Zacks Small-Cap Research

May 23, 2011
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Cytomedix, Inc (CMXI-OTC)

CMXI: Cytomedix Fundamentals Improving, Maintain Outperform Rating…

Current Recommendation	**Outperform**
Prior Recommendation	N/Al
Date of Last Change	01/30/2011
Current Price (05/23/11)	$0.39
Target Price	**$1.50**

Update

In our view, the biggest catalyst for shares of Cytomedix on the horizon is the submission for reconsideration of AutoloGel with Medicare / Medicaid. Based on our conversations with management, this filing should take place by the end of May 2011. We have seen a significant increase in data since the first submission was rejected by CMS in 2003. A final decision is expected in early 2012.Management is also in position to file several new 510(k) applications on Angel over the next few months. These include bone marrow aspirate processing and the retransfusion of packed red blood cells separated during the processing. We remain optimistic on the future of Cytomedix. We believe the shares are vastly undervalued today and recommend investors establish a position ahead of several near-term catalysts.

SUMMARY DATA

52-Week High	**$0.70**
52-Week Low	**$0.29**
One-Year Return (%)	**-40.88**
Beta	**1.46**
Average Daily Volume (sh)	**140,381**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**12.7**
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**
Zacks Rank	**2**

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	1.5 E	1.6 E	1.6 E	6.0 A
2012					7.7 E
2013					9.6 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	-$0.03 E	-$0.02 E	-$0.02 E	-$0.11 A
2012					-$0.06 E
2013					-$0.03 E

Zacks Projected EPS Growth Rate **N/A**

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WHAT'S NEW

Q1 Financial Results

Revenues: On May 17, 2011, Cytomedix reported financial results for the first quarter 2011. Total revenues in the quarter were $1.37 million, just shy of our $1.4 million estimate.

- AutoloGel sales in the first quarter were $87K, shy of our $100K estimate, but still up 38% year-over-year from the $63K in the first quarter 2010 and up 7% sequentially from the $81K in the fourth quarter 2010.

- Angel sales in the first quarter were $1.28 million, essentially in-line with our estimate of $1.3 million. Angel sales have grown each quarter since Cytomedix acquired the product from Sorin in April 2010. On the call, management noted that U.S. Angel sales grew 10% sequentially from the fourth quarter 2010. Management noted that international sales of ActivAT were impacted by supply issues. Had ActivAT sales met expectations, overall Angel & ActivAT sales would have exceeded our expectations.

Product Sales	Q1 2011		Comps	
	Reported	Zacks Est.	Q1 2010	Q4 2010
Angel & ActivAT	$1.28M	$1.30M	$1.10M	$1.21M
AutoloGel	$87K	$100K	$63K	$81K

Gross margin: Gross margin the first quarter was only 53%. Margin was negatively impacted by amortization of patents and technology, and depreciation payments on equipment. We expect the gross margin line to improve in the next several quarters as commission payments to Sorin have been completed and management effectively streamlines the supply chain activities now that Angel is 100% under Cytomedix control.

In the coming years we expect gross margin to improve to 70% based on Cytomedix contracting with a new OEM partner for the Angel System, 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 early 2012. 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 in the second quarter 2011. Likewise, expanding indications for Angel should help drive improved margin at the company.

Operating Expenses: Operating expenses were in-line with expectations in the first quarter, coming in at $2.2 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. 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.

Net Loss: Net loss for the first quarter totaled $1.50 million, or $0.03 per diluted share. This was less than our estimate of $1.79 million, or $0.04 per share.

Cash: Cytomedix exited the first quarter 2011, ended March 31, 2011, with $1.1 million in cash and investments. Operating burn was $1.3 million in the first quarter. Management continues to drawn down on its committed equity financing with Lincoln Park Capital (LPC), completing approximately $2.0 million so far in 2011. The company has access to an additionally $8.8 million over the next 17 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 late 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).

Sorin Debt: As a reminder, in April 2011, Cytomedix announced that it has entered into an agreement with Sorin in connection with to the $3.4 million in debt outstanding relating to the purchase of the Angel assets in April 2010. The original terms for the deal called for Cytomedix to pay Sorin a total of $7.0 million over six installments, including $3.6 million already paid ($2.0 million in April 2010, $0.8 million in October 2010, and $0.8 million in April 2011) plus $3.4 million still outstanding ($1.2 million due October 2011, $1.2 million due April 2012, $1.0 million due October 2012). Instead, the remaining $3.4 million outstanding payment was settled in full with a $2.1 million payment on April 29, 2011. The $2.1 million payment is being funded by a new $2.1 million, four-year, interest-only loan due April 2015. The note will bear interest at 12%, payable quarterly beginning September 30, 2011. Certain insiders and existing shareholders who funded and/or guaranteed repayment of the new loan will receive an aggregate of up to 2.5 million warrants to purchase shares of common stock at a price of $0.50 per share ($1.5 million which become available immediately). We believe the transaction above greatly reduces the debt burden and overhand on the shares. It also reduces potential dilution in the near-term through debt-to-equity conversions to fund the Sorin payments.

