Zacks Small-Cap Research

May 1, 2011
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Cytomedix, Inc. (CMXI-OTC)

CMXI: Financial Position Improves with Sorin Debt Repayment, Expecting Solid Q1 Results.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/16/2010
Current Price (05/01/11)	$0.33
Target Price	**$1.50**

UPDATE

Cytomedix announced this morning that it has restructured its outstanding debt with Sorin relating to the Angel acquisition in April 2010. The outstanding $3.4 million debt, due in three installments over the next 18 months, was retired for a one-time $2.1 million now. Cytomedix secured the $2.1 million through a four-year, 12% interested only loan due April 2015. We believe the transaction significantly improves the financial position at Cytomedix and removes a near-term financing risk.

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.

SUMMARY DATA

52-Week High	**$0.88**
52-Week Low	**$0.29**
One-Year Return (%)	**-60.68**
Beta	**1.46**
Average Daily Volume (sh)	**142,702**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**6.2**
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	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

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 E	1.5 E	1.6 E	1.6 E	6.1 E
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	-$0.04 E	-$0.03 E	-$0.02 E	-$0.02 E	-$0.12 E
2012					-$0.06 E
2013					-$0.03 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Sorin Debt Repaid

This morning 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. As a reminder, as part of the Angel asset acquisition, Cytomedix agreed 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.

…Cash Position Improved…

In addition, Cytomedix raised $325,000 in a private placement sold to accredited investors at a price of $0.33 per share (no warrants were issued). We estimate that Cytomedix exited the first quarter ended March 31, 2011 with roughly $1.2 million in cash. Adding in the $2.5 million raised through the loan and private placement, less the total $2.9 million paid to Sorin in April 2011, and we believe the current cash position is roughly $0.8 million.

We remind investors that Cytomedix has an existing equity purchase agreement with Lincoln Park Capital Fund, LLC (LPC) worth a total of up to $11.5 million. Cytomedix has acted on approximately $1.60 million of the $11.5 million Cytomedix so far. 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. Therefore, cash is not a concern. Dilution is, but our financial model forecasts that Cytomedix will be near breakeven levels on cash flow by the end of 2011, and cash flow positive in 2012.

CMS Meeting Scheduled for May 10th

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. We have seen a significant increase in data since the first submission was rejected by CMS in 2003. CMS asked Cytomedix to prepare a "net health benefit" presentation to discuss during a face-to-face meeting. This meeting will take place on May 10th. Below we highly some of this new data and discuss why we believe Cytomedix has an excellent chance to gain coverage with AutoloGel through CMS. We expect the formal dossier will be filed by the end of the month, with a preliminary decision expected in six months from the filing.

Fourth Quarter & 2010 Financials / Outlook for 2011

On March 30, 2011, Cytomedix reported financial results for the fourth quarter and full year 2010. Total revenues in the fourth quarter were $1.29 million, up 208% from the fourth quarter 2009. Revenues consisted of $1.21 million in sales of Angel and $81k in sales of AutoloGel.

Product Sales	Q4 2010		Comps	
	Reported	Zacks Est.	Q3 2010	Q4 2009
Angel & ActivAT	$1.21M	$1.25M	$1.16M	$1.20M
AutoloGel	$81K	$140K	$126K	$67K

Angel system: Angel sales were 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. We remind investors that Cytomedix took over Angel in April 2010. Total Angel sales in 2010, including the sales in the first quarter recorded at Sorin, were $4.6 million. There are an estimated 240 units in use, with about 85 accounts. Cytomedix shipped roughly 40 Angel units in 2010.

Throughout 2010, Cytomedix worked on transitioning customer service and order fulfillment from Sorin. Management continues to note high customer retention and satisfaction. The installed base remains around 150 customers, with about half accounting for the large majority of the revenues. 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 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.

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.

On the fourth quarter call in late March 2011, CEO Martin Rosendale 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. We discuss these market opportunities in greater detail in the body of the report, but we see these as a meaningful potential for drive Angel use in the coming years.

