Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTC)

CMXI: Cytomedix Announces Second Business Reorg, Focus Turns To AutoloGel.

UPDATE

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (09/18/13)	$0.40
Target Price	**$1.00**

On September 17, 2013, Cytomedix, Inc. announced it would restructure its R&D activities in the coming months to reduce cash burn and focus on profitability. This is the second major business reorganization in as many months for the company. Last month, the company announced it had signed a commercial partnership for its Angel, whole blood Concentrated PRP System.

Both moves are designed to move the company toward profitability as it prepares to dramatically ramp-up operations around AutoloGel, the company's point-of-care autologous PRP wound care product.

SUMMARY DATA

52-Week High	**$1.00**
52-Week Low	**$0.39**
One-Year Return (%)	**-58.38**
Beta	**0.31**
Average Daily Volume (sh)	**74,625**
Shares Outstanding (mil)	**105**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**21.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**High**
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)
2012	3.0 A	3.7 A	1.8 A	2.1 A	10.6 A
2013	2.3 A	2.4 A	1.4 E	0.9 E	7.0 E
2014					6.2 E
2015					10.9 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.07 A	-$0.09 A	-$0.04 A	-$0.04 A	-$0.24 A
2013	-$0.05 A	-$0.05 A	-$0.04 E	-$0.04 E	-$0.18 E
2014					-$0.12 E
2015					-$0.09 E

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WHAT'S NEW

On September 17, 2013, Cytomedix, Inc. announced it would restructure its R&D activities in the coming months to reduce cash burn and focus on profitability. This is the second major business reorganization in as many months for the company. Last month, the company announced it had signed a commercial partnership for its Angel, whole blood Concentrated PRP System. Both moves are designed to move the company toward profitability as it prepares to dramatically ramp-up operations around AutoloGel, the company's point-of-care autologous PRP wound care product.

Winding-Down RECOVER-Stroke

The primary focus of yesterday's announced reorganization will be to wind-down financial support of the current phase IIb RECOVER-Stroke trial and the underlying ALDH Bright Cell technology. It's a dramatic about-face from the company's bold acquisition of Aldagen back in February 2013. At the time of the Aldagen deal, Cytomedix told us that the company was embracing regenerative medicine head-on, with the ALDH Bright Cell technology as the center of the company's new focus on developing a pipeline of cardiovascular therapeutic products. The leading candidate was ALD-401, an autologous stem cell therapy based on ALDH Bright Cells for the treatment of patients post ischemic stroke with persistent neurological deficits.

But clinical trials cost money, and despite positive animal model and Phase I safety data in stroke, the company struggled to enroll patients in the trial. RECOVER-Stroke (NCT01273337) had a strict entry criteria. For example, to enroll in the study patients have to remain in the hospital overnight for observation. Bear-in-mind, this is 11-17 days after the actual stroke event. Patients also cannot have >50% stenosis or ulcerated plaque in their cortid artery, or have had recent cardiovascular events or renal insufficiency. Things like hemoglobin and platelet counts must all be within normal ranges. All concomitant medications must be stopped, such as warfarin, heparin, immuno-suppressants, and anti-angiogenic drugs. Finally, the study requires that patients undergo a bone marrow harvesting procedure to create the autologous ALD-401. The invasive bone marrow aspiration and the fact that patients then had to have an intracarotid / MCA infusion two days later turned patients and physicians off.

RECOVER-Stroke began enrollment in 2011. At the time of the Aldagen acquisition in February 2012, only six patients had been enrolled. Management believed that making some changes to the entry criteria (primarily around age and location of the stroke in the brain) and finding additional sites would speed enrollment. But it didn't work. A year after the deal, in March 2013, the number had grown to only 26 patients. As of today, the company tells us 39 patients have been enrolled. The original plan was to enroll 100 patients in a 60:40 randomization between ALD-401 and the control.

The company's present intention is to proceed with enrollment in the trial through 2013 year end with an enrollment goal of 50 patients, effectively cutting the size of RECOVER-Stroke in half. Depending on the success of these efforts to pursue strategic options for continuing its clinical programs, Cytomedix may determine to conclude the study beyond year end and unblind the study data at the assessments of the primary efficacy endpoint. The primary efficacy endpoint is recovery of mental and physical function at 90 days, with durability and safety endpoints at 3, 6, 9, and 12 months.

Beyond RECOVER-Stroke, Cytomedix is exploring a range of strategic options for continuing its clinical programs beyond year end 2013, which options may include, among others, technology transfer, spinout, licensing or other similar transactions involving the underlying technology. It's a dramatic about-face from the February 2012 acquisition. But the truth of the matter is that RECOVER-Stroke was simply costing too much money based on the slow pace of enrollment, and it was hurting the stock price.