INVESTMENT THESIS

AutoloGel Poised For Growth

In our view, the biggest catalyst for shares of Cytomedix on the horizon is the submission for reconsideration of AutoloGel with Medicare / Medicaid (CMS). As a reminder, Cytomedix has been in discussion with CMS on re-filing a reimbursement dossier for the past several months. The company met face-to-face with CMS on March 16, 2011 to discuss and present a significant amount of new data on AutoloGel since the first coverage dossier was submitted, and rejected, by CMS in 2003. At that meeting, CMS asked Cytomedix to prepare a “net health benefit” presentation to discuss during another face-to-face meeting. This meeting took place on May 10, 2011.

We expect the formal dossier will be filed by the end of the month. That will be followed by a 90-day “public comment” period where CMS will review the data. 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. Finally, roughly 90-day after that preliminary decision, CMS will finalize the decision. Therefore, a final decision on coverage reimbursement is expected during the first quarter of 2012.

We view CMS coverage as a meaningful driver of AutoloGel sales going forward. 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. Cytomedix is missing half the market opportunity due to non-coverage. With coverage, we expect AutoloGel sales to grow rapidly in 2012 and 2013.

…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.

Wound 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 such as the Symposium on Advanced Wound Care and Wound Healing Society (SAWC/WHS) in April 2010, the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists (WOCN/WCET) in June 2010, the SAWC Fall session in September 2010, the Academy of Spinal Cord Injury Professionals' meeting in September 2010, and the Diabetic Food Ulcer conference and Gems Wound Care Panel, both which took place in November 2010.

The most recent presentation took place at the Symposium on Advanced Wound Care (SAWC) in April 2011. At this meeting, data was presenting 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. The data are presented below:

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.

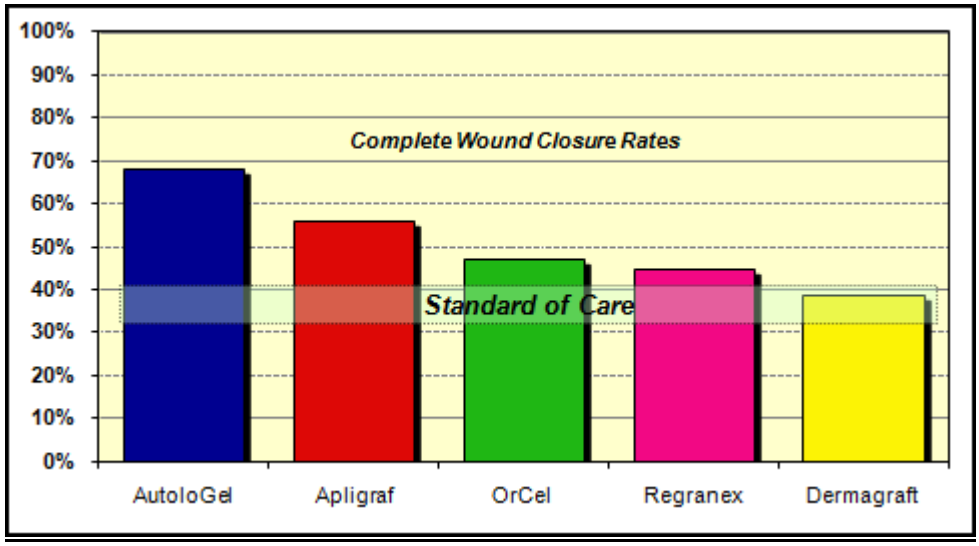
Actual (mean) cost of RPR (n=25):
➔ $11,850