AutoloGel: sales of $81K were a disappointment in the fourth quarter. Although this figure was up 21% from the fourth quarter 2009, it was down $45K sequentially from the third quarter 2010. Sales of AutoloGel had been making all-time quarterly highs in 2010, so the drop off in the fourth quarter is discouraging. Management attributed the decline in sales to lumpiness. We are expecting AutoloGel sales to remain lumpy while trending higher in 2011.

Over the near-term, AutoloGel sales will be driven by management's ability to increase education and awareness of the product through scientific presentations and peer-review articles. 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.

Earlier in the year, management held a pre-submission meeting with the Coverage and Analysis Group at the CMS to review clinical data collected over the past three years and prepare for a reconsideration request. CMS seems very interested in the overall health benefit (quality of life) demonstrated by use of AutoloGel. Cytomedix has compiled data in support of the quality of life benefit, such as the data above presented at SAWC in April 2011, and plans to meet for another face-to-face pre-submission meeting with CMS on May 10, 2011. The company may bring key opinion leaders and AutoloGel patients to the meeting to better inform CMS on the benefits of AutoloGel use. We expect that Cytomedix will be in position to file the coverage request for reimbursement by the end of May 2011. A final ruling from CMS is expected about nine months later, so sometime in early 2012.

Gross margin: Gross margin the fourth quarter was only 56%. For the full year 2010, gross margin was 53%. During 2010, Cytomedix had paid Sorin a 10% commission on sales of the Angel System and consumables. This 10% commission remained until the expiration of the transition period, which expired on December 15, 2010, and totaled $153k for the year. Cytomedix also recorded $118k in amortization of acquired technology, $186k in depreciation, $168,000k in charges relating to the write-up of inventory under purchase accounting rules, and $70k for final contract adjustments in 2010, all which negatively impacted the gross margin line. Excluding these charges, gross margin on product sales for 2010 was 71%.

In the coming years we expect gross margin to improve to 75% 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 increased sizably in 2010, which was to be expected considering the company now has control of the Angel business. However, 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. The company burned only $3.5 million in 2010 versus a net loss of $9.0 million. A lot of the costs were non-cash, related to depreciation, amortization, preferred stock, investor adjustments, and stock options. We think Cytomedix could be cash flow positive by the end of 2011, although we will most likely continue to see operating losses for the next several years.

Net Loss: Net loss in 2010 totaled $9.04 million. This equated to EPS of -23 cents per share. As noted above, operating cash burn was only $3.5 million. Cytomedix exited 2010 with $0.692 million in cash and investments. In October 2010, Cytomedix received $1.5 million through the sales of 3.7 million shares of common stock in a registered direct offering. Lincoln Park Capital Fund, LLC (LPC) led the transaction with a $500,000 investment in this registered direct offering. The company also secured an $11.5 million through an equity purchase agreement with. Cytomedix can sell up to 150,000 shares of common stock to LPC every other business day over a period of 25 months. Cytomedix controls the timing and amount of any sales of shares to LPC. So far in 2011, Cytomedix has received $1.6 million from LPC.

