late 2015.

PLC's near-to-mid term strategy includes completing the U.S. study, additional investigator-led studies in international markets, presentation of clinical data to bolster commercialization efforts, additional OUS distribution agreements, initiation of a full clinical trial in Japan to support an eventual regulatory filing in that country, and raising additional capital to help fund these programs and general operations.

At the most recent quarter-end (6/30/2013) PLC had $1.1MM in cash and equivalents. While recent financings allow PLC to get to the next step in the R&D process and maintain operations, given that revenue and related cash generation will likely be modest in the near-term, PLC will likely need to secure a significant amount of additional capital to sustain them until they can reach the point of self-sustainable cash flow generation.

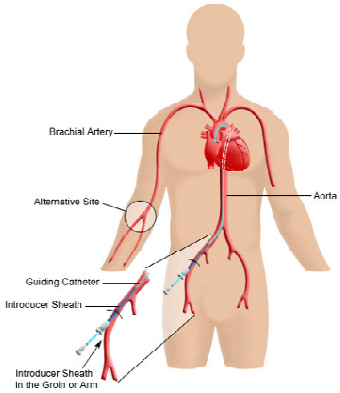
Despite certain material risks which we outline throughout this report, we believe the shares trade cheaper than fair value and are maintaining our Outperform rating on PLC Systems.

## CONTRAST-INDUCED NEPHROPATHY

**Cardiac Catheterization**

Contrast media are used to enhance the visibility of blood vessels and organs during radiographic imaging, which is often used for cardiovascular procedures including coronary angiography and percutaneous coronary intervention (PCI, or stenting).

Coronary angiograms are procedures that involve the insertion of a guide wire into the femoral (leg) artery which is threaded up to the aorta. Performed in a catheter lab (which is the setting for PLC's ongoing U.S. study), a catheter is then inserted (i.e. - cardiac catheterization) along the wire and a contrast agent injected into the arteries through the catheter - the contrast agent helps to highlight areas of arterial narrowing with an X-ray. Patients diagnosed with severe atherosclerosis (accumulation of plaque within the walls of the coronary arteries) may then undergo PCI in order to clear and re-open the arteries.




*SOURCE: Medtronic*

The contrast media is then processed through the kidneys and eventually flushed out in the urine. However, contrast administration results in a decrease in renal blood flow which can lead to ischemic injury of the kidneys which combined with already reduced kidney function and other risk factors that some patients suffer from, the contrast media can further impair renal function and lead to contrast-induced nephropathy.

There are different types of contrast agents with higher viscosity (i.e. - thickness) and higher osmolar media having been associated with a higher degree of CIN. While more modern non-ionic iso-osmolar and lower-viscosity contrast agents such as iodixanol are now used to try and limit CIN, it remains a significant problem especially in higher-risk patients. While one study (NEPHRIC) indicated iodixanol was associated with a lower incidence of CIN in high risk patients undergoing coronary angiography[1], there is no consensus that a particular contrast agent(s) is necessarily associated with lower risk of CIN compared to others. The 2011 ACCF/AHA updated guidelines for patients at risk of heart attack (and which may undergo coronary angiography) cover this topic and note that the "strength and consistency of relationships between specific isosmolar or low-osmolar agents and CIN or renal failure are not sufficient to enable a guideline statement on selection among commonly used low-osmolar and isosmolar media."[2] We make mention of this to point out that CIN risk appears to be independent of contrast agent selection. Also important to note is that even if one were to accept that, based on data from the NEPHRIC study, iodixanol may have some benefit in reduction of risk of CIN, in a clinical study (which we explain later in this report) which used iodixanol in both arms (RenalGuard and standard of care) RenalGuard still demonstrated a significantly lower incidence of CIN compared to patients hydrated with standard of care.

While mortality and morbidity rates directly related to CIN have been difficult to determine (as patients with CIN also often have other complications such as liver disease, sepsis, respiratory failure, bleeding, diabetes, etc. which can contribute to a poor prognosis), it's widely clinically accepted that CIN increases the risk of death and reducing its incidence will contribute to better patient outcomes. A paper published in the American Society of Nephrology in 2008 titled *Contrast-Induced Nephropathy: What Are The True Clinical Consequences?* concluded that, "The available literature has consistently shown that patients who develop CIN have a greater risk for dying, both during the short-term period of hospitalization and for up to a year or more after the contrast-enhanced procedure. The data demonstrating a temporal association between CIN and death, however, do not prove a causal relationship." The authors also noted that, "Published data to date indicate that, at the very least, CIN is a marker for increased mortality" and "reducing its (CIN) incidence should remain a goal in clinical practice as well as a target for future research."[3] Other studies have also indicated a link between CIN and death as well as between CIN and increased hospital stays and related costs.

Contrast-induced nephropathy is generally defined as acute renal failure occurring within 48 hours of exposure to radiographic contrast media that can not be attributed to other causes. The most common clinically accepted

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[1] *Nephrotoxic Effects in High-Risk Patients Undergoing Angiography.* Aspelin P., et al. New England Journal of Medicine. Feb 2003; 348: 491-499

[2] *2011 ACF/AHA Focused Update of the Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction (Updating the 2007 Guideline).* Wright RS, et al. ACC/AHA. JACC May 2011 57:19

[3] *Contrast-Induced Nephropathy: What Are The True Clinical Consequences?* Rudnick M, Feldman H. American Society of Nephrology, 3: 262-272, 2008

method for diagnosing CIN is by measuring the change in the patient's serum creatinine levels, with either a greater than 25% increase in serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dl following exposure to a contrast agent considered a positive diagnosis for CIN. Serum creatine is measured with a simple blood test.

Creatinine is a metabolized by-product of creatine, an organic acid found in the muscle tissues which supplies energy for muscle contraction. Creatinine is the waste product when creatine is metabolized and is removed from the bloodstream by the kidneys and excreted in the urine. When contrast media impairs kidney function (i.e. - CIN), less creatinine is excreted and which causes serum (blood) creatine levels to rise.

***Incidence High Among High-Risk Patients…***

The rate of incidence of contrast-induced nephropathy may vary depending on a number of factors including the the type of radiology procedure performed, the dose and type of contrast agent administered, the differing patient populations in regard to number and type of risk factors, and the length of patient follow-up.[4] Authors of a paper published in the December 2004 edition of the American Journal of Roentgenology cite various studies which "have shown that the overall incidence of CIN was 14.5% in a large epidemiologic study (defined as > 25% increase in serum creatinine levels over baseline in the first 5 days), but rates may vary from 0% to 90%, depending on the presence of risk factors, most notably chronic renal insufficiency (including kidney disease, end stage renal disease, etc), diabetes mellitus, and high contrast volume administered. Incidence among patients with diabetes has been reported to be 9–40% in patients with mild-to-moderate chronic renal insufficiency and 50–90% in those with severe chronic renal insufficiency. In contrast, the incidence in the general population is much lower and has been calculated to be less than 2%." [4] RenalGuard's intended use is for the prevention of CIN in higher risk patients (EGRFS of 60 ml/min or less).