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

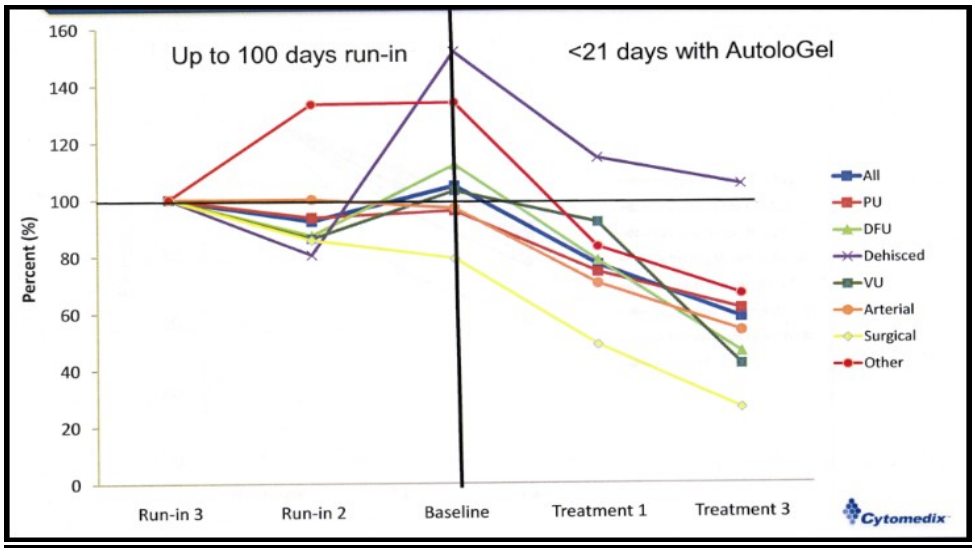
Total estimated cost savings of using PRP vs. NPTW:
➔ $14,319.

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. Presenting clinical data on AutoloGel at medical conferences and publishing in peer reviewed journals will remain a key focus for management's marketing and promotion of AutoloGel in 2011.

...AutoloGel Is Superior To Competing Technology…



...And Works On Previously Stalled Wounds…



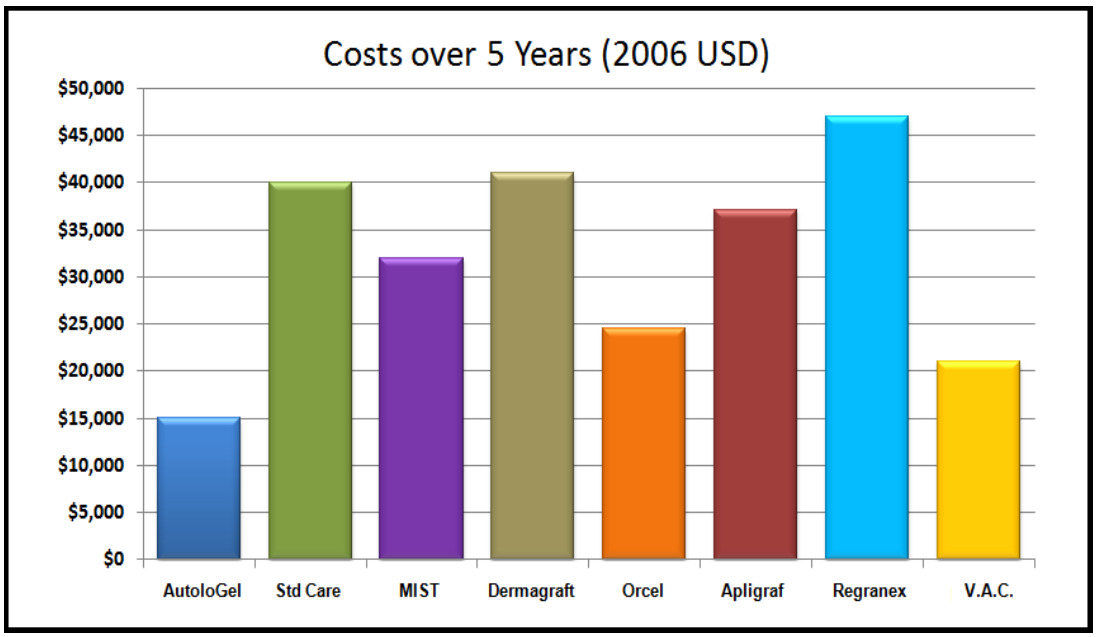
This is the kind of data we believe CMS is looking for with respect to AutoloGel. Signs of clear efficacy, especially in areas were existing products with coverage are failing. The AutoloGel System produced a favorable clinical response in 97% of the wounds treated, resulting in a mean reduction in wound 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.

Below we highlight some very impressive data presented by management in September 2010 at the Academy of Spinal Cord Injury Professionals' Annual Meeting. Spinal cord injury (SCI) represents a significant market opportunity for Cytomedix. Patients with SCI exhibit various challenges, such as decreased fibronectin activity, abnormal vascular reactions, deceased blood flow and blood supply, decreased blood pressure, and poor collagen synthesis. The data is from 10 SCI patients (13 wounds). The mean wound duration prior to treatment with AutoloGel was an astonishing 58 weeks, with one wound persisting for 106 weeks. After an average of 3.2 weeks (4.4 treatments with AutoloGel), Cytomedix saw 100% response.