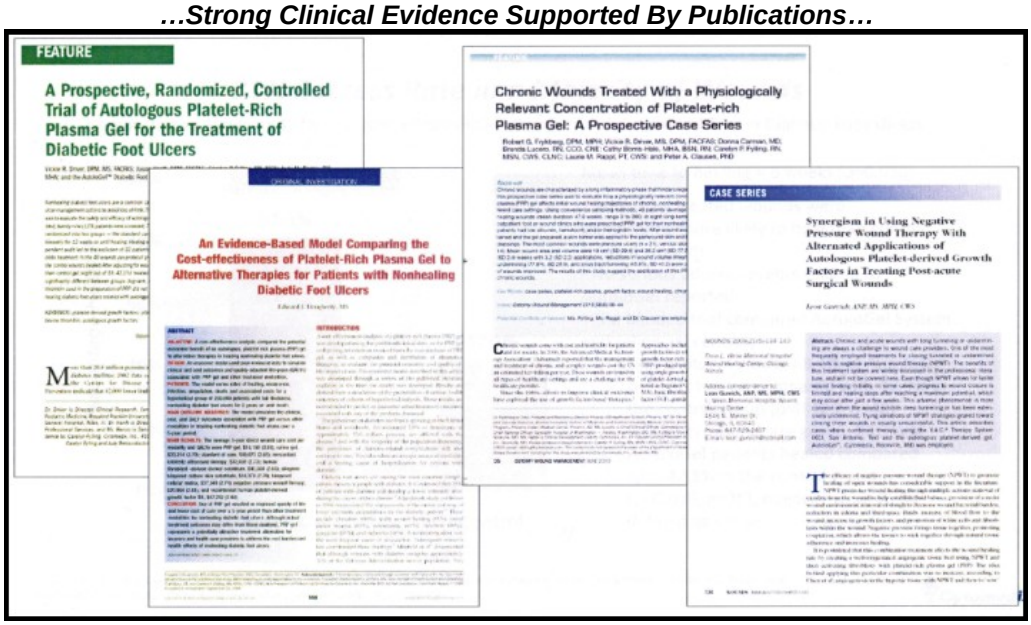
INVESTMENT THESIS

Ammunition For AutoloGel CMS Reconsideration Growing

Sales of AutoloGel have been steadily improving since 2008. We believe sales are benefiting from management's active scientific data education and awareness campaign, which has included both posters and oral presentations as key medical conferences over the past year. The campaign includes both posters and oral presentations as key medical conferences and scientific sessions over the past year.

Presenting clinical data on AutoloGel at medical conferences and publishing in peer reviewed journals remains a key focus for management's marketing and promotion. Presenting posters and publishing data are important part of the education process for physicians and it is clearly something CMS places significant weight on when considering national coverage for reimbursement.

…Strong Clinical Evidence Supported By Publications…



We view CMS coverage as the biggest potential catalyst for shares over the near-term. Following the pre-submission face-to-face meeting scheduled for May 10, 2011, Cytomedix should be in position to re-file the formal request dossier by the end of May 2011. 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.

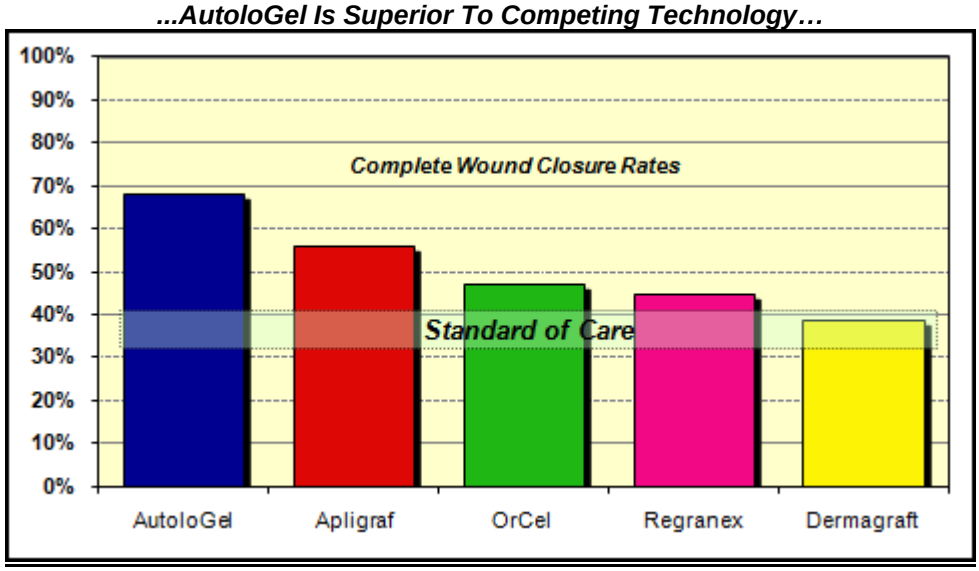
Back when CMS issued its non-coverage designation for AutoloGel in 2003, the decision was based on limited information that included data from only 40 diabetic foot ulcers. Since that time, management has been able to massive data on over 500 wounds – over 10 times the data previously submitted to CMS. 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**