***Diabetics With Impaired Kidney Function Particularly Susceptible To CIN…***

Risk of CIN is particularly high in patients with diabetes, regardless of whether diabetes (or something else) is the initial cause of kidney function impairment. In patients where reduced kidney function is associated with diabetes, studies have shown that as much as 56% that go on to experience CIN will have irreversible kidney failure. In addition, patients with diabetes who have advanced chronic renal failure (serum creatinine levels > 3.5 mg/dL) due to causes other than diabetic nephropathy are at significantly higher risk of developing contrast-induced nephropathy.[4, 5] There is also some evidence that diabetes alone (i.e. - in the absence of reduced kidney function) may be a risk factor for CIN, although other studies have failed to confirm this. There is, however, a link between diabetes and risk of renal failure - and a connection between renal failure and risk of CIN - so in a sequential sense, there is an association between diabetes alone (in the absence of reduced kidney function) and CIN.

## NO EFFECTIVE TREATMENT FOR CIN, ALTHOUGH HYDRATION HELPS

While the most effective way to address the risk of CIN is to use imaging modalities and procedures without the use of a contrast agent, that option is less viable with coronary angiography and PCI. Coronary imaging procedures, which may require two to three times the amount of contrast agent compared to other procedures, account for a significant portion of the clinical research on CIN which has found no effective way to treat the condition.

When avoidance of contrast media is not an option, general measures that have been used to reduce the risk of CIN include using the smallest effective dose of contrast media, eliminating nephrotoxic drugs (i.e. - NSAIDS, cisplatin, aminoglycoside antibiotics, cyclosporin A, and amphotericin B) for the 24 hours prior to the procedure, and maintaining a gap of at least 72 hours between contrast studies.

Various interventions have been investigated during contrast studies to reduce the risk of CIN including hydration, antioxidants (particularly *N*-acetylcysteine (NAC), different contrast media, diuretics, vasodilators (particularly atrial natriuretic peptide (ANP), calcium channel blockers, adenosine, dopamine, and hemodialysis/hemofiltration with varying degrees "success". Aside from minimizing the amount of contrast media and hydration/fluids, all the others have either been confirmed to have little to no benefit or at best, have yet to been deemed inconsistently beneficial. Consensus among various clinical studies seems to be that fluids and hydration is the most effective way of maintaining renal function with the PRINCE (Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation)

[4] *Review. Contrast-Induced Nephrology.* Gleeson TG, Bulugahapitiya S. American Journal of Roentgenology, 183 December 2004
[5] *Contrast nephropathy in azometic diabetic patients undergoing coronary angiography.* Manske CL, Sprafka JM, Strony JT, Wang Y. American Journal of Medicine, 89-5 November 1990

study, which was published in the February 1999 edition of the Journal of the American College of Cardiology, showing that a higher urine flow is associated with lower risk CIN in patients undergoing angiography.[6]

These findings seem to be supported in the *2011 Guideline for Percutaneous Coronary Intervention* report of the American College of Cardiology (ACC), American Heart Association (AHA) Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Interventions (SCAI). Relative to reducing the risk of CIN, the report recommends[7];

- Patients should be assessed for risk of contrast-induced acute kidney injury (AKI) before PCI
- Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration
- In patients with chronic kidney disease (creatinine clearance _60 mL/min), the volume of contrast media should be minimized
- Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI

***Better Hydration Methods Needed…***

While it's still not completely clear why intravenous fluids and related intravascular volume expansion reduces the risk of CIN, evidence suggests it could be a result of a number factors including; an increase in free water excretion and dilution of the contrast agents, increased renal blood flow, and reduction in renal production of nitric acid. Despite the ambiguity over cause and effect, there seems little question that hydration helps to reduce the risk of CIN. Now the question is how to do it the most effectively.

The CIN Consensus Working Panel is an international multidisciplinary group that reviewed almost 900 published papers with the goal of better understanding CIN including the epidemiology and pathogenesis of CIN, baseline renal function measurement, risk assessment, identification of high-risk patients, contrast medium use, and preventive strategies.

Relative to reducing risk of CIN via hydration, the CIN Consensus Working Panel recommends a regimen of intravenous isotonic crystalloid (1-1.5 mL/kg/h) for 3 to 12 hours before the procedure and continuing for 6 to 24 hours afterwards. For hospitalized patients, hydration should begin 6 hours before the procedure and continued for 6 to 24 hours post-procedure. Outpatients should receive fluids 3 hours prior and 12 hours post-procedure. While this hydration regimen is believed to be the most effective, it's often not followed in practice given the cumbersome length of time required and related cost (as a result of the time required which often means inpatient admission). As a result, bolus (i.e. - rapidly at one time) administration is sometimes used. Clinical trials have shown that bolus administration to be inferior to overnight intravenous administration relative to intravenous volume expansion as well as in incidence of CIN.[8, 9] We think this bodes well for demand for a better alternative that can more effectively (with lower burden than overnight hydration) provide optimal hydration and reduce side-effects of over or under hydration.

While the CIN Consensus Panel noted that it was not useful to recommend a target urine output to guide the rate of intravenous fluid replacement, the aforementioned PRINCE trial showed that there was a benefit from using a forced diuretic to produce a high urine flow. PLC Systems' ongoing clinical trials with RenalGuard aim to support this theory that was first demonstrated in the PRINCE trial that inducing and maintaining high urine output through the kidneys may reduce the risk of CIN (PLC already demonstrated this in their completed European clinical trials).

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## RENALGUARD

The concept behind RenalGuard is relatively simple and is based on the proven theory that kidney health benefits from lower exposure to toxins and this can be accomplished with increased urine output. RenalGuard maintains

[6] *A prospective randomized trial of prevention measures in patients at high risk for contrast nephropathy: results of the P.R.I.N.C.E. Study. Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation*. Stevens MA, McCullough PA, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Timmis GC, O'Neill WW. Journal of the American College of Cardiology, 1999 Feb;33(2)

[7] *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.* Levine GN, et al. ACC,AHA,SCAI. Journal of the American College of Cardiology, 2011 58:24

[8] *What is the best hydration regimen to prevent contrast media-induced nephrotoxicity?* Bader BD, Berger ED, Heede MB, Silberbaur I, Duda S, Risler T, Erley CM. Clinical Nephrology 2004;6:1–7.

[9] *Optimal timing of hydration to erase contrast-associated nephropathy: the OTHER CAN study*. Krasuski RA, Beard BM, Geoghagan JD, Thompson CM, Guidera SA. Journal of Invasive Cardiology 2003;15:699–702

optimal hydration (reducing side-effects of over or under hydration) through matching the amount of intravenous fluids with the amount of urine output. The RenalGuard System (console and single-use sterile disposable) can be seamlessly integrated and incorporated into existing catheter labs and hospital work flow. And while CIN is clearly the initial focus, PLC believes RenalGuard is a true platform technology with potential utility in other applications including for other contrast procedures, clearance of other toxic agents such as chemotherapy, for sepsis, kidney transplant and other indications where fluid therapy could be of benefit.

(The following description of from PLC's public documents)
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. The console relies on proprietary, patented software and electronic weight measurements to control the rate at which fluid is infused and to monitor urine volume. The console is mounted on a standard IV pole and is equipped with an internal battery that allows operation while the patient is being transported within a hospital. A unique sterile disposable kit is required for each procedure.

**RenalGuard System**



*SOURCE: PLC Systems*

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.