AutoloGel In Patients With SCI (n=10)
13 Wounds Mean Duration of 52 Weeks
After An Average of 4.4 Treatments (3.2 Weeks) With AutoloGel
100% Response Rate
62% Improvement in Volume
51% Improvement in Area
69% Improvement in Undermining
30% Improvement in Sinus Tract / Tunneling

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.

Cost Calculation: 1.3x PRP used vs. NPWT saved	
Total no. patients PRP treatment	25
Patients included in NPWT savings	17
Total PRP treatments and dressing kits for inclusive patients	34
Cost each PRP dressing kit	$300.00
Total cost dressing kits	$10,200.00
Cost each PRP Reagent kit	$150.00
Reagent kits used (average 1 reagent kit/3 treatments)	11 kits
Total cost reagent kits	$1,650.00
Total cost PRP dressing and reagent kits	**$11,850.00**
Estimated **NPWT** days/weeks saved	289 total days = 2.43 wks /pt
NPWT rental/day	$61.71
• Total NPWT rental cost savings	$17,834.19
Cost/NPWT canister	$36.37
Weekly cost NPWT canisters @ 2/wk/pt	$72.74
• Total cost NPWT canisters (2.43 weeks x $72.74/week x 17 patients)	$3004.89
Cost/NPWT medium black dressing kit	$43.01
Weekly cost NPWT Dressings @ 3/wk/pt	$129.03
• Total cost NPWT dressings (2.43 weeks x $129.03/week x 17 patients)	$5330.23
Total cost NPWT rental days, canisters, dressings	**$26,169.31**

Above we have also highlighted data from a small (n=25) study conducted at the Asheville Specialty Hospital, in Asheville, NC, presented at the April 2011 SAWC meeting. The data show the average cost of NPWT costs around $26,169 per patient. The actual cost of AutoloGel for the 25 patients in the study was only $11,850. Therefore, using AutoloGel resulted in an estimated savings per patients of approximately $14,319.

The data also showed:

- ✓ Average number of days of treatment with AutoloGel was reduced to 7.3 days vs. 9.2 day with NPWT.
- ✓ Average number of treatments was reduced to 1.7 vs. 4.1.
- ✓ Improvement in total wound area reduction of 27.5% vs. 25.8%
- ✓ Improvement in total wound volume reduction of 54.9% vs. 40.7%.

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.

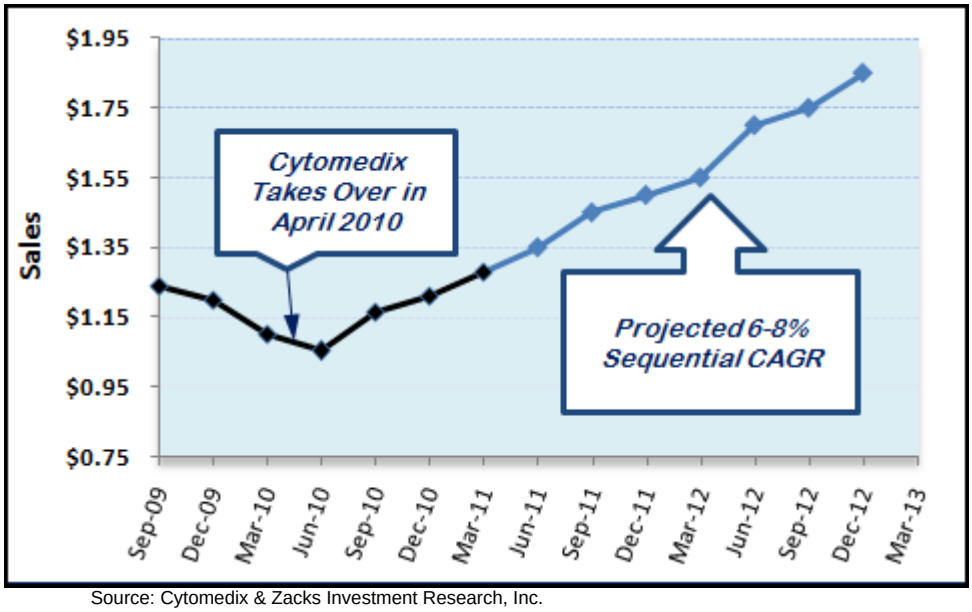
…510(k) on AutoloGel 2.0 in Q2-2011…

Cytomedix is working to bring an enhanced next-generation AutoloGel – AutoloGel 2.0 – to the market in 2012. The company is 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 expect a U.S. 510(k) application for the next-generation AutoloGel during the second quarter of 2011. The new version should improve the company's intellectual property protection around AutoloGel and deliver enhanced profitability for the future.