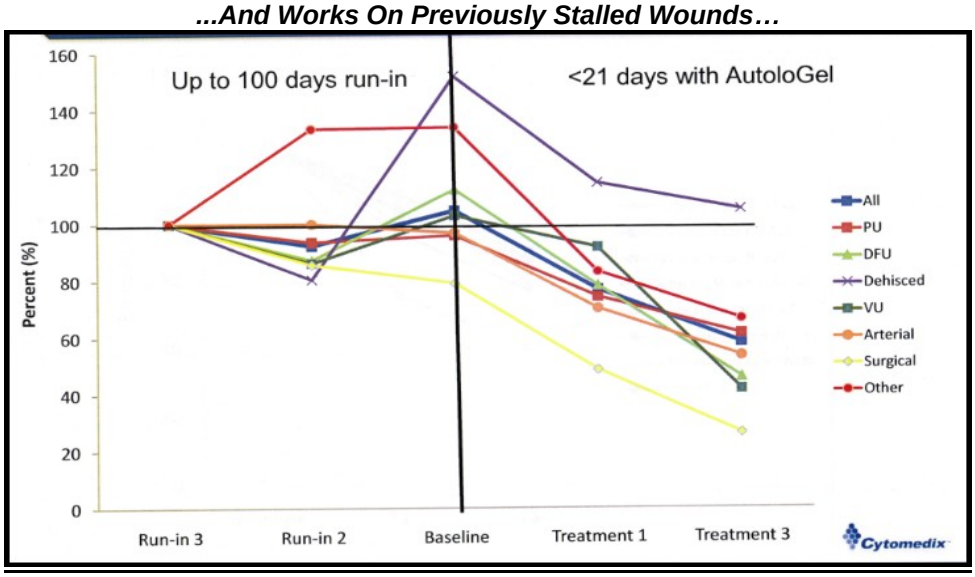
Wounds In Market Registry	No. of Wounds
Pressure Ulcers	142
Diabetic Ulcers	41
Venous Ulcers	32
Dehisced Wounds	24
Surgical Wounds	27
Traumatic Wounds	11
Other Wounds	8

It is clear to us that the sheer amount of data Cytomedix expects to resubmit to CMS dwarfs that the previous submission. We also note that during the 2002/2003 campaign for coverage, several of Cytomedix' competitors were active in lobbying congress to reject approval of the company's "new" technology. Over the past several years it has become obvious this new technology works, and Cytomedix CEO, Martin Rosendale, has been on the offensive making sure congress is aware of all the new data the company has to offer. What was an original submission with only 40 wounds, will now include over 500. And the data is solid in our view:

...AutoloGel Is Superior To Competing Technology…



...And Works On Previously Stalled Wounds…

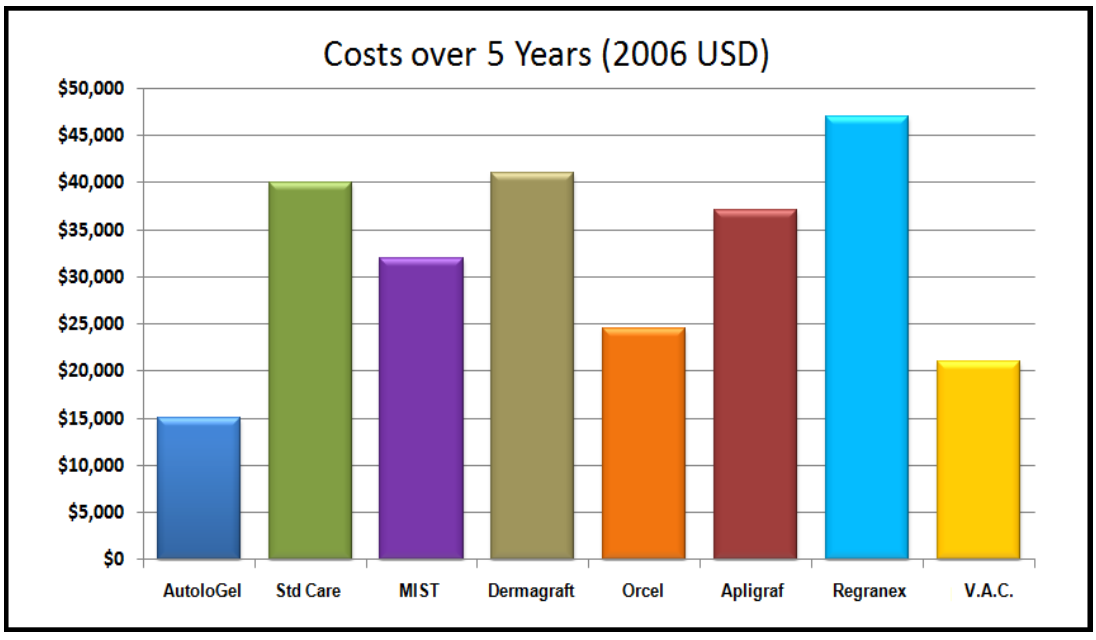


This is the kind of data we believe CMS is looking for with respect to AutoloGel. Signs of clear efficacy, especially in areas were existing products with coverage are failing. The AutoloGel System produced a favorable clinical response in 97% of the wounds treated, resulting in a mean reduction in wound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



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.

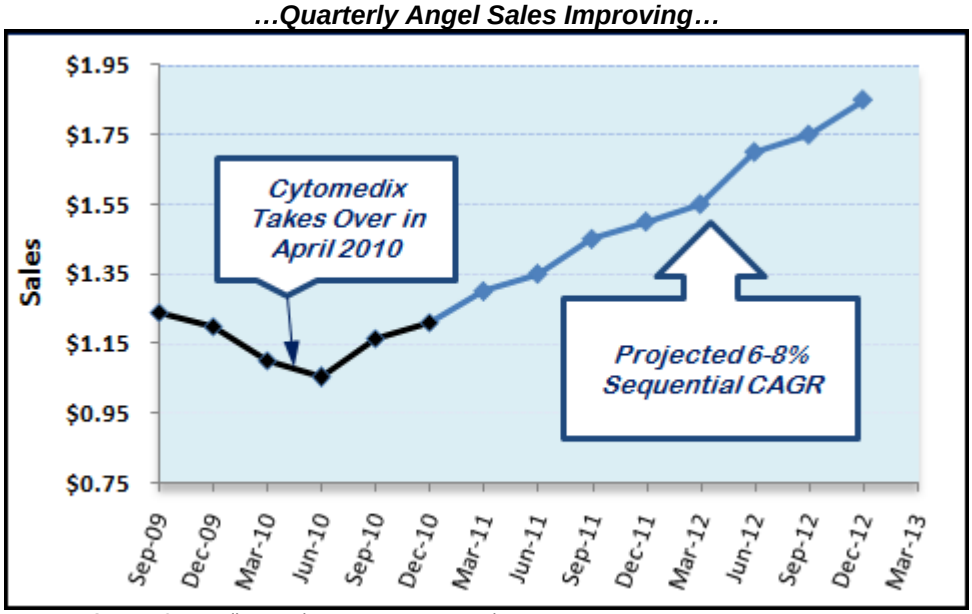
…510(k) on AutoloGel 2.0 in Q2-2011…

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 Drive Top-Line

Angel sales were 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. We remind investors that Cytomedix took over Angel in April 2010. Total Angel sales in 2010, including the sales in the first quarter recorded at Sorin, were $4.6 million. There are an estimated 240 units in use, with about 85 accounts. Cytomedix shipped roughly 40 Angel units in 2010.

…Quarterly Angel Sales Improving…



Source: Cytomedix & Zacks Investment Research, Inc.

Throughout 2010, Cytomedix worked on transitioning customer service and order fulfillment from Sorin. Management continues to note high customer retention and satisfaction. The installed base remains around 150 customers, with about half accounting for the large majority of the revenues. 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 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…