***Regulatory Status…***
RenalGuard is CE Marked for sale in Europe (where it is now commercially available) and, depending on results of an ongoing pivotal U.S. study and subsequent timely success in gaining FDA approval, we think the system could launch in the U.S. sometime in mid-to-late 2015. In January 2012 PLC announced their intended path towards approval in Japan which included a leading Japanese cardiologist using RenalGuard with two patients for prevention of CIN (which has been completed) and then the doctor meeting with the Japanese Ministry of Health to outline a process for regulatory approval of RenalGuard in that country. The expectation is to be granted approval to move forward on a ~60- patient Japan-based study which PLC believes could complete in 8 - 10 months. We expect to hear more about this in the near future.

***Patent Protection…***
PLC holds several U.S. patents covering the RenalGuard technology, and importantly, includes the method patent which provides broad coverage for the use of matched fluid replacement with diuresis for prevention of CIN. In June 2013 the company was granted another key U.S. method patent which covers the use of RenalGuard to protect the kidneys from potentially toxic therapeutic agents - which expands their existing patent portfolio to now include additional toxic agents and in more therapeutic settings. The company also has concept patents covering creating and maintaining equilibrium state urine flow to eliminate iodine. The method and concept patents are of particular importance as they should provide a significant barrier to competition given their assumed defensibility in the case of a patent challenge. PLC also has full technology patents in Japan and Canada and E.U. patents are pending. In Q2 2013 the company was granted its first European patent for RenalGuard. The patent covers the core RenalGuard device and its redundant infusion rate monitoring which allows RenalGuard to safely infuse saline

at very high and accurate rates. The patent has a term extending to April 2027. PLC's patents expire between 2026 and 2029.

***Clinical Data…***

RenalGuard has been studied in two randomized, open-label investigator-sponsored clinical trials, MYTHOS and REMDEDIAL II, both conducted in Italy. Both studies indicated RenalGuard was more effective than standard of care in reducing the incidence of CIN in at-risk patients undergoing coronary angiography/PCI (which is essentially the label that PLC is pursuing for the U.S. market). Results of the studies were published in highly-respected peer-reviewed journals and REMEDIAL II was presented in 2011 at ACC, considered the Super Bowl of cardiology conferences. RenalGuard is currently being studied in a pivotal U.S. clinical trial which (assuming positive results) is expected to support a PMA filing for FDA approval.

**MYTHOS**

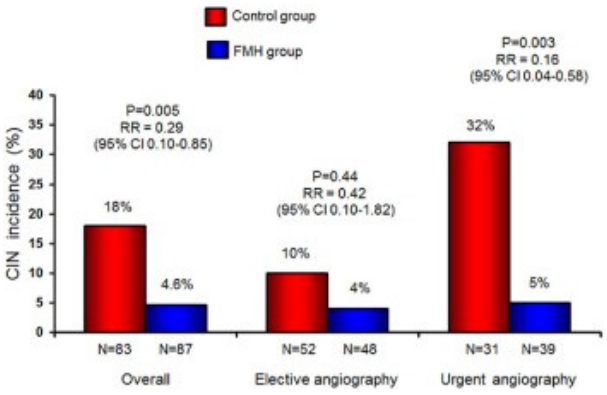
MYTHOS was a single-site, randomized, open-label trial conducted at the Centro Cardiologico Monzino University in Milan, Italy which was designed to determine safety and effectiveness of RenalGuard in prevention of CIN in at-risk patients. The study, which completed in 2010, enrolled 170 patients (87 RenalGuard/83 control) patients with chronic kidney disease (CKD) undergoing PCI (either elective or urgent) and compared safety and effectiveness of RenalGuard to standard overnight hydration therapy. Primary endpoint was the incidence of CIN (defined by ≥25% or ≥0.5mg/dl rise in serum creatinine over baseline) at 48 to 72 hours.

RenalGuard patients received intravenous saline for 30 minutes followed by a bolus of intravenous furosemide. Hydration (saline) with RenalGuard began ~60 minutes prior to the start of the catheterization procedure. Hydration, matched to the amount of urine produced, continued during and until about four hours following the procedure. Control patients received intravenous saline for a minimum of 12 hours prior to catheterization, during and for a minimum of 12 hours following the procedure.

Results of the trial showed four (4.6%) RenalGuard patients developed CIN versus 15 (18%) control patients. The difference (i.e. - 74% lower incidence of CIN) was statistically significant (95% CI, p=0.005). A lower rate of in-hospital clinical complications was also observed in the RenalGuard group compared to control (8% vs. 18%, p=0.052). Safety was considered good with no device or therapy related complications in the RenalGuard cohort.

The investigators concluded that in patients with CKD undergoing coronary procedures, furosemide-induced high urine output with matched hydration significantly reduces the risk of CIN and may be associated with improved in-hospital outcomes. The results were published in January 2012 in the *Journal of the American College of Cardiology (JACC) - Cardiovascular Interventions*[10].

**MYTHOS: RenalGuard More Effective**




*SOURCE: sciencedirect.com / JACC / PLC Systems*

**MYTHOS: Less Adverse Events in RenalGuard Group***

Centro Cardiologico Monzino

| | RenalGuard Group (n=80) | Control Group (n=77) | P value |
|---|---|---|---|
| CIN requiring RRT | 1 (1.2%) | 3 (4%) | NS |
| Acute myocardial infarction | 0 (0%) | 1 (1.3%) | NS |
| Atrial fibrillation | 0 (0%) | 2 (3%) | NS |
| Emergency CABG | 0 (0%) | 0 (0%) | NS |
| Acute heart failure | 5 (6%) | 9 (12%) | NS |
| Hypotension/shock | 0 (0%) | 0 (0%) | NS |
| In-hospital death | 1 (1.2%) | 3 (4%) | NS |
| All clinical events | 7 (9%) | 18 (23%) | 0.012 |

RRT= renal replacement therapy

*Top-line data includes 157 patients. Full data (170 patients) showed AE rate of 8% RenalGuard and 18% control

*SOURCE: PLC Systems*

**REMEDIAL II**

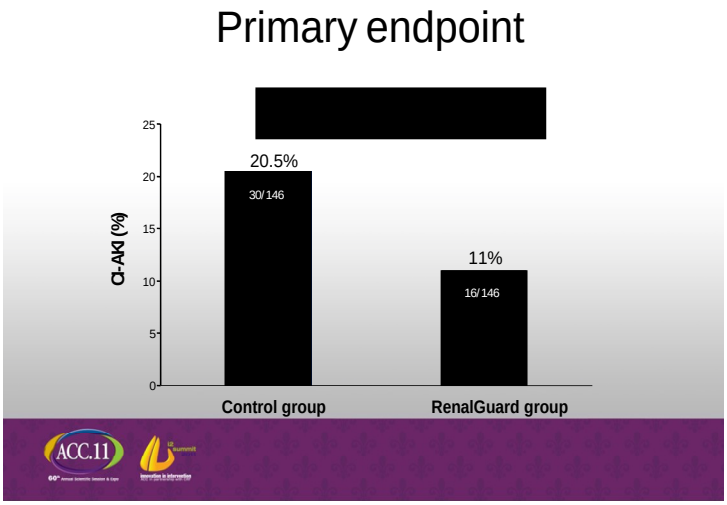
REMEDIAL II (REnal Insufficiency Following Contrast MEDIA Administration II TriaL) was a multi-site, randomized, open-label trial conducted at the Clinica Mediterranea in Naples, Italy and three other hospitals in Italy designed to determine safety and effectiveness of RenalGuard in reduction of CIN in high-risk patients. The

