Zacks Small-Cap Research

November 15, 2011
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Cytomedix, Inc (CMXI-OTC)

CMXI: Investors Starting To Take Notice As Fundamentals Continue To Improve…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/30/2011
Current Price (11/15/11)	$0.84
Target Price	**$2.00**

Update

We believe fundamentals are continuing to improve at Cytomedix. Sales of Angel have increased every quarter since the company acquired the product from Sorin in April 2010. Label expansion and market penetration offer significant upside to Angel in the coming years. With AutoloGel, the CMS reimbursement dossier is now under view and we expect a decision by CMS in May 2012. However, the big wildcard event that could drive the stock meaningfully higher in the company months is a potential U.S. commercial partner for AutoloGel. In October 2011, Cytomedix received a $2 million option negotiation fee from an undisclosed partner. A deal could bring an upfront payment, backend milestones, and royalties on sales. We remain optimistic and are increasing our target to $2.

SUMMARY DATA

52-Week High	**$0.89**
52-Week Low	**$0.28**
One-Year Return (%)	**79.80**
Beta	**1.24**
Average Daily Volume (sh)	**242,174**
Shares Outstanding (mil)	**55**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**40**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**17.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0.2 A	1.1 A	1.3 A	1.3 A	3.9 A
2011	1.4 A	1.4 A	1.5 A	3.6 E	7.9 A
2012					8.2 E
2013					14.9 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.03 A	-$0.11 A	-$0.04 A	-$0.05 A	-$0.23 A
2011	-$0.03 A	-$0.02 A	-$0.04 A	-$0.00 E	-$0.08 E
2012					-$0.07 E
2013					$0.02 E

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WHAT'S NEW

Q3 Financial Results

Revenues: On November 14, 2011, Cytomedix reported financial results for the third quarter 2011. Total revenues in the quarter were $1.53 million, just above of our $1.5 million estimate.

- AutoloGel sales in the second quarter were $99K, slightly below our estimate. Sales were down 21% year-over-year from the $126K reported in the third quarter 2010, and down 10% sequentially from the $111K reported in the second quarter 2011. AutoloGel sales have been difficult to forecast in the recent quarters. We do not see the miss in the third quarter 2011 as a trend. Instead, we think the decline in sales was just based on timing of orders and are expecting snap-back in the fourth quarter 2011.

- Angel sales in the third quarter were $1.43 million, just above our estimate of $1.4 million. Angel sales were up 23% year-over-year and 12% sequentially from the second quarter 2011. We think Angel has enormous upside in the coming years on label expansion and new market penetration.

Product Sales	Q3 2011		Comps	
	Reported	Zacks Est.	Q3 2010	Q2 2011
Angel & ActivAT	$1.43M	$1.40M	$1.16M	$1.28M
AutoloGel	$99K	$110K	$126K	$110K

Gross margin: Gross margin the second quarter was 53.1%, down 1.1% from the second quarter 2011. Margin was lower than we expected on continued investment in the Angel manufacturing process and supply chain. Management noted that there were significant "inefficiencies" within the supply chain at Sorin that Cytomedix is still working through, but that in time the margin should climb to 60-65%.

Other things that should improve margin in the coming years include a new OEM partner, Byers Peak, Inc., which management believes will yield a 10% improvement in margins over the historic Sorin business, and launching a new AutoloGel 2.0 product in 2013. The new product design and packaging eliminates steps and redundant components, as well as simplifies the procedure. The "bioengineered" product should also offer improved intellectual property protection. Cytomedix should be in position to file the U.S. 510(k) application on AutoloGel 2.0 around mid-2012. Likewise, expanding indications for Angel should help drive improved margin at the company.

Operating Expenses: Operating expenses were in-line with expectations in the third quarter, coming in at $1.85 million. In order to achieve profitability, we believe management must work to reduce costs while not sacrificing growth. It's a difficult balance. Cytomedix is growing its distribution networks and funding pilot R&D programs to expand the Angel business. These are good costs. But they are also spending heavily on professional and consulting fees and lobbying. It remains to be seen if these costs will pay off.

In the meantime, most of the transition costs with Angel are behind the company, and Cytomedix has successfully worked to integrate supply chains, customer service, logistics, and other areas of a fragmented and neglected business acquire from Sorin in April 2010. It's been a challenge, but we believe Cytomedix is now finally in position to start dramatically improving Angel operating profits over the next several quarters. Management has guided to breakeven operations by late 2012.

None cash expenses during the first nine months of the year include $222,000 in depreciation, $118,000 in amortization and $57,000 in certain non-recurring adjustments

Net Loss: Net loss for the third quarter totaled $2.29 million, or $0.04 per diluted share. This was far greater than our estimate of $1.09 million, or $0.02 per share. However, we note the company recorded a $1.17 million non-cash charge due to change in fair value of derivative liabilities associated with embedded conversion options in the convertible notes from the July 2011 debt financings. We note as Cytomedix' stock price increases, the value of the liability also increases. Upon probable conversion of these notes in 2012, the then existing derivative liability will cease to exist and the balance would transfer to stockholder's equity. Backing out this non-cash adjustment and net loss was virtually dead-on with our forecast.

Cash: Cytomedix exited the third quarter 2011 with $0.868 million in cash and investments. Operating burn was $1.11 million during the quarter. Total burn for the first nine months of the year is $3.76 million.

Management continues to drawn down on its committed equity financing with Lincoln Park Capital (LPC), completing approximately $3.0 million so far in 2011, about $0.2 million of which was in the third quarter. The company has access to an additionally $7.9 million over the next 12 months. Under terms of the agreement with LPC, Management can sell up to 150,000 shares of common stock to LPC every other business day over a period ending in November 2012. Cytomedix controls the timing and amount of any sales of shares to LPC.

In April 2011, Cytomedix raised $325,000 in a private placement sold to accredited investors at a price of $0.33 per share (no warrants were issued). In July 2011, the company raised an aggregate $1.2 million through two separate offerings of convertible debt. Cytomedix placed a three year convertible note with a single accredited investor totaling $1.3 million, with an initial funding of $600,000, another $200,000 available within 60 days of the closing, and the remaining $500,000 anticipated to be available in monthly installments beginning in February 2012. The company also placed an aggregate of $600,000 in 12% short-term convertible notes with several accredited investors and long term shareholders. Quarterly cash interest payments under these notes will commenced on September 30, 2011, with the notes maturing on March 31, 2012.