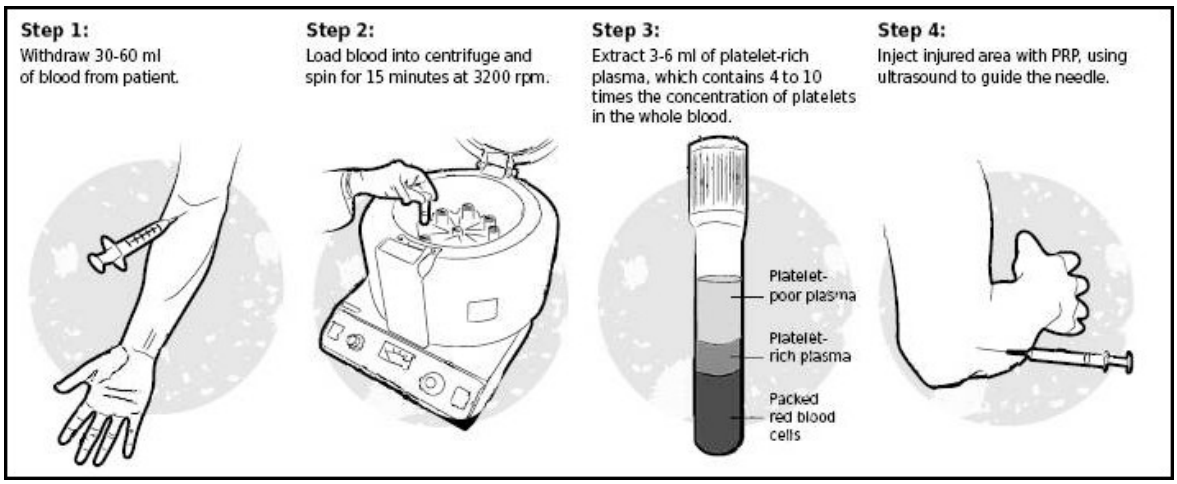
On the fourth quarter call in late March 2011, CEO Martin Rosendale highlighted the potential for new indications for the Angel system. These include bone marrow aspirate processing, blood reinfusion during surgery, and expanding uses of the device in the orthopedic / sports medicine market.

- Bone Marrow Aspirate: 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 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 are expecting the U.S. 510(k) application for this indication in the third quarter 2011.

- 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 into reinfusion by the end of the second 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.



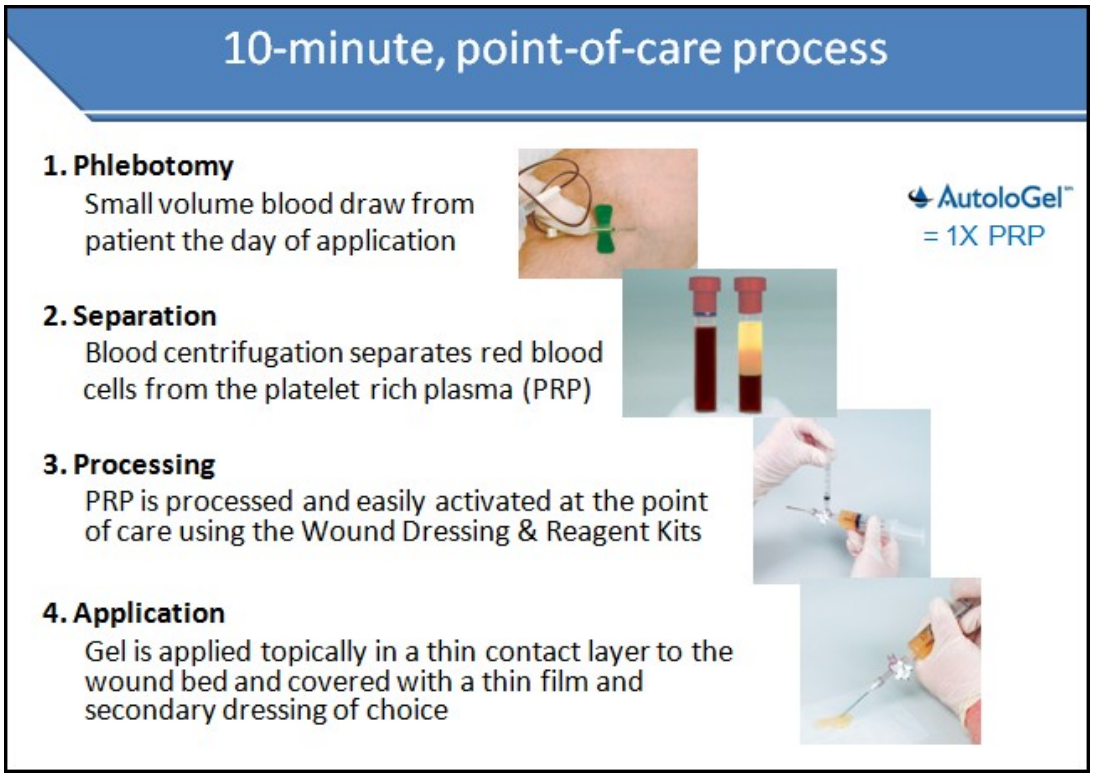
Source: Jenny Vrentas & Michael Guillen, Star Ledger