[10] *Prevention of Contrast Nephropathy by Furosemide With Matched Hydration:The MYTHOS (Induced Diuresis With Matched Hydration Compared to Standard Hydration for Contrast Induced Nephropathy Prevention) Trial.* Marenzi G., et al. JACC: Cardiovascular Interventions Jan 2012 5:1 90-97

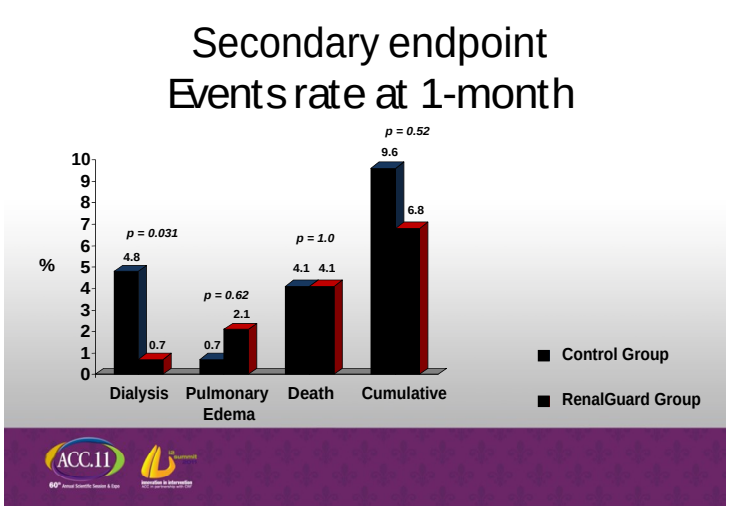
study was conducted by Dr. Carlo Briguori, considered a world-renowned CIN prevention specialist. Primary endpoint was the rate of CIN with CIN defined as ≥0.3mg/dl rise in serum creatinine over baseline at 48 hours. Secondary endpoints included an increase in serum creatinine of ≥25% and ≥0.5mg/dl at 48 hours, changes in serum creatinine concentration at 24 and 48 hours, the rate of acute renal failure requiring dialysis, and the rate of adverse events. The study enrolled 294 patients (147 RenalGuard/147 control, 146 in each group completed treatment) with CKD undergoing coronary angiography or PCI (or both) which were randomized to either hydration with RenalGuard with normal saline and N-acetylcysteine (NAC) or control hydration which consisted of sodium bicarbonate and NAC, which is often considered standard of care for prevention of CIN in clinical practice. Iodixanol was used as the contrast agent which is common for coronary angiographic and PCI procedures.

RenalGuard patients received a run-in regimen similar to the MYTHOS trial with intravenous bolus saline one hour pre-procedure followed by furosemide in order to achieve the optimal urine flow. Hydration by saline plus NAC, matched to urine output via RenalGuard, was then continued for the duration of the procedure and for up to 4 hours afterwards. Control patients received intravenous hydration by sodium bicarbonate plus NAC one hour before, during and six hours after the procedure. Control patients also received NAC orally the day before the procedure and the day of the procedure.

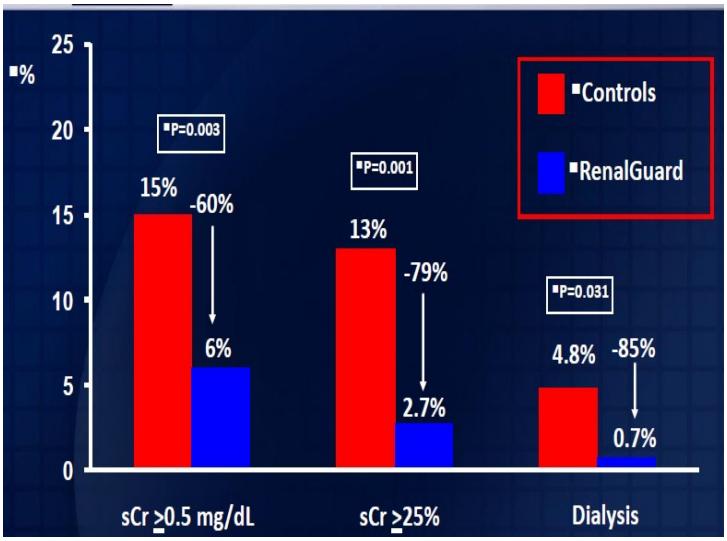
**REMEDIAL II: RenalGuard More Effective**




**REMEDIAL II: RenalGuard Favorable AE's**




**REMEDIAL II: Secondary Efficacy Endpoints Also in Favor of RenalGuard**




## Secondary endpoints

| | Control group (n= 146) | RenalGuard group (n= 146) | P |
|---|---|---|---|
| **Changes in creatinine at 48 hours** | | | |
| Increase ≥0.3 mg/dL | 30 (20.7%) | 16 (11%) | 0.025 |
| Increase ≥0.5 mg/dL | 22 (15%) | 9 (6%) | 0.003 |
| Increase ≥25% | 19 (13%) | 4 (2.7%) | 0.001 |
| Increase ≥50% | 11 (7.5%) | 1 (0.7%) | 0.003 |
| **Changes in cystatin C at 24 hours*** | | | |
| Increase ≥0.3 mg/dL | 21 (15.5%) | 11 (8.5%) | 0.07 |
| Increase ≥10% | 33 (24%) | 22 (16%) | 0.13 |
| Increase ≥15% | 23 (17%) | 17 (12%) | 0.29 |
| Increase ≥25% | 14 (10%) | 5 (3.5%) | 0.04 |
| **Changes in cystatin C a 48 hours*** | | | |
| Increase ≥0.3 mg/dL | 29 (21%) | 16 (12%) | 0.045 |
| Increase ≥10% | 47 (34%) | 29 (22%) | 0.027 |
| Increase ≥15% | 35 (25.5%) | 21 (16%) | 0.050 |
| Increase ≥25% | 23 (17%) | 11 (8.5%) | 0.039 |

*SOURCE: PLC Systems*

Results of the trial showed 16 (11%) RenalGuard patients developed CIN versus 30 (21%) control patients. The difference (47% lower incidence of CIN) was statistically significant (95% CI, p=0.025). This trial used a definition

of a rise in serum creatinine for its primary endpoint of ≥ 0.3mg/dl. A better comparison to the literature is the secondary endpoints which were also in favor of RenalGuard. With CIN defined as an absolute increase in serum creatinine of ≥0.5mg/dl, only 9 (6%) of RenalGuard patients developed CIN, compared to 22 (15%) of control (60% reduction in favor of RenalGuard, p=0.003). With CIN defined as an increase in serum creatinine of ≥25%, only 4 (2.7%) of RenalGuard patients developed CIN, compared to 19 (13%) of control (80% reduction in favor of RenalGuard, p=0.001). The RenalGuard group also had a lower rate of dialysis compared to control (0.7% versus 4.1%, p=0.056). In aggregate, adverse events were lower in the RenalGuard group compared to control.