In October 2011, management received a non-refundable option fee of $2.0 million from an undisclosed global pharmaceutical company for the exclusive right to negotiate a license and supply agreement whereby the AutoloGel System would be distributed exclusively through the pharmaceutical company's dedicated, hospital-based sales force for the U.S. chronic wound market. Talks continue as of November 15, 2011. We expect any final agreement, which remains subject to the successful conclusion of due diligence and negotiation between the parties, is expected to incorporate an upfront license payment, a product development milestone payment covering the second generation AutoloGel device, and a negotiated profit sharing arrangement on future U.S. sales.

We are eagerly awaiting an update on this front. Cytomedix current uses an independent contract sales force of approximately6 part-time representatives to promote AutoloGel in the U.S. chronic wound market. On the third quarter call, management notes the global pharmaceutical company they are in discussions with has a hospital-based sales force of over 100 representatives. This sort of tier-1 promotion coupled with CMS reimbursement could cause AutoloGel sales to soar in the coming years. AutoloGel posts sales of only $99K in the third quarter 2011. With significant promotion and CMS coverage, peak sales could eclipse $50 million.

INVESTMENT THESIS

AutoloGel

...CMS Dossier Filed…

On August 31, 2011, Cytomedix provided an update on AutoloGel coverage and reimbursement following its recent meeting with the Centers for Medicare & Medicaid Services (CMS). As a reminder, management filed a submission for reconsideration of the National Coverage Determination (NCD) for AutoloGel in May 2011. This process dates back over seven years, to when CMS first reviewed and rejected the original NCD application in 2003 based on a lack of significant evidence on safety, efficacy, and cost-effectiveness. The submission in May 2011 culminates over seven years of data collection and diligent work by management to file for reconsideration.

Management met with the agency face-to-face in both March and May 2011 before the filing. In March, CMS asked Cytomedix to prepare a "net health benefit" presentation to discuss during the May. The filing came two weeks after this second meeting. CMS recently asked Cytomedix back for a third meeting in August 2011. At that meeting, CMS provided its initial review of the data and laid out its plan to provide Coverage with Evidence Development (CED). CED allows for Medicare coverage for the appropriate use of an item or service while additional data is collected to support its ongoing use for Medicare beneficiaries. It's full coverage with no restrictions or limitations. The best algology would be an "accelerated approval" or an approval with the requirement of a phase 4 (post-market) surveillance study.

CMS has formally accepted the filing and we are currently in the 90-day "public comment" period where CMS will review the data. This period end December 9, 2011. Following this review, CMS will invite Cytomedix back for another meeting to discuss the data. This is followed by another 90-day data review and public comment period, after which CMS will publish a preliminary decision. This is expected in May 2012.

In the meantime, Cytomedix and CMS will be working closely together to design appropriate treatment protocols and clinical data endpoints to be collected in an ongoing prospective wound care registry of patients. Cytomedix will collect this data under CMS' CED policy. We believe management will expand / alter the existing AutoloGel wound registry program to collect this data. Cytomedix included data from 285 patients in this registry in the May 2011 dossier. At this point, questions remain on just how many more patients and what endpoints CMS would like to see. Nevertheless, we do not believe expanding the existing registry to comply with CMS' guidance will be significantly expensive. And, the new patients that CED brings in should more than make up for the added cost of expanding the registry program.

We believe coverage could be a meaningful driver of AutoloGel sales. There are approximately 2.0 million pressure ulcers and 1.5 million diabetic foot ulcers each year in the U.S. where AutoloGel could be an effective product. However, approximately half of these are in patients covered by Medicare / Medicaid, and non-coverage has been an issue for uptake. Management has been focusing on private pay procedures, like the new effort to market AutoloGel in hair restoration, and chronic wounds in long-term acute care facilities and VA hospitals. We believe that CMS coverage could effectively double sales of the product.

…Data Supports Coverage…

Back when CMS issued its non-coverage designation for AutoloGel in 2003, the decision was based on limited information that included data from only 40 diabetic foot ulcers. Since that time, management has been able to collect data on over 500 wounds – over 10 times the data previously submitted to CMS. And, the data includes new wound types such as pressure ulcers, venous ulcers, and other surgical wounds.

ound Data Source	**No. of Wounds**
Original Data	40
Market Registry	285
Millennium Group	100
TAPS phase 4 Study	100
New Total	**~525**

Wounds In Market Registry	**No. of Wounds**
Pressure Ulcers	142
Diabetic Ulcers	41
Venous Ulcers	32
Dehisced Wounds	24
Surgical Wounds	27
Traumatic Wounds	11
Other Wounds	8

…Coverage & Awareness Should Drive Sales…

Management's strategy to drive AutoloGel sales has been to increase education and awareness among physicians through presenting this new data on AutoloGel. The campaign includes both posters and oral presentations as key medical conferences, including:

- ✓ The Symposium on Advanced Wound Care and Wound Healing Society (SAWC/WHS) in April 2010 and again in April 2011.
- ✓ The Wound Ostomy and Continence Nurses Society in June 2010 and The World Council of Enterostomal Therapists (WOCN/WCET) in June 2010
- ✓ The SAWC Fall session and The Academy of Spinal Cord Injury Professionals' meeting in September 2010
- ✓ The Diabetic Food Ulcer conference and The Gems Wound Care Panel in November 2010.

Cytomedix recently announced publication of compelling clinical data from a wound outcomes registry in the *International Wound Journal* and published data from a comprehensive systematic review and meta-analysis (statistical pooling) of the use of PRP gel in wound healing in *ePlasty*, the openaccess journal of the *Journal of Plastic Surgery.* Data at SAWC in April 2011 highlighted comparing the use of platelet rich plasma (PRP) gel (AutoloGel) and negative pressure wound therapy (NPWT) in the long-term acute care setting. Results demonstrate that PRP greatly improved the wound healing outcomes while also cutting costs associated with the overall treatment. The study was conducted at the Asheville Specialty Hospital, in Asheville, NC.