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 E	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
AutoloGel	$0.23	$0.37	$0.10	$0.13	$0.15	$0.12	$0.49	$0.85	$1.35	$1.85
YOY Growth	124.0%	61.8%	58.1%	31.6%	15.1%	48.1%	33.9%	73.5%	58.8%	37.0%
Angel System	*$4.74*	$3.42	$1.30	$1.35	$1.45	$1.50	$5.60	$6.85	$8.25	$9.75
YOY Growth	N/A	N/A	18.2%	28.3%	24.6%	24.0%	63.7%	22.3%	20.4%	18.2%
Product Sales	**$0.23**	**$3.79**	**$1.40**	**$1.48**	**$1.60**	**$1.62**	**$6.09**	**$7.70**	**$9.60**	**$11.60**
YOY Growth	124.0%	1574.5%	2113.1%	28.6%	23.6%	25.5%	60.8%	26.4%	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**	**$1.40**	**$1.48**	**$1.60**	**$1.62**	**$6.09**	**$7.70**	**$9.60**	**$11.60**
YOY Growth	-1.2%	89.3%	683.3%	28.6%	22.9%	25.5%	55.7%	26.4%	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	$0.49	$0.49	$0.49	$0.49	$1.96	$2.16	$2.59	$3.07
Product Gross Margin	74.1%	52.5%	65.0%	67.0%	69.0%	70.0%	67.9%	72.0%	73.0%	73.5%
R&D	$0.23	$0.42	$0.10	$0.11	$0.12	$0.13	$0.46	$0.50	$0.55	$0.60
% R&D	11.0%	10.6%	7.1%	7.5%	7.5%	8.0%	7.6%	6.5%	5.7%	5.2%
SG&A, Other Fees	$4.83	$7.29	$2.15	$1.85	$1.75	$1.65	$7.40	$7.25	$7.50	$8.00
% G&A	233.7%	186.3%	153.6%	125.4%	109.7%	101.9%	121.5%	94.2%	78.1%	69.0%
Operating Income	($3.45)	($5.40)	($1.34)	($0.97)	($0.77)	($0.65)	($3.73)	($2.21)	($1.04)	($0.07)
Operating Margin	0.0%	-138.1%	-	-	-	-	-61.2%	-28.6%	-10.9%	-0.6%
Interest & Other Income	$0.19	($1.40)	($0.35)	($0.25)	($0.20)	($0.20)	($1.00)	($0.65)	($0.15)	$0.20
Pre-Tax Income	($3.26)	($6.80)	($1.69)	($1.22)	($0.97)	($0.85)	($4.73)	($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	$0.10	$0.10	$0.10	$0.10	$0.40	$0.40	$0.40	$0.40
Net Income	($3.27)	($9.04)	($1.79)	($1.32)	($1.07)	($0.95)	($5.13)	($3.26)	($1.59)	($0.27)
Net Margin	0.0%	-231.1%	-	-	-	-	-84.2%	-42.3%	-16.6%	-2.4%
Reported EPS	**($0.09)**	**($0.23)**	**($0.04)**	**($0.03)**	**($0.02)**	**($0.02)**	**($0.11)**	**($0.06)**	**($0.03)**	**($0.00)**
YOY Growth	-	150.7%	-	-	-	-	-52.3%	-44.4%	-53.3%	-84.2%
FAS-123R Expense	$0.44	$0.41	$0.10	$0.11	$0.12	$0.14	$0.47	$0.50	$0.60	$0.70
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	43.0	46.0	47.0	48.0	46.0	52.5	55.0	60.0