Angel Driving Top-Line

Angel sales have been generally in-line with our expectations. The product has grown each quarter since the Cytomedix takeover and has clearly recovered from the slow bleed that persisted the last few quarters when Sorin will still in control of the distribution. For the full year 2010, Cytomedix recorded Angel sales of $3.4 million. Sales in the first quarter 2011 were $1.28 million. There are an estimated 250 units in use, with about 90 accounts.

…Quarterly Angel Sales Improving…



Source: Cytomedix & Zacks Investment Research, Inc.

A significant opportunity exists for management to expand use at the smaller practices where Angel system utilization is low. With the transition complete, this can be a core area of focus for management in 2011. 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 2011. 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. As of the end of March 2011, 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. Management believes that sales in the first quarter 2011 will be up 10% sequentially from the fourth quarter 2010. This would put Angel sales above $1.35 million in the quarter, an all-time high.

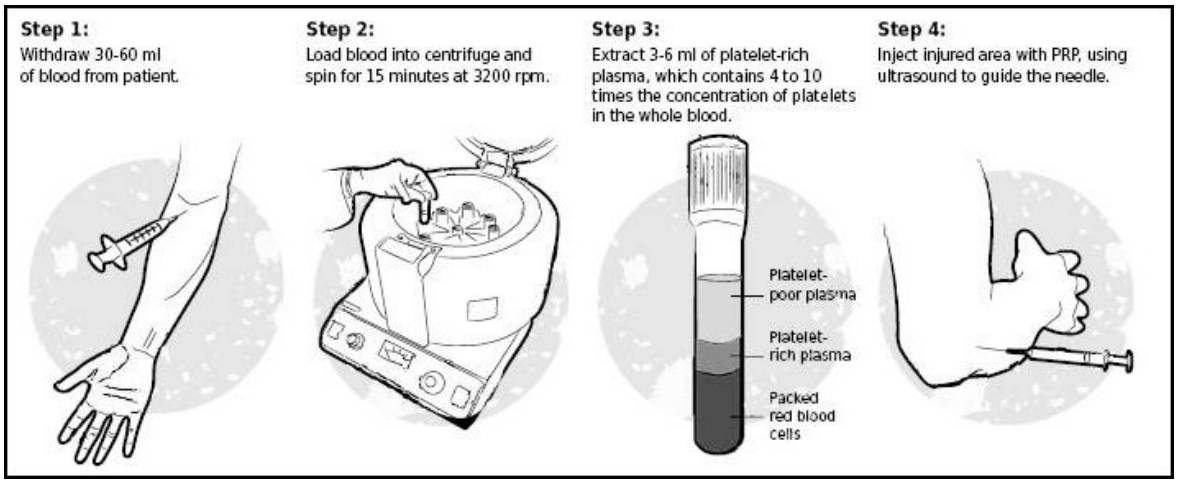
…New Indications to Drive Growth…

CEO Martin Rosendale recently highlighted the potential for new indications for the Angel system. These include bone marrow aspirate processing, blood reinfusion during surgery, and expanding uses of the device in the orthopedic / sports medicine market.

- Bone Marrow Aspirate Processing: 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. 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 Treatment Repair Cells (TRCs) used to treat peripheral arterial disease such as critical limb ischemia (CLI) or myocardial ischemia. The knock on Aastrom is that, although they are 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. We are expecting the U.S. 510(k) application for this indication by the end of the second quarter 2011.

- Reinfusion Of Cells: 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. This filing should take place by the end of the third quarter 2011. We think this opens the door for potential use in the surgical setting by cardiologists.

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. Data presented at the American Academy of Orthopaedic Surgeons in March 2010 demonstrated that PRP was 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 LA Dodgers, Seattle Mariners, Denver Nuggets, and Dallas Cowboys have all embraced the use of PRP. The use of PRP is clearly on the rise in professional sports. 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 an injury.