Wound Healing Rates PRP vs. NPWT								
			Area			Volume		
	Avg No. Days Treated	Avg No. Treatments	Total % Reduction	% Reduction/ Day	% Reduction /Week	Total % Reduction	% Reduction /Day	% Reduction /Week
PRP	7.3	1.7	27.5	1.4	**10**	54.9	11.4	**79.6**
NPWT	9.2	4.1	25.8	0.9	**6.4**	40.7	6.4	**45.1**
PRP was used fewer days and required fewer dressing changes, yet yielded faster healing rates.								

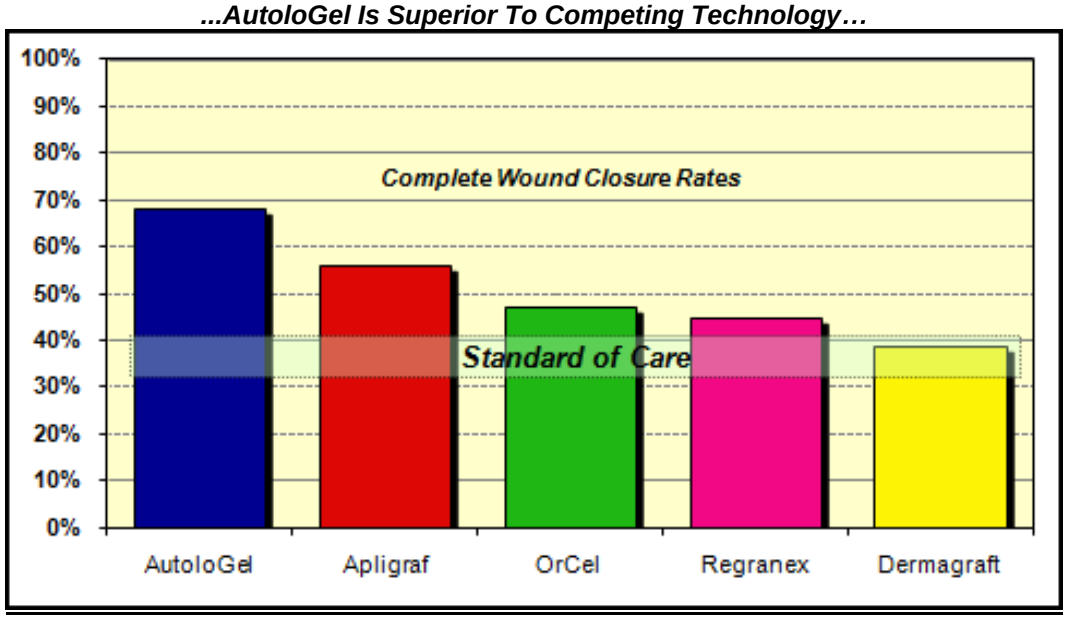
Actual (mean) cost of RPR (n=25):
➔ $11,850

Estimated (mean) cost of NPTW using historical data (n=17):
➔ $26,169

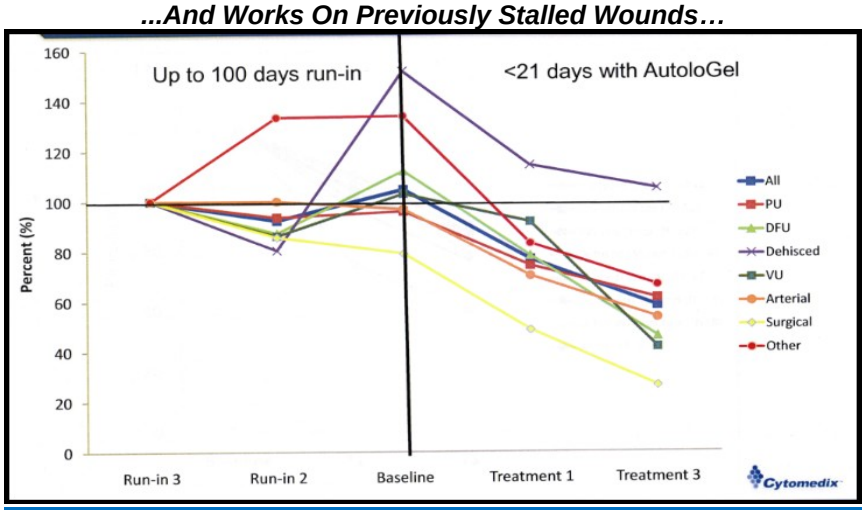
Total estimated cost savings of using PRP vs. NPTW:
➔ $14,319.

We believe this is strong data in Cytomedix favor, and exactly the kind of stuff Centers for Medicare and Medicaid Service (CMS) is looking for. Not only did AutoloGel heal patients faster and more effectively, but it also costs about 60% less than traditional treatment.

...AutoloGel Is Superior To Competing Technology…



...And Works On Previously Stalled Wounds…

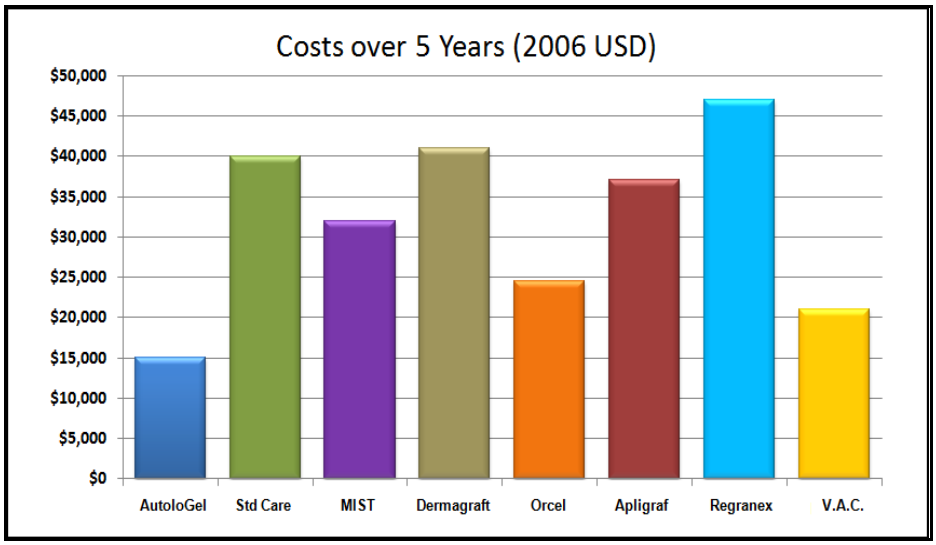


In August 2011, Cytomedix published data from the 285 wounds in the market registry demonstrating AutoloGel provides rapid and consistent improvement in healing in the peer-reviewed journal, Advances in Skin and Wound Care, in an article entitled, "The Clinical Relevance of Treating Chronic Wounds with an Enhanced Near-Physiological Concentration of Platelet-Rich Plasma Gel."