The investigators concluded that RenalGuard is superior to sodium bicarbonate and NAC in preventing contrast-induced acute kidney injury in high-risk patients. Results of the study were presented at the American College of Cardiology's (ACC) conference in a Late Breaking Clinical Trial Session in April 2011. The ACC annual conferences are considered the preeminent cardiology conference and attended by industry and thought leaders from across the globe. The study results were also published in *Circulation*, a peer-reviewed journal of the American Heart Association, in September 2011.

**U.S Clinical Trial**

RenalGuard is currently in a multi-site (~30), open label, randomized pivotal U.S. clinical trial dubbed CIN-RG being conducted under the supervision of principal investigators at Northwestern University Medical School, University of Vermont College of Medicine, and Mount Sinai School of Medicine. Enrollment will include at least 326 patients and up to 652, depending on the outcome of a sample size re-estimation after 163 patients. The study will compare RenalGuard hydration with standard intravenous saline in patients with increased risk of CIN in the setting of a catheterization lab. It is expected to build on results and insights gained in the European studies and (assuming positive results) will be used as primary support for a PMA filing seeking FDA approval. Primary endpoint is incidence of CIN with CIN defined as an increase of serum creatinine of ≥25% and/or a rise of 0.5 mg/dl over baseline within 96 hours. Secondary endpoints include major adverse events at 90 days, mean peak increase in serum creatinine at 72 hours, incidence of CIN at 7 days, and proportion of patients who maintain a rise in serum creatinine at 7 days.

From initiation to completion, CIN-RG is expected to take approximately 18 - 24 months. The first patient was enrolled in January 2012 and, per management's May 2013 presentation, 12 sites are actively enrolling. Our current estimated timelines, which are subject to change, include completing trial enrollment in late 2013 followed by finalized data analysis, a peer-reviewed publication and PMA filing by mid-to-late 2014, and U.S launch in mid-to-late 2015.

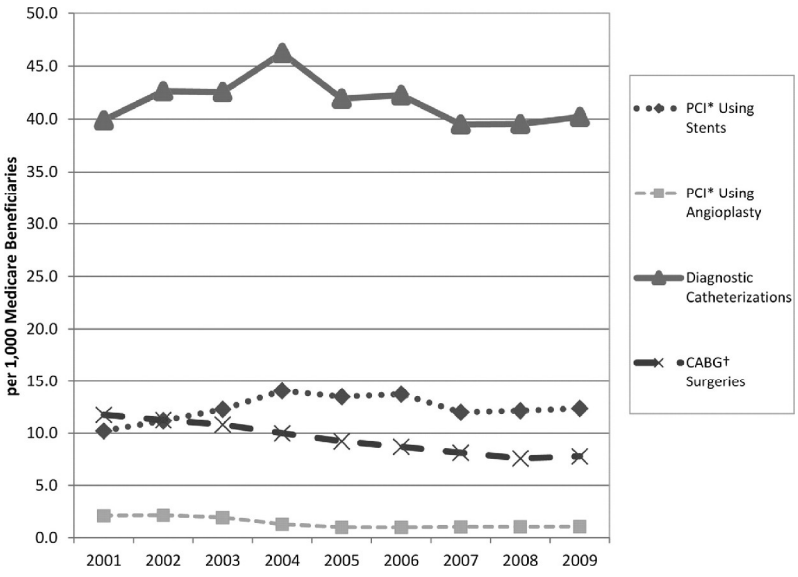
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## MARKET TRENDS

While future applications for other indications may offer additional opportunity, we confine our market trend discussion to CIN prevention in at-risk patients undergoing coronary imaging procedures including coronary angiography and PCI as it represents the initial market for RenalGuard.

The increasingly sedentary lifestyles and poor diets in the U.S. has contributed to an estimated one in three Americans having some form of cardiovascular disease. While mortality from cardiovascular disease has been on the decline since the 1950's due to lower rates of smoking and advances in medical care, it remains the number one killer in the U.S. Demand for coronary angiography and PCI has declined from its peak reached about 10 years ago but has

**Coronary Catheterization Rates In The U.S[11]**



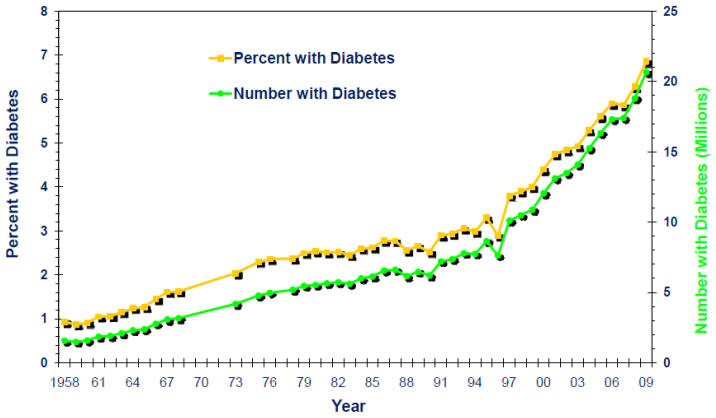

[11] *Trends in Coronary Revascularization in the U.S. From 2001 to 2009*. Riley R. et.al. Circulation: Cardiovascular Quality and Outcomes. 2011;4:193-197

since stabilized and remains a huge part of cardiac healthcare with over 1 million of these procedures done each year in the U.S. (and over 7 million worldwide, including 3+ million in Europe). This relatively stabilized demand for cardiac catheterization combined with the growth in diabetes (which, as noted earlier increases the risk of CIN) has created a large and rapidly growing market opportunity for RenalGuard. We believe the attractive underlying market fundamentals combined with the already unmet demand for a better solution to prevent CIN (and RenalGuard's significantly superior efficacy vs. standard of care as seen in clinical trials to-date) should bode well for PLC and interest in RenalGuard.

***Diabetes Incidence On The Rise…***

According to the American Diabetes Association, approximately 26 million Americans have diabetes with another 79 million classified as prediabetic. Worldwide, it is estimated 285 million are afflicted with diabetes. Less than 1% of the U.S. population was diagnosed with diabetes in 1960 but due to factors such as by poor diet and exercise habits, along with the increase in the proportion of higher risk demographics (i.e. -the elderly and minority groups) the incidence of diabetes has skyrocketed over the last 50 years. Approximately 8% of the U.S. population currently has been diagnosed with diabetes - this is expected to grow to as much as 33% by the year 2050.

**Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2009**




*SOURCE: cdc.gov*

## FINANCIAL CONDITION / CAPITAL STRUCTURE

PLC exited the most recent reporting period (Q2 ending 6/30/2013) with $1.1MM in cash and equivalents (plus $500k in restricted cash which is escrowed for investor relations purposes). Cash used in operating activities (ex-changes in working capital) has averaged roughly $1MM per quarter.

During Q1 2013 PLC sold $4.0 million ($3.5 million net proceeds) in common stock. While recent financings allow PLC to get to the next step in the R&D process and maintain operations, given that revenue and related cash generation will likely be modest in the near-term, PLC will likely need to secure a significant amount of additional capital to sustain them until they can reach the point of self-sustainable cash flow generation.

