Zacks Small-Cap Research

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# Cytomedix, Inc (CMXI-OTC)

## *CMXI: AutoloGel Gets CMS Conditional Coverage, Angel 510(k) For BMAC Filed…*

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 01/30/2011 |
| Current Price (09/01/11) | $0.35 |
| **Target Price** | **$1.00** |

## Update

Cytomedix has had a busy past few weeks. Management recently met with CMS to discuss the national coverage determination resubmission dossier filed in May 2011. At that meeting, CMS laid out its plans to provide Coverage with Evidence Development (CED) for AutoloGel. We see this as very good news for the company, and expect full coverage to go into effect during the first half of 2012.

This morning, Cytomedix announced it had filed a 510(k) application with the U.S. FDA to expand the Angel label to include bone marrow aspirate processing. We see this as an enormous opportunity for the company, allowing expansion into the lucrative orthopedic and cardiovascular surgery markets.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.64** |
| **52-Week Low** | **$0.28** |
| **One-Year Return (%)** | **-32.69** |
| **Beta** | **1.39** |
| **Average Daily Volume (sh)** | **63,500** |
| **Shares Outstanding (mil)** | **51** |
| **Market Capitalization ($mil)** | **$18** |
| **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 (%)** | **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 | 1.4 A | 1.5 E | 1.5 E | 5.8 A |
| 2012 | | | | | 7.3 E |
| 2013 | | | | | 9.1 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 | -$0.02 E | -$0.02 E | -$0.09 A |
| 2012 | | | | | -$0.05 E |
| 2013 | | | | | -$0.03 E |

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

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## WHAT'S NEW

**Update on CMS Reimbursement**

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.

The past few months, Cytomedix has been working with CMS toward the ultimate goal of gaining a full coverage determination for AutoloGel. 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.

We expect CED to go into effect in March / April 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.

**Angel 510(k) For BMAC Filed**

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.

***…Angel Upside Significant…***

Management is planning another 510(k) application later this year for reinfusion of the BMAC. Before Cytomedix took over, Sorin was already seeing real-world use of the Angel device during surgery for total blood management. Approval for reinfusion 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. Harvest Technologies has a similar device. Aastrom uses bone marrow aspirate to develop Treatment Repair Cells (TRCs) used to treat peripheral arterial disease such as critical limb ischemia (CLI) and dilated cardiomyopathy (DCM). 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.

Besides surgical procedures, 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.

However, 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. 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.

## RECOMMENDATION

***…Stock Looks Significantly Undervalued…***

With a current capitalization of only $18 million, we believe the market is far undervaluing Cytomedix. We estimate the company should generate revenues in 2011 of $5.75 million thanks to growing sales of the Angel System and AutoloGel. The current value of only 3x revenues is below the peer-group average of roughly 4-5x revenues, and revenues in 2012 are expected to be up over 25% to over $7 million.

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 $10 million by 2014. B

Based on our DCF analysis, a market capitalization closer to $50 million, or approximately $1.00 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 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 | #REF! | $3.42 | $1.28 | $1.28 | $1.35 | $1.40 | $5.31 | $6.45 | $7.75 | $9.00 |
| *YOY Growth* | N/A | N/A | 16.4% | 22.1% | 16.0% | 15.7% | 55.4% | 21.4% | 20.2% | 16.1% |
| **Product Sales** | **$0.23** | **$3.79** | **$1.37** | **$1.39** | **$1.47** | **$1.52** | **$5.75** | **$7.30** | **$9.10** | **$10.85** |
| YOY Growth | 124.0% | 1574.5% | 2058.7% | 21.5% | 14.0% | 17.7% | 51.8% | 26.9% | 24.7% | 19.2% |
| **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** | **$1.39** | **$1.47** | **$1.52** | **$5.75** | **$7.30** | **$9.10** | **$10.85** |
| YOY Growth | -1.2% | 89.3% | 664.0% | 21.5% | 13.3% | 17.7% | 47.1% | 26.9% | 24.7% | 19.2% |
| Cost of Sales | $0.06 | $1.80 | $0.65 | $0.64 | $0.63 | $0.64 | $2.56 | $2.56 | $3.00 | $3.26 |
| *Product Gross Margin* | 74.1% | 52.5% | 52.7% | 54.2% | 57.0% | 58.0% | 55.6% | 65.0% | 67.0% | 70.0% |
| R&D | $0.23 | $0.42 | $0.06 | $0.04 | $0.06 | $0.06 | $0.22 | $0.26 | $0.30 | $0.35 |
| *% R&D* | 11.0% | 10.6% | 4.4% | 3.0% | 4.1% | 3.9% | 3.9% | 3.6% | 3.3% | 3.2% |
| 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% | 139.9% | 119.0% | 111.8% | 131.2% | 99.3% | 82.4% | 73.7% |
| Operating Income | ($3.45) | ($5.40) | ($1.48) | ($1.24) | ($0.97) | ($0.88) | ($4.57) | ($2.77) | ($1.70) | ($0.76) |
| *Operating Margin* | 0.0% | -138.1% | - | - | - | - | -79.5% | -37.9% | -18.7% | -7.0% |
| Interest & Other Income | $0.19 | ($1.40) | $0.08 | $0.45 | $0.05 | $0.05 | $0.63 | $0.02 | $0.05 | $0.10 |
| Pre-Tax Income | ($3.26) | ($6.80) | ($1.41) | ($0.79) | ($0.92) | ($0.83) | ($3.94) | ($2.75) | ($1.65) | ($0.66) |
| 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 | $0.09 | $0.09 | $0.09 | $0.35 | $0.35 | $0.35 | $0.35 |
| Net Income | ($3.27) | ($9.04) | ($1.50) | ($0.88) | ($1.01) | ($0.92) | ($4.29) | ($3.10) | ($2.00) | ($1.01) |
| *Net Margin* | 0.0% | -231.1% | - | - | - | - | -74.7% | -42.4% | -22.0% | -9.3% |
| **Reported EPS** | **($0.09)** | **($0.23)** | **($0.03)** | **($0.02)** | **($0.02)** | **($0.02)** | **($0.09)** | **($0.05)** | **($0.03)** | **($0.01)** |
| YOY Growth | - | 150.7% | - | - | - | - | -63.5% | -37.0% | -42.8% | -53.4% |
| FAS-123R Expense | $0.44 | $0.41 | $0.10 | $0.04 | $0.03 | $0.05 | $0.22 | $0.25 | $0.30 | $0.35 |
| *EPS Impact of FAS-123R* | *($0.01)* | *($0.01)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.01)* |
| Weighted Ave. Shares Out | 35.1 | 38.7 | 46.1 | 50.6 | 51.5 | 53.0 | 50.3 | 57.5 | 65.0 | 70.0 |