The data above show signs of clear efficacy, especially in areas were existing products with coverage are failing. The AutoloGel System produced a favorable clinical response in 96.5% of the wounds treated, resulting in a mean reduction in wound volume of 62% in less than three weeks of treatment on average. The data also demonstrated reductions in area, undermining, and sinus tracts / tunneling in a mean of 2.8 weeks with 3.2 treatments. This is powerful data that should not only help drive uptake of AutoloGel in the coming quarters, but work to convince CMS that this is a product worthy of full coverage under Medicare / Medicaid.

Additional pieces of ammunition for Cytomedix include an independent pricing study conducted by B&D Consulting in September 2007. B&D is an independent advisory and advocacy firm located in Washington. The firm completed a cost effectiveness analysis of AutoloGel compared to alternative therapies for patients with diabetic foot ulcers. Results of this study demonstrate AutoloGel offers a lower cost and better healing outcomes than the other therapies analyzed. According to B&D's findings, the estimated 5-year average direct wound care costs (exclusive of lost work, disability, etc.; inclusive of recurrent wounds, amputations) when AutoloGel was used to treat the most commonly sized diabetic foot ulcers were approximately $15,000. This compared very favorably to alternative therapies ranging from $24,000 to $47,000, including standard of care (gauze / advanced dressings) at $40,000. B&D's work also suggests a measurable increase in Quality Adjusted Life Years (a function of increased survival rates and fewer wound complications) with AutoloGel.

...Net Health Benefit Obvious…



This study was published in the journal Advances in Skin and Wound Care in December 2008. Prior to the publishing of this paper, CMS would not consider this data as part of the reconsideration package. Cytomedix now plans to include the above data when it re-files shortly. We believe when price is factored into the equation the product becomes even more impressive.

…Hair Restoration & Plastic Surgery…

CMS coverage is clearly important to the future of AutoloGel, but we note that management is making inroads into the private pay market with AutoloGel was well. In June 2011, Cytomedix launched AutoloGel into the hair restoration market and in July 2011 management held a webinar for specialty plastic surgeons that generated strong product interest. In September 2011, management will have an exhibit at the annual meeting of the International Society of Hair Restoration Surgery, where hair restoration specialist, Dr. Robert J. Reese, will moderate a panel discussion on the use of physiologically relevant concentrations of platelet rich plasma (PRP) in hair restoration surgery. Management plans to use this promotion, along with other efforts, to drive sales of AutoloGel in this new market opportunity. So far the feedback has been outstanding. The good thing about the private pay market is it is not subject to national coverage or CMS reimbursement issues.

…510(k) on AutoloGel 2.0 Pushed Back To 2012…

Cytomedix is working to bring an enhanced next-generation AutoloGel – AutoloGel 2.0 – to the market in 2012. The company has been working with bioengineers to develop a simplified and more cost-effective product. AutoloGel 2.0 employs optimized technology through changes to the centrifuge and the design of a new separation device that operates in a semi-closed system where the blood will be drawn directly into the device, removing any margin for error and providing for much better management of the waste material. This streamlines the process making the clinical procedure more efficient.

We had previously expected the U.S. 510(k) application for the next-generation AutoloGel during the third quarter of 2011; however, management has pushed back the filing into 2012 due to resource constraints and focusing on CMS reimbursement. Management has decided that national coverage through CMS should take a priority over finalizing the AutoloGel 2.0 application. While we are disappointed to hear the filing will be pushed back by 2-3 quarters, we understand that without CMS coverage the same issues that hold back AutoloGel will also hold back AutoloGel 2.0. If CMS reimbursement is established, we expect management to move quickly with the 510(k) application. The new version should improve the company's intellectual property protection around AutoloGel and deliver enhanced profitability for the future.

...A U.S. Distribution Partner Could Be The Key…

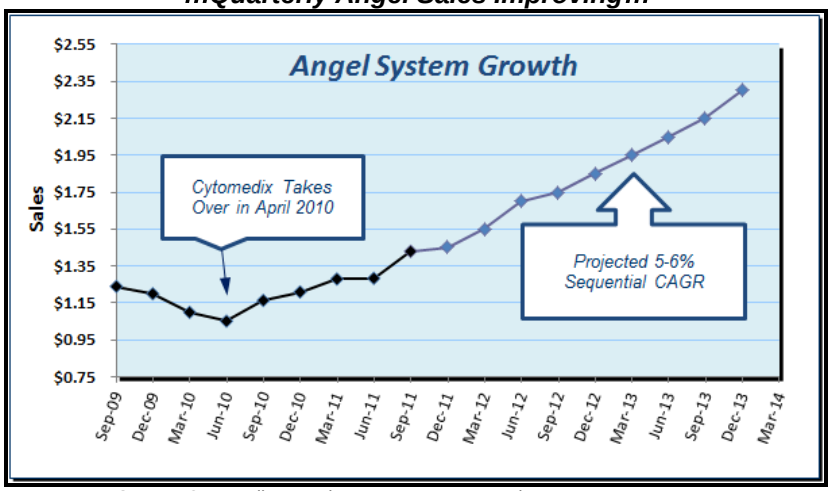
In October 2011, management received a non-refundable option fee of $2.0 million from an undisclosed global pharmaceutical company for the exclusive right to negotiate a license and supply agreement whereby the AutoloGel System would be distributed exclusively through the pharmaceutical company's dedicated, hospital-based sales force for the U.S. chronic wound market. Talks continue as of November 15, 2011. We expect any final agreement, which remains subject to the successful conclusion of due diligence and negotiation between the parties, is expected to incorporate an upfront license payment, a product development milestone payment covering the second generation AutoloGel device, and a negotiated profit sharing arrangement on future U.S. sales.