We estimate core operations (ex-clinical studies) cash burn of approximately $2.5 million per year and that the U.S. clinical trial will require between $5 million and $10 million more (depending on total enrollment and ballparking ~$15k per patient) to fully fund. As such we think PLC will need to raise significantly more capital through roughly 2015 to finance operations and complete the U.S. study.

**Debt**

Debt consists of $4.95 million in 5% senior secured convertible notes ($3.7MM due February 2014, $1MM due July 2015, $250k due January 2016) sold to GCP IV LLC under a February 2011 securities purchase agreement. The notes are secured by all assets of the company and are convertible at $0.10 at the option of the holder.

The February 2011 securities purchase agreement with GCP IV LLC included an initial sale of $4 million of convertibles with 100% warrant coverage (40 million) at a $0.15 strike (subsequently amended to a $0.098 strike) with 5-year expiration. Terms of the agreement also provided that PLC could sell an additional $2 million (including 20 million warrants), in two separate $1 million tranches (considered the second and third closings - see our 11/5/2012 initiation report for further detail on the GCP agreement). In July 2012 PLC sold to GCP (after certain terms were amended) an additional $1 million in convertibles under this agreement. PLC sold an additional $250k to GCP in January 2013. Per terms of the aforementioned $4.0 million stock sale in February 2013, the $750k remaining under the GCP securities purchase agreement was cancelled. In Q2 2013 $300k of the 2/2014 notes were converted to equity.

We continue to use the ongoing assumption that any outstanding convertible debt eventually converts to common stock at the respective conversion prices (i.e. - the conversion features are in-the-money prior to bond maturity), which is reflected in our modeled interest expense and outstanding share counts.

**Derivative Liabilities**
PLC uses ASC 825-10-10 accounting treatment to measure fair value of their debt - which combines both the fair value of the debt conversion feature as well as the straight debt together on one line item ("convertible notes") on the balance sheet (we only note this to explain the difference between the $4.95 million in outstanding convertible bonds and the $5.9 million of debt listed on PLC's balance sheet as of Q2).

The fair value of both the debt conversion feature and outstanding warrants can change from period-to-period (largely based on the value of the underlying asset, the price of the common stock) which can cause potentially large non-cash gains or losses which run through "other income" on the income statement (as an example, Q1 2013 saw $6.6 million non-cash expenses related to these and Q2 had a $9.3 million gain).

## OUTLOOK / RECOMMENDATION / VALUATION

***International Status…***
On the heels of the publication and presentation of the compelling data from the Italian clinical trials (MYTHOS and REMEDIAL II), in October 2011 PLC brought on ACIST Medical Systems as its exclusive distributor of RenalGuard in France and Germany, the two largest countries in the E.U. A subsidiary of worldwide leader in diagnostic imaging and contrast agents the Bracco Group, ACIST brings wide distribution reach and along with RenalGuard's strong trial data, offers a potentially potent combination to grow sales in Europe. PLC also sells RenalGuard in Italy through their distributor, Artech, which in 2011 accounted for over 50% of RenalGuard sales. With the recent addition of other distributors in larger markets, the customer base will be much more diversified and reduce any customer concentration risk.

In March 2012 PLC announced they received approval to sell RenalGuard in Brazil and, through their Brazilian distributor, DISCOMED, is in the midst of the initial roll-out in that country. Initial stocking orders were sold to DISCOMED in Q4 2012. Also in March 2012 PLC received approval for sale of RenalGuard in Israel and announced A.M.I. Technologies will distribute the product in the Middle East. The Latin America market is serviced by RenalGuard's distributor, Girlow USA, which exhibited RenalGuard in August at SOLACI 2012, the annual meeting of the Latin America Society of Interventional Cardiology which is attended by over 2,000 clinicians and other industry professionals.

A key near-term focus for PLC is to continue to increase the number of distributors selling RenalGuard and to expand their international reach. This could include other countries in Europe, South and Latin America, the Middle East and Asia.

Japan could be the next major international market launch but will likely not happen until at least late 2013 or sometime in 2014, following completion of the proposed 60-patient study and regulatory approval in that country.

***U.S. Status…***
While the recent capital infusions are a clear positive and allow PLC to get to the next step in the R&D process and maintain operations, as noted above, in order to complete the U.S. clinical study PLC will need to raise additional capital. We assume they're able to successfully do so on an ongoing basis. Our model assumes financing comes in the form of either convertible debt or common stock, although we have no particular insight into the source or type of potential future financing.

The U.S. strategy includes completing the U.S. clinical trial and, assuming positive results, an eventual PMA filing and U.S. launch. As a placeholder and until the 163-patient re-estimation total enrollment decision-point (i.e. - either 326 or 652 patients) is attained, we assume total enrollment will be 326. Our current modeled timelines relative to the U.S. trial and commercialization include completing trial enrollment in late 2013 followed by finalized data analysis, a peer-reviewed publication and PMA filing by mid-to-late 2014, and U.S launch in mid--to-late 2015. We note, that if PLC/trial investigators decide enrollment needs to be 652 (in order to increase the chance of hitting efficacy endpoints), our projected timelines would be pushed back and our modeled expenses and assumed financing needs would materially increase.

Our model assumes U.S. distribution is also handled by a third party - it's still early and management hasn't discussed their selling/marketing plans for the U.S market so this assumption is also a placeholder for now (3rd party distribution is reflected in our gross margins and SG&A expenses).

***Revenue…***

We expect to see revenue climb from here on out (although there will likely be some quarterly gyrations), initially benefitting from the addition of new international distribution agreements in new geographic territories, including the several penned since early 2012 covering large markets in Europe, South America and the Middle East. Revenue has been, and will likely continue to be over the near-term, somewhat lumpy as a result of initial stocking orders from new distributors. We expect to see this smooth over the longer term. PLC's "razor/razor blade" business model affords the potential for revenue, cash flow and earnings to ramp relatively quickly assuming they can continue to grow the consoles ("razor") installed base and there's sufficient pull-through demand for the single-use consumables ("razor blade").

Our modeled revenue through 2014 includes only sales outside of the U.S. We project revenue from consoles to be roughly equal to that from consumables through the end of 2013 but then sales from consumables, which should be feeding an ever larger installed base, to begin to outpace that of consoles beginning in 2014. We look for total revenue of $1.6 million in 2013 and $3.0 million in 2014. We think RenalGuard could enter the U.S. market in mid-to-late 2015, a small contribution from which is reflected in our $5.7 million revenue figure for that year.

Relative to domestic sales, we currently model somewhat of a measured ramp in revenue at the outset of entrance into the U.S. (2015) and over the following (approximately) five years as third-party reimbursement specific to RenalGuard or for the prevention of CIN may yet to be in existence. We think that while lack of specific reimbursement could temper the ramp at outset of commercialization in the U.S., meaningful long-term demand could be cultivated from economic incentives being borne from recent and ongoing domestic healthcare reform measures aimed at reducing unnecessary costs. For instance, the move away from a "fee-for-service" to a "pay-for-performance" model should increase demand for lower-cost and more efficacious treatments and products - such as RenalGuard. And while there may not be reimbursement specific to RenalGuard/CIN-prevention at the outset, PLC could (and likely would) initiate or support the process of applying for Medicare reimbursement shortly following FDA approval.

## VALUATION / RECOMMENDATION

Given that we model PLC to generate a net loss through 2015, valuation via DCF is more appropriate than other common methodologies such as P/E or PE/G comps.