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

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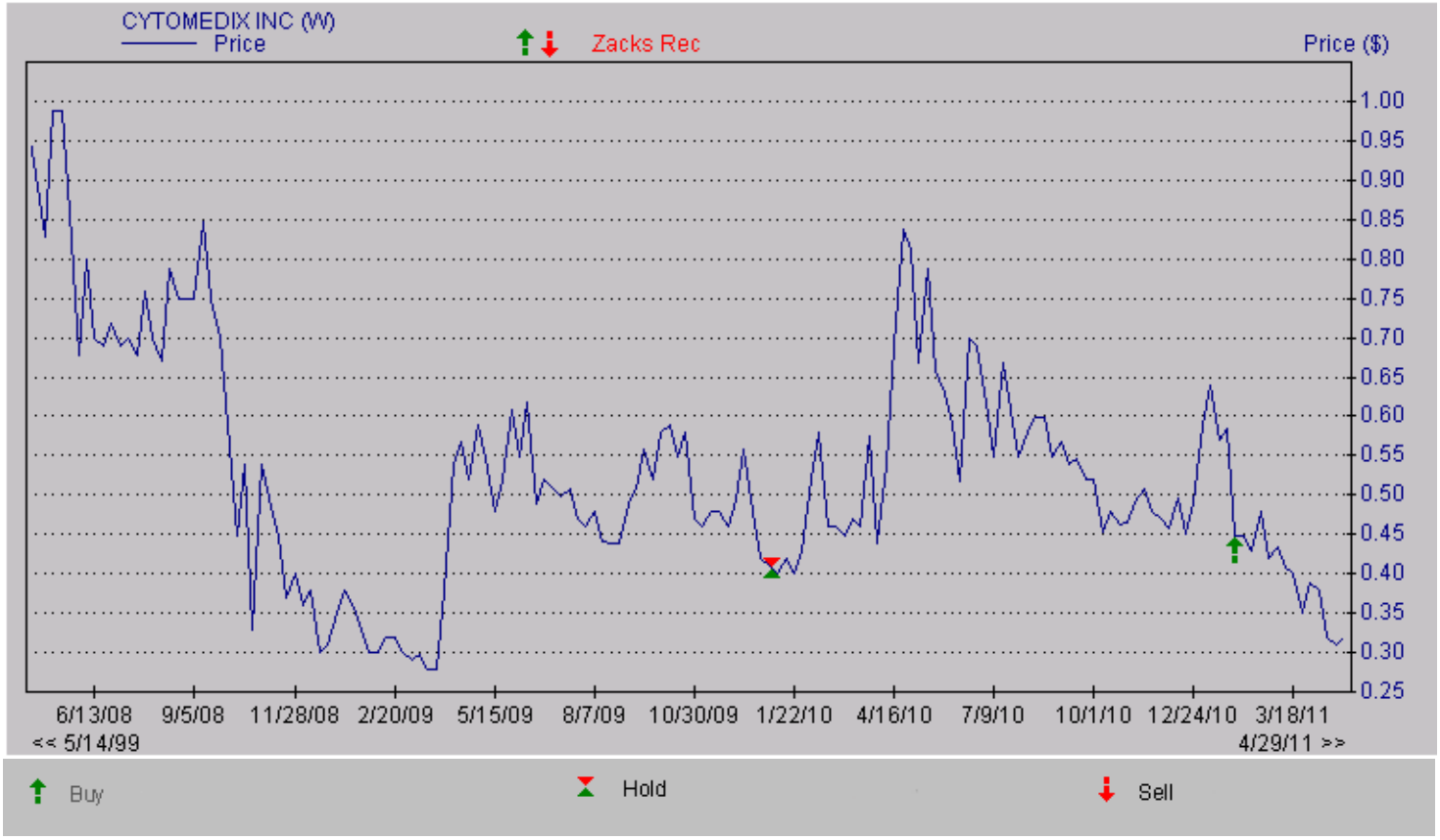

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