We are eagerly awaiting an update on this front. Cytomedix current uses an independent contract sales force of approximately6 part-time representatives to promote AutoloGel in the U.S. chronic wound market. On the third quarter call, management notes the global pharmaceutical company they are in discussions with has a hospital-based sales force of over 100 representatives. This sort of tier-1 promotion coupled with CMS reimbursement could cause AutoloGel sales to soar in the coming years. AutoloGel posts sales of only $99K in the third quarter 2011. With significant promotion and CMS coverage, peak sales could eclipse $50 million.

Angel

Angel sales were slightly above expectations in the third quarter 2011, coming in at $1.43 million vs. our estimate of $1.40 million. Sales were up 29% year-over-year and 12% sequentially. The trajectory looks fantastic since Cytomedix took over full Angel promotion in April 2010.

…Quarterly Angel Sales Improving…



Source: Cytomedix & Zacks Investment Research, Inc.

We believe a significant opportunity exists for management to expand use of the device at the smaller perfusionist practices where Angel system utilization is low. This will be a core area of focus for management in the coming quarters. In the meantime, customer retention remains high. Over 90% of the revenues are from reorders of the single-use consumable sets sold for the system. And similar to previous quarters, over 90% of the revenues came from the U.S. Cytomedix is looking to expand its distribution network in Europe. In February 2011, Cytomedix received CE Mark certification for Angel and ActivAT throughout the 28 country European Economic Area (EEA). This finalized the transfer outside the U.S from Sorin. Cytomedix continues to build out its sales infrastructure. The company employed 6 regional sales managers and 20 independent agents. This number of independent reps has grown each quarter as Cytomedix expands its network.

…New Indications to Drive Growth…

Management has been making some headway with expanding the Angel market opportunity into cardiovascular indications and orthopedics. CEO Martin Rosendale recently highlighted the potential for new indications for the Angel system. These include bone marrow aspirate processing (BMAC), blood reinfusion during surgery, and expanding uses of the device in the orthopedic / sports medicine market.

BMAC: On September 1, 2011, Cytomedix announced that it had filed a 510(k) application to the U.S. FDA for use of the Angel Whole Blood Separation System for the processing of bone marrow aspirate. The expanded indication includes processing a mixture of blood and bone marrow, a rich source of stem cells, to create a bone marrow aspirate concentrate (BMAC). *In vitro p*erformance testing with Angel yielded statistically significant improvement in the concentrations of hematopoietic progenitor / stem cells, reduced presence of pro-inflammatory cells, and provided better separation of platelet rich plasma (PRP) and red blood cells compared to alternative devices.

Angel has the potential to deliver RPR with highly viable bone marrow stems cells in a real-time, point-of-care setting for use in orthopedic or cardiovascular indications. There are approximately 300,000 spinal fusion procedures performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard to support effective fusion. The biologics market associated with spinal fusion procedures is approximately $800 million annually. We note that some clinicians are already successfully using Angel in this indication today. However, FDA clearance will allow Cytomedix to market the Angel System for this significant opportunity. The ease-of–use, separation efficiencies, and high quality output, are of notable benefit and competitive advantage compared with other commercially available systems.

Reinfusion: Before Cytomedix took over, Sorin was already seeing real-world use of the Angel device during surgery for total blood management. Cytomedix is looking to file a 510(k) application to expand the label to include the reinfusion of packed red blood cells separated during the bone marrow processing procedure. The company needs to conduct a small human study prior to filing the 510(k). We think this opens the door for potential use in the surgical setting by cardiologists. This would be a hybrid business model to what Aastrom Biosciences, with their stem-cell bone marrow aspirate product and Cytori Therapeutics with their Celution System are doing. Aastrom uses bone marrow aspirate to develop ixmyelocel-T used to treat peripheral arterial disease such as critical limb ischemia (CLI) and dilated cardiomyopathy (DCM). Although Aastrom is using highly potent bone marrow cells, it still takes 14-day to culture and expand the cells off-site. Cytori uses a point-of-care approach with its Celution System. This real-time processing is a significant advantage in acute settings, but Cytori uses adipose tissue and questions remains on the viability of the product extracted from adipose. If Angel can deliver real-time highly viable stem cells along with PRP, this could be an enormous revenue opportunity for Cytomedix. We note that some clinicians are already successfully using Angel in this indication today.

Aesthetic Applications: Angel is being used in the U.K. for aesthetic applications, where physicians are injecting PRP under the skin to facilitate skin rejuvenation. Angel PRP is also being used in fat transfer procedures to improve graft survival and aesthetic outcomes. These innovative applications represent development opportunities for future Angel indications. It places Angel squarely in competition with Cytori's PureGraft and Celgraft products for these aesthetic and plastic surgery market.

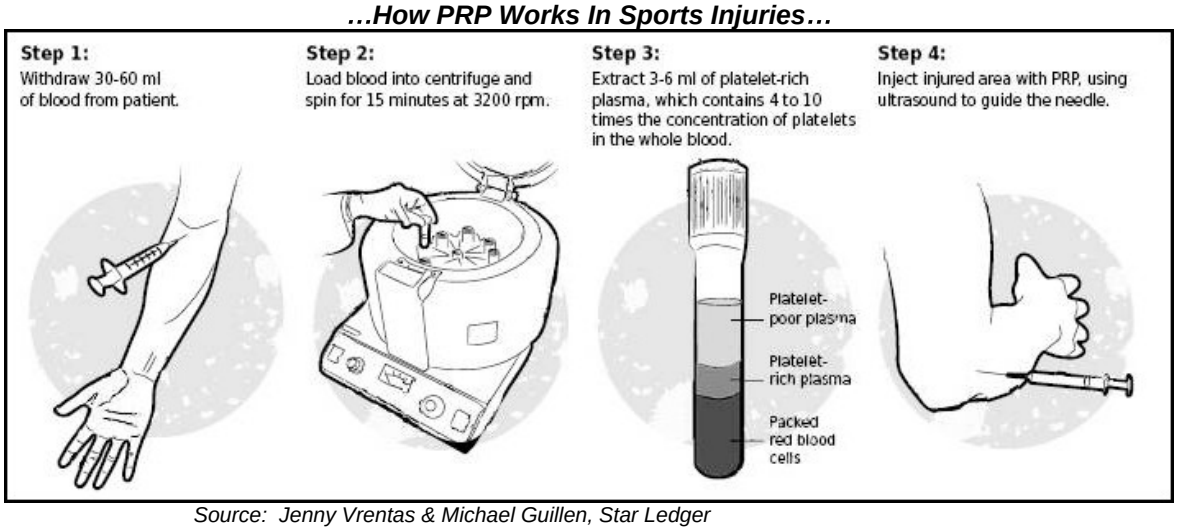
Sports Medicine: Sports medicine remains the "Holy Grail" for Angel. Evidence that using PRP to shorten and improve healing with knee, ankle, elbow, or an ACL or MCL sprains is growing rapidly. We have seen clinical data demonstrating PRP is effective at treating chronic tennis elbow, severe Achilles tendonitis and osteoarthritis of the knee. Tiger Woods was reported to use PRP to shorten his recovery time after his ACL tear in 2008. Pittsburgh Steelers' Hines Ward and Troy Polamalu both used PRP to recover from an injury during the 2008 NFL season in which the team won the Super Bowl. New York Mets all-star center fielder Carlos Beltran used PRP to aid in his recovery from a bone bruise on his right knee.