Based on our 10-year DCF model which uses a 14% discount rate (based on CAPM) and 2% terminal growth rate, PLCSF is valued at $0.30/share (share count figured on a fully-diluted basis). The stock currently trades at about $0.07 which indicates the shares remain undervalued. We recommend accumulating towards our $0.30/share price target and are maintaining our Outperform rating.

## RISK FACTORS

- **Novel Technology**: RenalGuard is a novel technology with only a limited amount of use in clinical practice. Despite trial data to-date which has consistently indicated the system is safe and effective in reducing risk of CIN in high-risk populations, this may not translate into meaningful interest from healthcare providers. Hesitance in adoption of novel (albeit potentially superior) technologies in favor of the standard of care is not uncommon among healthcare providers given their "we know what to expect from the standard of care" mentality and related risk aversion.

- **Operating Capital**: PLC had (at 6/30/2012) about $1.1 million of cash. While recent financings are a clear positive and allow PLC to get to the next step in the R&D process and maintain operations, in order to complete the U.S. clinical study PLC will need to raise additional capital. We estimate that the combination of a somewhat elongated ramp in projected revenue and the expenses related to the U.S. clinical trial will result in an average quarterly cash burn of ~$1.25MM over the next 6 quarters and ~$1MM over the next 14 quarters. This means PLC will need to raise additional operating capital (likely on an ongoing basis) to fund operations and complete the U.S. clinical trial. We currently model that PLC will not generate positive cash flow until the year 2016.

- **U.S. Development / Regulatory Approval**: the total cost and duration of the U.S. study is difficult to estimate given that the expected total enrollment won't be known until the 163-patient mark is met. Our model currently uses the assumption that enrollment is only 326. If, however, it's determined that the study needs to enroll the larger 652-patient set, our assumptions relative to expenses, financing needs, and U.S. launch (and related U.S. revenue) timelines would all need to be adversely adjusted. And even if our 326-patient enrollment assumption proves correct, there remains risk of delays to the study, cost over-runs, and/or failure to meet efficacy/safety endpoints, any of which could negatively impact our financial projections. Clearly the most detrimental risk relative to U.S. commercialization would be if RenalGuard fails to gain FDA approval.

- **Reimbursement**: we are not aware of any reimbursement specific to RenalGuard or for the prevention of CIN anywhere in the world. This does not necessarily preclude providers from being paid by private or public payers for the use of RenalGuard but in general makes the prospect of that potentially more likely. In parts of Europe providers using RenalGuard can and have submitted for claims under standard diagnosis related group (DRG) reimbursement related to cath lab experience (which could encompass a range of therapies, supplies and procedures) - presumably some of these claims have been paid while others may have been denied. In the U.S., as we detailed earlier, specific reimbursement may not be in existence if and when RenalGuard enters the U.S. market. This risk may be somewhat mitigated by other potential incentives to use the device including, initially those borne our of healthcare reform measures, and later possibly CPT codes for reimbursement specific to RenalGuard/CIN-prevention.

## FINANCIAL MODEL

PLC Systems Inc.

| | 2012 A | Q1A | Q2A | Q3E | Q4E | 2013 E | 2014 E | 2015 E |
|---|---|---|---|---|---|---|---|---|
| Total Revenues | $1,080.0 | $348.0 | $372.0 | $392.5 | $470.3 | $1,582.8 | $2,943.8 | $5,675.0 |
| *YOY Growth* | *61.0%* | *1640.0%* | *2.5%* | *85.1%* | *-3.0%* | *46.6%* | *86.0%* | *92.8%* |
| Cost of Goods Sold | $541.0 | $179.0 | $135.0 | $192.6 | $233.3 | $739.9 | $1,321.9 | $2,241.3 |
| Gross Income | $539.0 | $169.0 | $237.0 | $199.9 | $236.9 | $842.9 | $1,621.9 | $3,433.8 |
| *Gross Margin* | *49.9%* | *48.6%* | *63.7%* | *50.9%* | *50.4%* | *53.3%* | *55.1%* | *60.5%* |
| SG&A | $2,633.0 | $685.0 | $965.0 | $685.0 | $715.0 | $3,050.0 | $2,770.0 | $2,960.0 |
| *% SG&A* | *243.8%* | *196.8%* | *259.4%* | *174.5%* | *152.0%* | *192.7%* | *94.1%* | *52.2%* |
| R&D | $2,032.0 | $554.0 | $558.0 | $595.0 | $652.0 | $2,359.0 | $1,944.0 | $1,765.0 |
| *% R&D* | *188.1%* | *159.2%* | *150.0%* | *151.6%* | *138.6%* | *149.0%* | *66.0%* | *31.1%* |
| Operating Income | ($4,126.0) | ($1,070.0) | ($1,286.0) | ($1,080.1) | ($1,130.1) | ($4,566.1) | ($3,092.1) | ($1,291.3) |
| *Operating Margin* | *-382.0%* | *-307.5%* | *-345.7%* | *-275.2%* | *-240.3%* | *-288.5%* | *-105.0%* | *-22.8%* |
| Total Other Income (Expense) | ($4,285.0) | ($6,738.0) | $9,232.0 | ($152.0) | ($157.0) | $2,185.0 | ($600.0) | ($600.0) |
| Pre-Tax Income | ($8,411.0) | ($7,808.0) | $7,946.0 | ($1,232.1) | ($1,287.1) | ($2,381.1) | ($3,692.1) | ($1,891.3) |
| Tax expense (benefit) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | - | - | - | - | - | - | - | - |
| Net Income (continuing ops) | ($8,411.0) | ($7,808.0) | $7,946.0 | ($1,232.1) | ($1,287.1) | ($2,381.1) | ($3,692.1) | ($1,891.3) |
| *YOY Growth* | *29.4%* | *15.2%* | *-650.3%* | *-61.1%* | *-142.9%* | *-71.7%* | *55.1%* | *-48.8%* |
| *Net Margin* | *-778.8%* | *-2243.7%* | *2136.0%* | *-313.9%* | *-273.7%* | *-150.4%* | *-125.4%* | *-33.3%* |
| EPS (continuing ops) | ($0.27) | ($0.19) | $0.06 | ($0.02) | ($0.02) | ($0.03) | ($0.02) | ($0.01) |
| *YOY Growth* | *26.6%* | *-16.1%* | *-223.8%* | *-81.5%* | *-121.7%* | *-88.6%* | *-20.6%* | *-60.6%* |
| Diluted Shares O/S | 31,043 | 41,670 | 137,764 | 64,000 | 64,000 | 76,859 | 150,000 | 195,000 |

*Brian Marckx, CFA*

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## LEADERSHIP

### < MANAGEMENT >

**Mark R. Tauscher**
**President and CEO**
Mark Tauscher joined PLC Medical Systems in January 2000, bringing more than 30 years of medical product sales, marketing and general management experience in the medical products field. Most recently, he was executive vice president of sales and marketing at Quinton, a developer, manufacturer and marketer of cardiology products. Prior to Quinton, Mr. Tauscher served as division president for Marquette Medical Systems. Mr. Tauscher's experience also includes general management, sales and marketing positions at Hewlett-Packard Medical Products Group for their Diagnostic Cardiology and Supplies divisions, and National Accounts Program.