Source: Jenny Vrentas & Michael Guillen, Star Ledger

…Growing The Business…

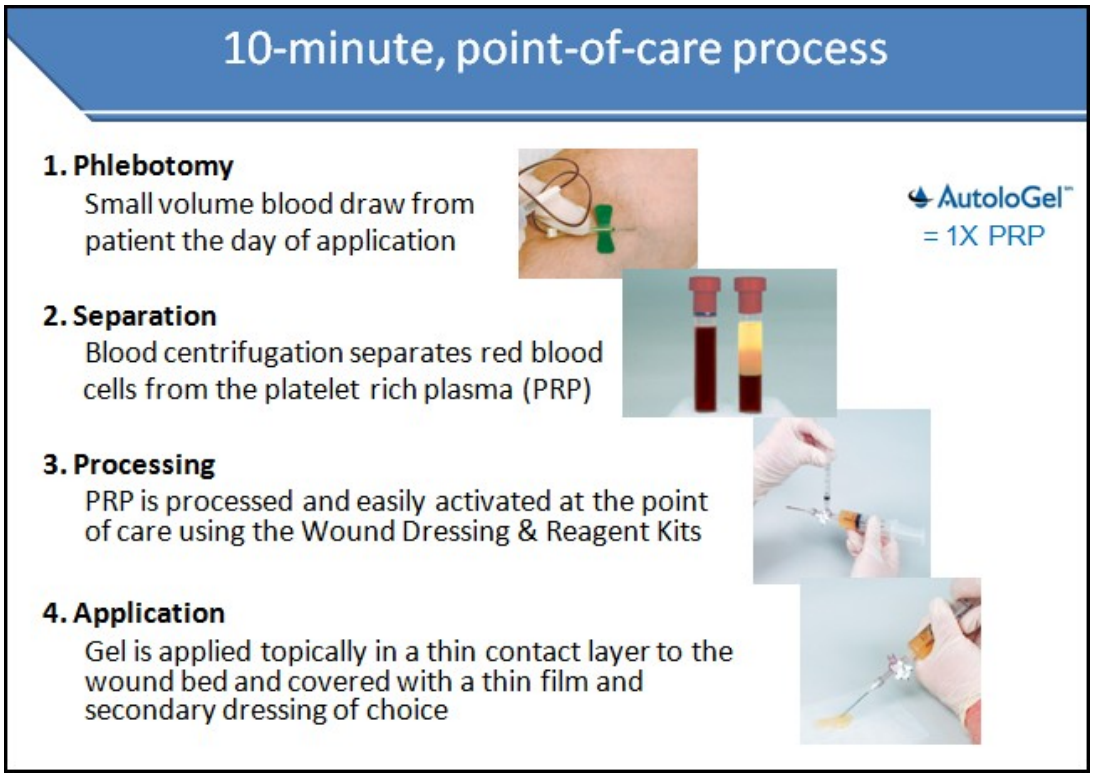
In March 2011, Cytomedix appointed Gary R. Otto to the newly-created position of Director of National Accounts. Mr. Otto will be responsible for all aspects of the commercial business with major corporate customers such as healthcare networks, group purchasing organizations, U.S. government accounts, and managed care organizations. This is the second high-profile higher for the company into a newly-created position. In July 2010, Cytomedix hired Patrick P. Vanek, R.Ph. to the newly-created position of Vice President of Operations. Mr. Vanek is responsible for all aspects of the technical business including oversight of the manufacturing process by OEM partners, quality assurance and control, distribution, warehousing and all other operational and logistical aspects of the process.

OVERVIEW

AutoloGel

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 should take place in the second quarter 2011. A decision is expected during the first quarter of 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.

INVESTMENT THESIS

Filings, Filings, and More Filings…

We see a significant near-term opportunity for Cytomedix shareholders considering the number of filings the company plans to submit over the next few months. These include:

- Filing the reconsideration for coverage dossier with Center for Medicare / Medicaid Services (CMS).
  - This should take place in late May 2011, with a decision roughly 9 months later.
  - We place the odds high that reimbursement will be instituted given the massive amount of new data the company will submit compared to the first request in 2003.
  - Along the way there will be a face-to-face meeting with CMS approximately 90-days after the filing, and a preliminary decision from CMS approximately 90-day after the meeting.

- Filing a 510(k) application for AutoloGel 2.0.
  - This should take place in the second quarter 2011.
  - A decision is expected in approximately six months. Odd are very high it is approved. AutoloGel 2.0. is a next-generation AutoloGel product that utilizes an optimized 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.

- Filing a 510(k) application to expand Angel's label into blood reinfusion
  - This filing should take place in the third quarter 2011.
  - Sorin did much of the initial work here. The product already has sizable real-world use in this indication.
  - We expect a decision in six to nine months after the filing.

- Filing a 510(k) application to expand Angel's label into bone marrow aspirate processing.
  - This filing should take place in the second quarter 2010.
  - This is potentially an enormous market for Cytomedix that would provide surgeons the ability to deliver bone marrow derived stem cells with RPR in a real-time application.
  - We expect a decision in six to nine months after the filing.