The use of PRP is clearly on the rise in professional sports. The LA Dodgers, Seattle Mariners, Denver Nuggets, and Dallas Cowboys have all embraced the use of PRP. In fact, we are now beginning to see use in college and amateur athletics. Standards have yet to be set however, and some sports purists are bringing up ethical questions regarding the use of PRP. In fact, the World Anti-Doping Agency, as of January 1, 2010, has banned the use of PRP in international competition when injected directly into muscle. The agency continues to allow PRP use for tendon, bone, and ligament injuries. Nevertheless, for the non-professional athlete, PRP could represent a cheap and quick alternative to a lengthy recovery processes following orthopedic surgery or a minor injury such as a muscle sprain or strain.

In the next few months we expect Cytomedix to see additional data on the use of PRP in treating sports injuries. Cytomedix is working with Dr. Peter H. Edwards, Jr, a board certified orthopedic surgeon with a fellowship trained specialty in Sports Medicine. Dr. Edwards practice has an emphasis on arthroscopic surgery of the knee and sports injuries of the lower extremity. He is a team physician for the U.S. Men's and Women's National Soccer Teams. Dr. Edwards has amassed data from roughly 60 patients with Achilles tendonitis, and plans to present the data at an upcoming medical meeting.

Cytomedix is also working with an Angel customer in the Northeast that plans to look at the use of PRP in 20 patients with plantar fasciitis. We view teaming up with cutting-edge physicians like this as key to the company's strategy to grow Angel in this potentially enormous market opportunity. We think the product offers doctors and trainers excellent characteristics, including improved processing time, greater sterility, and enhanced administration.

…How PRP Works In Sports Injuries…



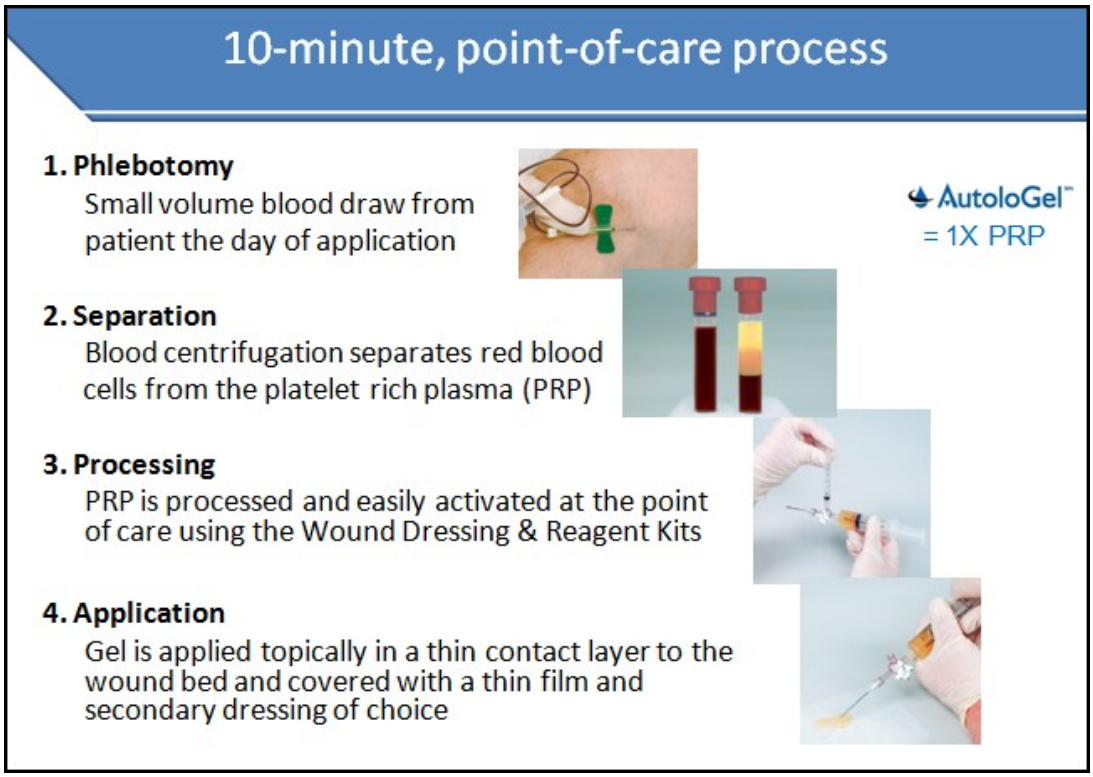
Source: Jenny Vrentas & Michael Guillen, Star Ledger

OVERVIEW

AutoloGel – Autologous PRP

The AutoloGel system is a unique technology that enables rapid isolation and activation of PRP from a patient's own blood. The system was approved by the U.S. FDA on September 20, 2007 with the following indication: "The AutoloGel System is intended to be used at point-of-care for the safe and rapid preparation of platelet rich plasma (PRP) from a small sample of the patient's own blood. Under the supervision of a healthcare professional, the PRP gel produced by the AutoloGel System is suitable for exuding wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and for the management of mechanically and surgically debrided wounds."