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

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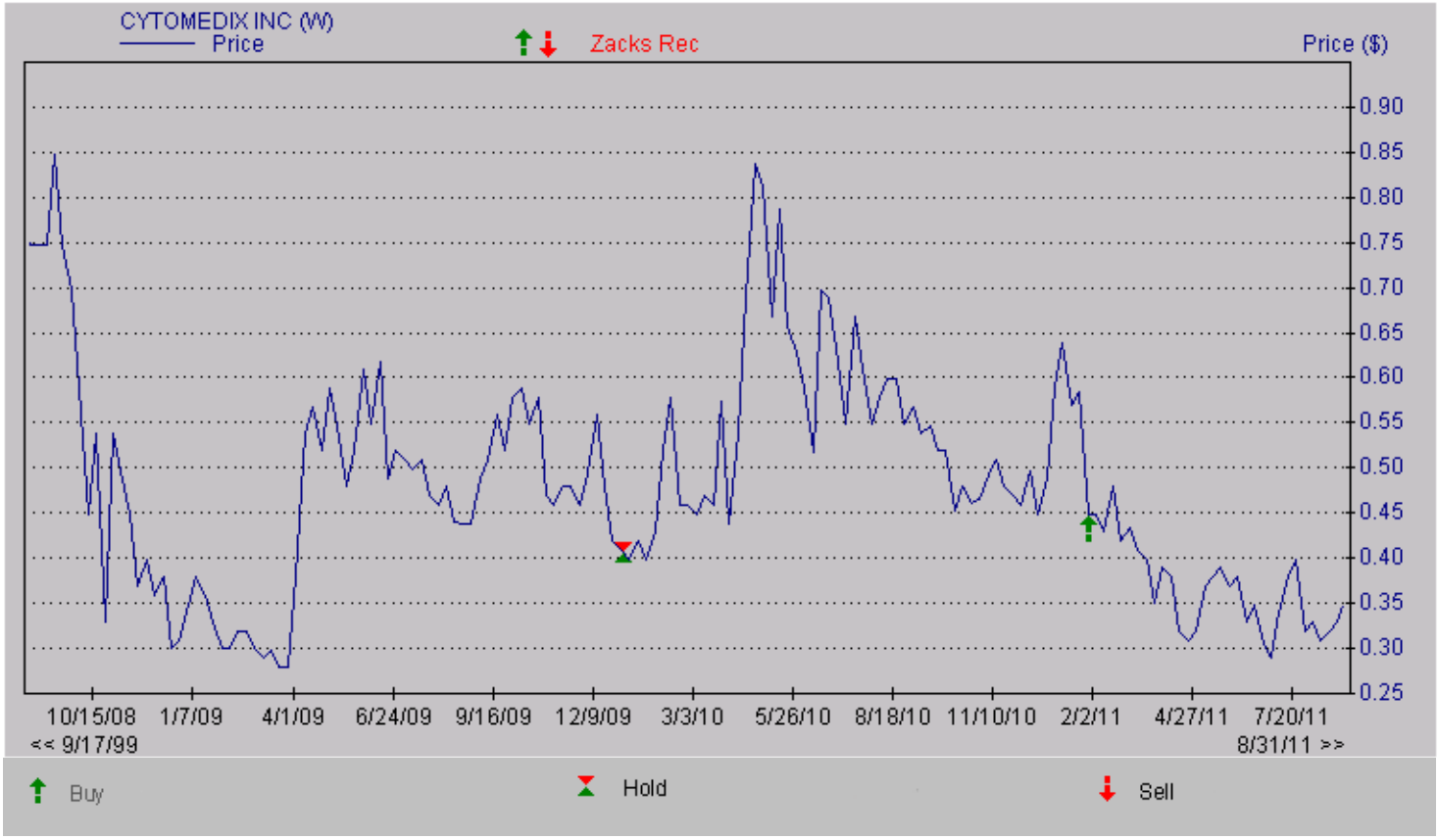
## HISTORICAL ZACKS RECOMMENDATIONS

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