**Gregory Mann**
**Chief Financial Officer**
Gregory Mann joined PLC Medical Systems in October 2011, bringing more than 13 years of financial and operational management experience in a variety of industries including biotech. Most recently, he was Business Unit CFO of the Healthcare, Insurance, Financial Transformation, and Emerging Markets business units at Virtusa Corp, a publicly traded IT services company. At Virtusa, Mr. Mann was involved in its successful IPO, and responsible for the company's M&A activity. Prior to Virtusa, Mr. Mann held various finance and accounting roles of increasing responsibility at companies including Acusphere, InterGen Energy, and BeFree Inc.

**Kenneth J. Luppi**
**Vice President, Operations**
Ken Luppi came to PLC Medical Systems in 1993 as Director of Service Operations, after spending a number of years as National Service Manager for Candela Laser Corporation, a medical laser company. In 1997, he was named Vice President of Operations for PLC Medical Systems, and has served in that capacity since then. Mr. Luppi received his B.S. degree in Biomedical Engineering from Boston University

**Susan Papalia, R.N., B.S.N.**
**Vice President, Clinical Affairs**
Ms. Papalia joined PLC in 2011, bringing more than 20 years of experience in clinical research. Most recently, she was Vice President Clinical Affairs at Correx, Inc., where she played a key role in the first clinical implantation of a novel device for use by cardiovascular surgeons performing aortic valve bypass. Prior to Correx, she was Director of Clinical Affairs at Mitralign, Inc., also and held a variety of management positions in both US and International Clinical Research at Boston Scientific. Ms. Papalia began her research career in cardiovascular medicine at New England Medical Center and St. Elizabeth's Hospital (Boston, MA), and held nursing management positions in New York and Massachusetts.

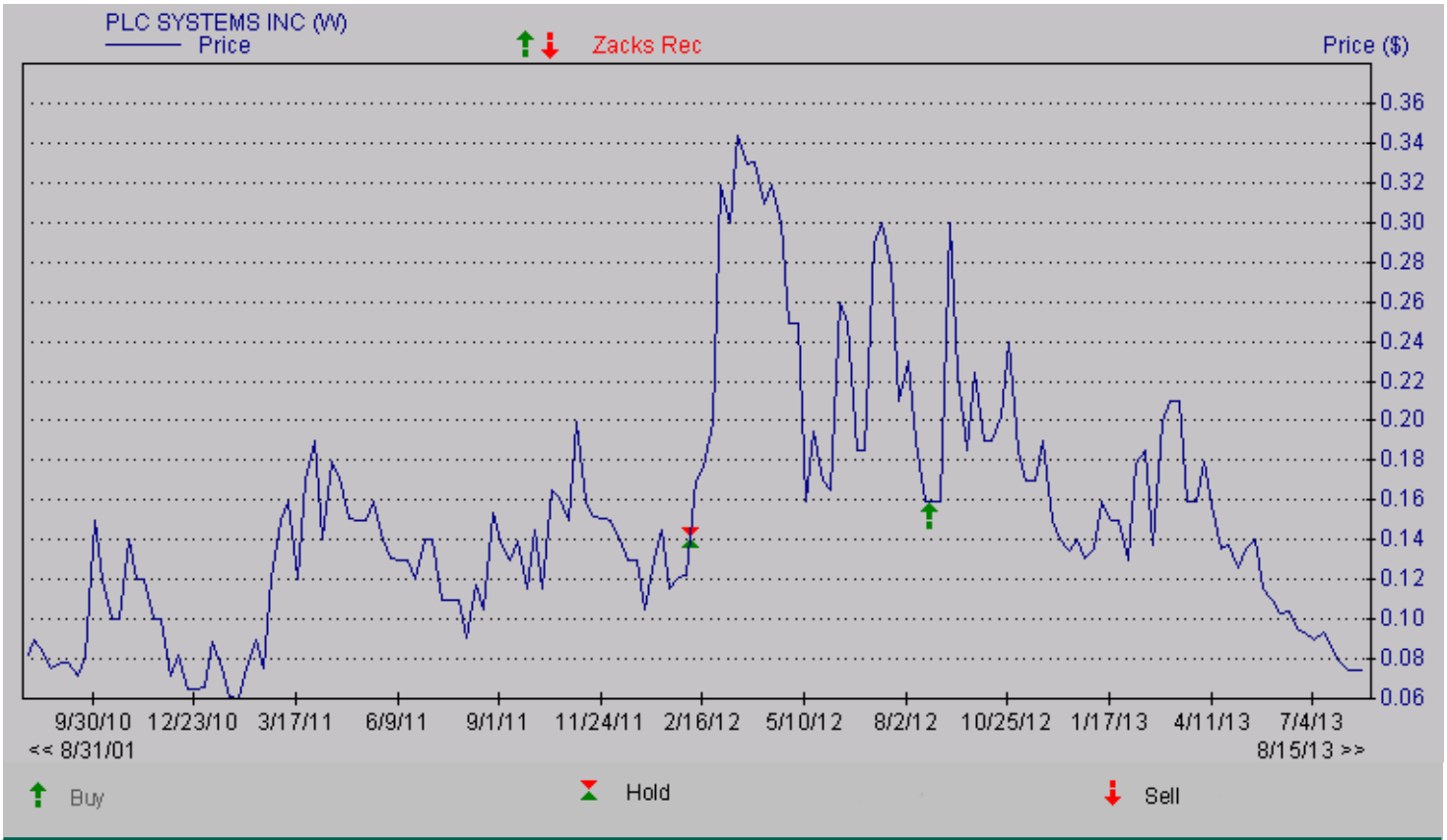
**Andrew Halpert**
**Director of Marketing**
Andrew Halpert joined PLC in 2006, with more than 13 years of experience in the medical device industry. Most recently, he worked for Coridea, a medical device incubator, where he developed a number of devices including the initial prototype for RenalGuard. Prior to Coridea, he acquired start-up experience as a member of the team that developed CHF Solution's Aquadex System, and led a team of engineering interns who built and tested the Dobelle Institute's first portable artificial vision system to restore vision to blind volunteers. Mr. Halpert received his M.B.A. degree from Babson College and his B.S. in electrical engineering from Columbia University.

### < SCIENTIFIC ADVISORY BOARD >

| Name | Title | Location | Specialty |
|---|---|---|---|
| Jeff Brinker, MD | Professor of Cardiology and Radiology | Johns Hopkins University<br>Baltimore, MD | Interventional Cardiologist |
| Peter McCullough, MD | Chief, Division of Preventive Medicine | William Beaumont Medical Center<br>Ann Arbor, Michigan | Cardiologist/CIN Prevention |
| Michael Rudnick, MD | Chief, Section of Nephrology and Hypertension | Penn Presbyterian Medical Center<br>Philadelphia, PA | Nephrologist/CIN Prevention |
| Fred Resnic, MD | Chair, Cardiovascular Medicine<br><br>Associate Professor, Harvard University | Lahey Clinic<br>Burlington, MA | Interventional Cardiologist<br>Cardiology Informatics |
| Richard J. Solomon, MD | Professor of Medicine | University of Vermont College of Medicine<br>Burlington, VT | Nephrologist/CIN Prevention |

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