Use of AutoloGel is a simple process that takes only 10 minutes to prepare. This is an enormous improvement over older technology for preparing active PRP that can still take as long as 30 minutes. AutoloGel is the only FDA approved PRP device for wound care, giving the product significant advantages over the competition. Cytomedix' reagent formulation includes ascorbic acid, a proven free radical scavenger, as well as aiding in the synthesis of collagen to add stability to the forming structure. Thrombin (King's JMI) is also added to active the platelets in the PRP. Cytomedix has designed AutoloGel so that the final PRP concentration is only 1x, in concert with physiological platelet concentration proven to be optimal for wound care by an abundance of clinical data and scientific journal reports. In fact, overly high concentrated PRP was show to have an inhibitory effect on tissue regeneration and wound healing (Han et al. Cell Prolif. 2007, 40: 241–252).



Use of AutoloGel is limited right now due to a lack in Medicare / Medicaid reimbursement. Cytomedix is in the process of filing a reconsideration request with the Center for Medicare / Medicaid Services (CMS). This filing took place in May 2011. A decision is expected in May 2012.

Angel – Whole Blood Separation

In April 2010, Cytomedix acquired the Angel Whole Blood Separation System from Sorin Group. Angel gives Cytomedix one of the leading products on the market today for platelet rich plasma (PRP) preparation, and a direct entry into the surgical market. Angel was cleared by the U.S. FDA in August 2005 and posted worldwide sales in 2010 of roughly $4.6 million (90% in the U.S.), down slightly from $4.8 million posted in 2009. Angel is a closed system that maintains aseptic conditions critical for the surgical setting. The device processes greater volumes of blood, allowing for lots between 40ml and 180 ml of four-to-six fold increased platelet rich plasma. The system is also very user-friendly, with a Microsoft Windows based operating platform, easy one button push to start, continuous volume counting and monitoring, self-loading pumps, and pre-assembled consumable (disposable) packets for fast and safe use.

The Angel System



Orthopedic surgeons are a significant user of PRP for common procedures including rotator cuff repairs, knee ligament reconstruction, meniscal repairs, ACL reconstructions, Achilles and patellar tendon repairs, and chronic tendinopathy such as “tennis elbow”. The benefits of PRP include enhanced and shorter recovery times, reduction in bleeding and pain, and reduction in infection. Thus, the sports medicine avenue for future PRP use is significant in our view. Finally, cardiovascular surgeons also use PRP to improve healing times and reduce bleeding risk during open heart surgery. Yet, despite the fact that PRP separation and concentration is an exact science, there exists on the market today dozens of approved devices to prepare PRP.

The current size of the PRP surgical market is approximately $40 to 50 million. We estimate that Angel holds around 12% market share. No one product has over 30% share; so at this point things remains wide open. Angel has certain advantages that should lead to share gains in the future. The product is built on the tried-and-true apheresis technology surgeons are familiar and comfortable with. Plus, the system is completely closed (aseptic), able to handle larger volumes than competitors, and fully customizable. However, we do not believe this is only a market share grab play. The opportunity is significant because the entire market is growing at over 20% CAGR. The company’s efforts are focused on pursuing independent arrangements aggressively to drive sales. It provides a low-cost opportunity to develop annuity-like revenues in the future through a “razor / razor blade” business model.

The economics of the product are very strong. We estimate gross margins on the disposable device is >70%, and with only about 240 installed units (systems) the majority (~90%) of the sales are re-orders of the single-use consumable device. The centrifugation unit costs an estimated $7,500 and a single consumerable runs about $150 in the U.S. and about €160 in the E.U. Over 90% of the manufacturing is outsourced and Cytomedix has assumed these OEM agreements.

RECOMMENDATION

…Stock Remains Undervalued…

Cytomedix stock is up nearly 200% since the beginning of September 2011. Investors are finally starting to pay attention to the strong fundamental story. Yet, the market capitalization is still only $43 million. We estimate the company should generate revenues in 2011 of $7.9 million thanks to growing sales of the Angel System and AutoloGel and the $2.0 million option fee from an undisclosed pharmaceutical partner. Revenues in 2012 are expected to be up over $8 million, and that includes no upfront or milestone payment from a deal on AutoloGel.

We believe the company is on a clear path toward cash flow profitability thanks to growing revenues, higher margin products, and a lower cost structure. Management has spent much of the last year streamlining the supply chain and removing inefficiencies from the Angel business model masked within the larger Sorin organization. As new indications for Angel come online, and reimbursement and use for AutoloGel improves, we think the company can achieve cash-flow breakeven levels in 2013, with revenues exceeding $30 million by 2014 driven by AutoloGel reimbursement and Angel label expansion.

Based on our DCF analysis, a market capitalization closer to $165 million, or approximately $2.00 per share, more accurately values Cytomedix. We see the market as under-estimating the future earnings potential for the company with AutoloGel and Angel.