…Sorin Debt Repaid…

On May 1, 2011, Cytomedix announced that it has entered into an agreement with Sorin in connection with to the $3.4 million in debt outstanding relating to the purchase of the Angel assets in April 2010. Instead, the remaining $3.4 million outstanding payment was settled in full with a $2.1 million payment on April 29, 2011. The $2.1 million payment is being funded by a new $2.1 million, four-year, interest-only loan due April 2015. The note will bear interest at 12%, payable quarterly beginning September 30, 2011. We believe the transaction above greatly reduces the debt burden and overhand on the shares. It also reduces potential dilution in the near-term through debt-to-equity conversions to fund the Sorin payments.

…Stock Looks Significantly Undervalued…

With a current capitalization of only $16 million, we believe the market is far undervaluing Cytomedix. We estimate the company should generate revenues in 2011 above $6 million thanks to growing sales of the Angel System and AutoloGel. The current value of only 2.5x revenues is below the peer-group average of roughly 6x revenues, and revenues in 2012 are expected to be up over 25%. We believe the company is on a clear path toward cash flow profitability thanks to growing revenues, high margin products, and a low-cost structure.

Based on our NPV analysis, a market capitalization closer to $60 million, or approximately $1.50 per share, more accurately values Cytomedix and the future earnings potential for the company with AutoloGel and Angel.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
AutoloGel	$0.23	$0.37	$0.09	$0.11	$0.12	$0.12	$0.44	$0.85	$1.35	$1.85
YOY Growth	124.0%	61.8%	37.5%	15.8%	-4.8%	48.1%	19.4%	94.5%	58.8%	37.0%
Angel System	*$4.74*	$3.42	$1.28	$1.35	$1.45	$1.50	$5.58	$6.85	$8.25	$9.75
YOY Growth	N/A	N/A	16.4%	28.3%	24.6%	24.0%	63.2%	22.8%	20.4%	18.2%
Product Sales	**$0.23**	**$3.79**	**$1.37**	**$1.46**	**$1.57**	**$1.62**	**$6.02**	**$7.70**	**$9.60**	**$11.60**
YOY Growth	124.0%	1574.5%	2058.7%	27.3%	21.7%	25.5%	58.8%	28.0%	24.7%	20.8%
Royalties & Collabs	**$1.84**	**$0.12**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-7.5%	-100.0%	-	-	-	-	-	-	-	-
Total Revenues	**$2.07**	**$3.91**	**$1.37**	**$1.46**	**$1.57**	**$1.62**	**$6.02**	**$7.70**	**$9.60**	**$11.60**
YOY Growth	-1.2%	89.3%	664.0%	27.3%	21.0%	25.5%	53.8%	28.0%	24.7%	20.8%
Cost of Royalties	$0.40	($0.19)	$0	$0	$0	$0	$0	$0	$0	$0
Royalty Net Margin	78.3%	-	-	-	-	-	-	-	-	-
Cost of Sales	$0.06	$1.80	$0.65	$0.48	$0.49	$0.49	$2.10	$2.16	$2.59	$3.07
Product Gross Margin	74.1%	52.5%	52.7%	67.0%	69.0%	70.0%	65.1%	72.0%	73.0%	73.5%
R&D	$0.23	$0.42	$0.06	$0.08	$0.10	$0.11	$0.35	$0.50	$0.55	$0.60
% R&D	11.0%	10.6%	4.4%	5.5%	6.4%	6.8%	5.8%	6.5%	5.7%	5.2%
SG&A, Other Fees	$4.83	$7.29	$2.14	$1.95	$1.75	$1.70	$7.54	$7.25	$7.50	$8.00
% G&A	233.7%	186.3%	156.9%	133.6%	111.5%	104.9%	125.4%	94.2%	78.1%	69.0%
Operating Income	($3.45)	($5.40)	($1.48)	($1.05)	($0.77)	($0.68)	($3.98)	($2.21)	($1.04)	($0.07)
Operating Margin	0.0%	-138.1%	-	-	-	-	-66.1%	-28.6%	-10.9%	-0.6%
Interest & Other Income	$0.19	($1.40)	$0.08	($0.25)	($0.20)	($0.20)	($0.57)	($0.65)	($0.15)	$0.20
Pre-Tax Income	($3.26)	($6.80)	($1.41)	($1.30)	($0.97)	($0.88)	($4.55)	($2.86)	($1.19)	$0.13
Taxes	$0	$0.01	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Preferred A, B, & D	$0.01	$2.22	$0.09	$0.10	$0.10	$0.10	$0.39	$0.40	$0.40	$0.40
Net Income	($3.27)	($9.04)	($1.50)	($1.40)	($1.07)	($0.98)	($4.93)	($3.26)	($1.59)	($0.27)
Net Margin	0.0%	-231.1%	-	-	-	-	-82.0%	-42.3%	-16.6%	-2.4%
Reported EPS	**($0.09)**	**($0.23)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.02)**	**($0.11)**	**($0.06)**	**($0.03)**	**($0.00)**
YOY Growth	-	150.7%	-	-	-	-	-55.0%	-41.1%	-53.3%	-84.2%
FAS-123R Expense	$0.44	$0.41	$0.10	$0.10	$0.10	$0.10	$0.40	$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	46.5	47.0	48.0	46.9	52.5	55.0	60.0

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

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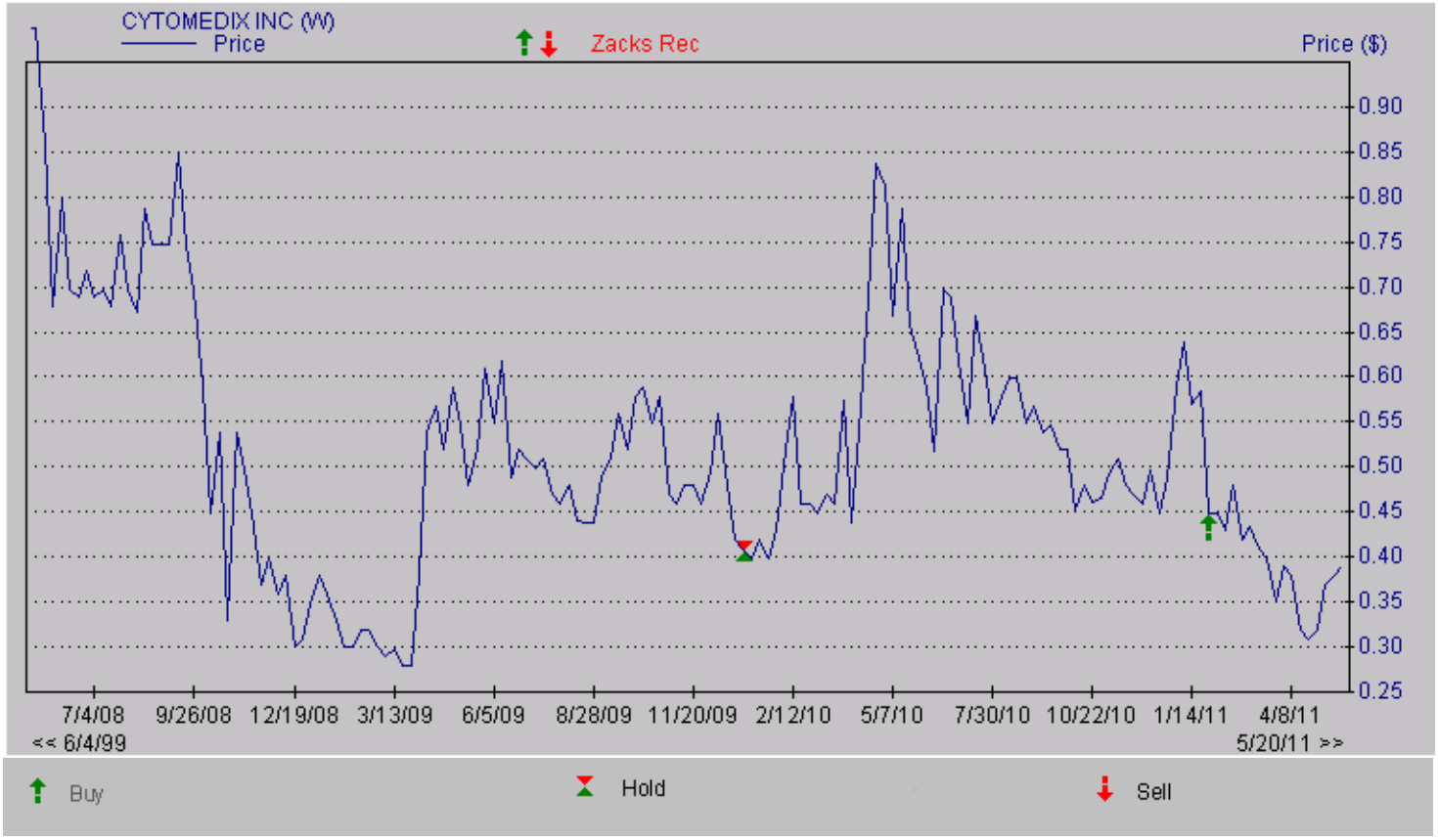

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