PROJECTED FINANCIALS

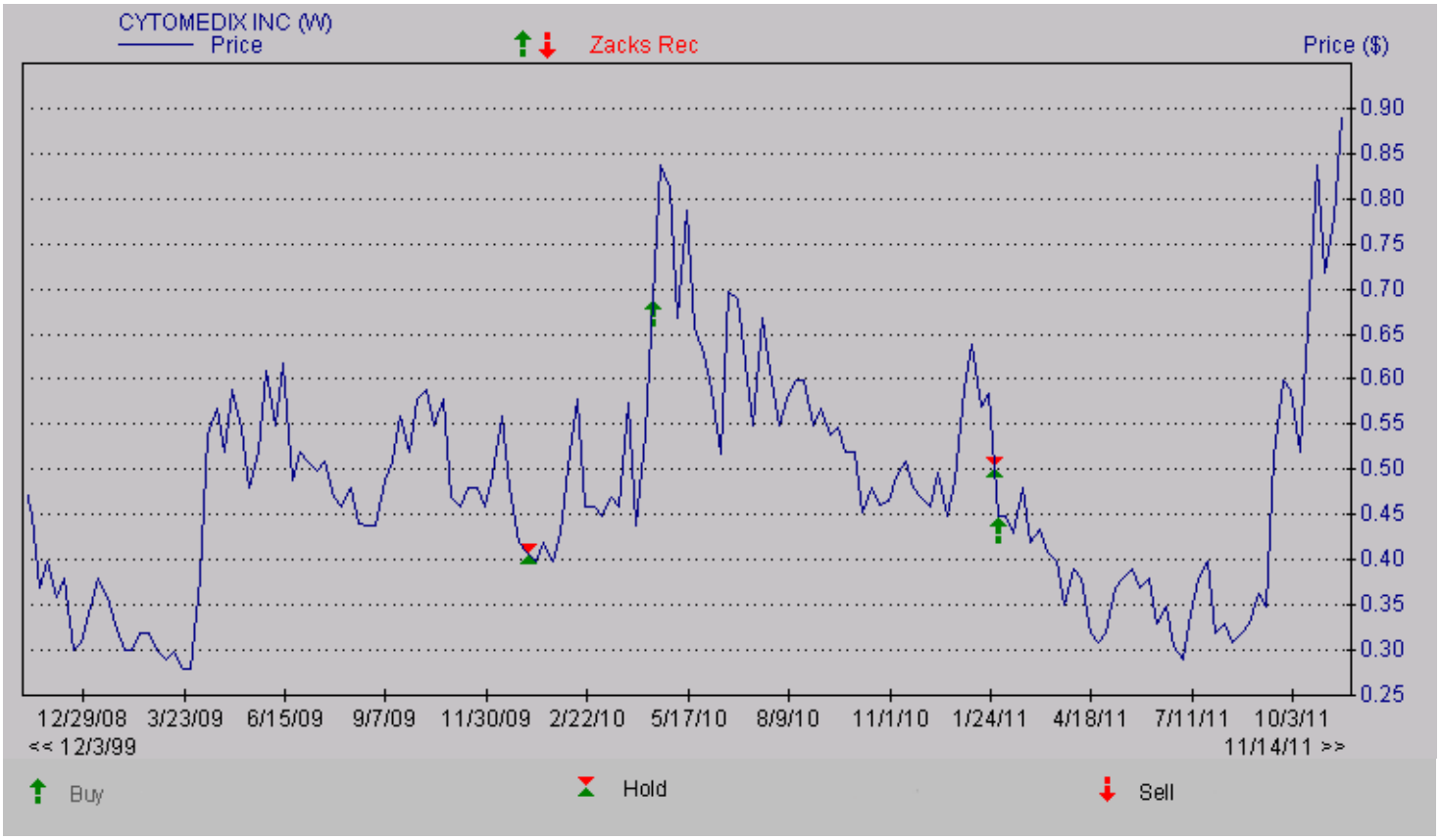
Cytomedix, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E	2014 E
Product Sales	**$0.23**	**$3.79**	**$1.37**	**$1.39**	**$1.53**	**$1.57**	**$5.86**	**$8.20**	**$14.95**	**$30.70**
YOY Growth	124.0%	1574.5%	2058.7%	21.5%	18.5%	21.6%	54.7%	39.9%	82.3%	105.4%
Royalties & Collabs	**$1.84**	**$0.12**	**$0**	**$0**	**$0**	**$2.0**	**$2.0**	**$0**	**$0**	**$0**
YOY Growth	-7.5%	-100.0%	-	-	-	-	1524.7%	-	-	-
Total Revenues	**$2.07**	**$3.91**	**$1.37**	**$1.39**	**$1.53**	**$3.57**	**$7.86**	**$8.20**	**$14.95**	**$30.70**
YOY Growth	-1.2%	89.3%	664.0%	21.5%	18.1%	176.5%	101.0%	4.3%	82.3%	105.4%
Cost of Sales	$0.06	$1.80	$0.65	$0.64	$0.72	$0.71	$2.71	$2.79	$4.49	$8.29
Product Gross Margin	74.1%	52.5%	52.7%	54.2%	53.1%	55.0%	53.8%	66.0%	70.0%	73.0%
R&D	$0.23	$0.42	$0.06	$0.04	$0.00	$0.02	$0.13	$0.20	$0.25	$0.30
% R&D	11.0%	10.6%	4.4%	3.0%	0.3%	0.6%	1.6%	2.4%	1.7%	1.0%
SG&A, Other Fees	$4.83	$7.29	$2.14	$1.95	$1.84	$1.80	$7.74	$8.00	$8.25	$8.50
% G&A	233.7%	186.3%	156.9%	139.9%	120.3%	50.4%	98.4%	97.6%	55.2%	27.7%
Operating Income	($3.45)	($5.40)	($1.48)	($1.24)	($1.03)	$0.54	($2.71)	($2.79)	$1.97	$13.61
Operating Margin	0.0%	-138.1%	-	-	-	-	-34.5%	-34.0%	13.1%	44.3%
Interest & Other Income	$0.19	($1.40)	$0.08	$0.45	($1.17)	($0.50)	($1.14)	($0.65)	($0.15)	$0.20
Pre-Tax Income	($3.26)	($6.80)	($1.41)	($0.79)	($2.20)	$0.04	($3.85)	($3.44)	$1.82	$13.81
Taxes	$0	$0.01	$0	$0	$0	$0	$0	$0	$0	$1.4
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	10.0%
Preferred A, B, & D	$0.01	$2.22	$0.09	$0.09	$0.09	$0.09	$0.35	$0.35	$0.35	$0.35
Net Income	($3.27)	($9.04)	($1.50)	($0.87)	($2.29)	($0.05)	($4.20)	($3.79)	$1.47	$12.08
Net Margin	0.0%	-231.1%	-	-	-	-	-53.5%	-46.2%	9.8%	39.3%
Reported EPS	**($0.09)**	**($0.23)**	**($0.03)**	**($0.02)**	**($0.04)**	**($0.00)**	**($0.08)**	**($0.07)**	**$0.02**	**$0.17**
YOY Growth	-	150.7%	-	-	-	-	-64.4%	-20.9%	-134.2%	665.7%
FAS-123R Expense	$0.44	$0.41	$0.10	$0.04	$0.07	$0.10	$0.31	$0.45	$0.50	$0.60
EPS Impact of FAS-123R	*($0.01)*	*($0.01)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.01)*	*($0.01)*	*($0.01)*	*($0.01)*
Weighted Ave. Shares Out	35.1	38.7	46.1	50.6	52.3	53.0	50.5	57.5	65.0	70.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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HISTORICAL ZACKS RECOMMENDATIONS



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