All is not lost at Aldagen though. The company will continue to support third party funded studies based on ALDH Bright Cells. For example, the ongoing Phase II PACE (Patients with Intermittent Claudication Injected with ALDH Bright Cells) study, is funded by the National Heart, Lung and Blood Institute, and is looking at the safety and value of the technology for the treatment of Intermittent Claudication, a form of peripheral arterial disease. The 80 patient PACE trial is being managed by the Cardiovascular Cell Therapy Research Network (CCTRN). The primary endpoints of the study are safety and the change in peak walking time at 6 months compared to baseline. Management believes enrollment in this study should complete around the end of the year and offer data seven months later.

Angel Monetized

Last month, the company announced a commercial partnership on Angel. Cytomedix announced that it had signed a five-year exclusive worldwide licensing agreement with Arthrex, Inc., for the commercialization of the Angel Concentrated PRP System. Under the terms of the agreement, Cytomedix will retain ownership of Angel, but has granted Arthrex an exclusive worldwide right to develop, manufacture, and commercialize the product. Arthrex paid Cytomedix an upfront payment of $5 million, and will make royalty payments on future sales in the low teen range (we model 13.5%). The term of the agreement is five years, with a three year renewal option.

Cytomedix wasn't exactly struggling with Angel on its own. The company generated roughly $8 million in revenues with only 10 full-time sales representatives over the past 12 months. But similar to RECOVER-Stroke, ramping-up Angel required a significant investment by the company. Cytomedix reported only $3.4 million in cash as of June 2013. Compare that to Arthrex, Inc. with its 2,000 sales representatives and a full suite of orthopedic and orthobiologic products, and Cytomedix believed that Angel can do far better in the hands of Arthrex than staying in-house.

We think there are several things Arthrex can do to drive Angel sales. These include increasing the selling price, ramping-up marketing and promotion, and co-mingling the product with other Arthrex products to create custom kits or solutions for orthopedic surgeons. In Cytomedix hands, Angel looked like a $15 million product at best. In the hands of Arthrex, we think Angel could do closer to $50 million. So even at a low teens royalty, the net cash profits to Cytomedix on Angel should be higher as a result of this transaction.

Focus Shifts To AutoloGel

The two strategic decisions made by management above are designed to reduce cash burn and increase profitability. By winding-down RECOVER-Stroke, Cytomedix will save an estimated $4-5 million in R&D in 2014. By out-licensing Angel, Cytomedix picked-up $5 million in cash and hopefully will increase future payments down the line. Both decisions were made to streamline the organization and refocus efforts on the now reimbursed AutoloGel product.

The company believes it is finally in position to see significant AutoloGel growth in the coming quarters. It has been a long and arduous process for management gaining CMS reimbursement for AutoloGel, but there have clearly been signs of progress over the past year, and the long-waited finish line is visible.

For example, on July 10, 2013, Cytomedix, Inc. announced that CMS has issued proposed payment regulations under the Physician Fee Schedule (PFS) and the Hospital Outpatient Prospective Payment System (HOPPS) that include proposed guidelines covering Medicare reimbursement for AutoloGel. We believe this was a net-net positive event for the company (see our July 10, 2013 Seeking-Alpha article). The company's registry program is underway and already collecting data. Cytomedix previously announced they are working with wound care centers around the country to build-up the program.

But the chronic wound market may be in for a major structural change in 2014 if new proposed changes by CMS to the Outpatient Prospective Payment System (OPPS) hold. Under the new plan, CMS is suggesting reimbursement of skin substitutes be bundled to include the graft and the procedure in one payment at only $840. That would be a major impediment to hospitals using products like Dermagraft (Shire Pharma) and Apligraf (Organogenesis), both of which cost over $1,500 for the graft alone. AutoloGel costs only $450 per use, which leaves potential for reimbursement for the procedure at a comparable rate.

If this new proposed policy holds, which we think it can, AutoloGel immediately jumps from non-coverage and "extremely disadvantaged" in 2012 to full-coverage and "extremely advantaged" in 2014. Products like Dermagraft and Apligraf post worldwide sales over $100 million. The data suggest AutoloGel compares well, if not superior to these two market leaders. These changes could have a profound impact on how physicians treat chronic wounds, and AutoloGel could easily capture 5-10% share in this $600 million market. It is clear now why management at Cytomedix is looking to shift focus and concentrate on AutoloGel.

Conclusion

Back in August 2013, we speculated that Cytomedix may make a decision to cut the size of RECOVER-Stroke (see our August 8th Report). Therefore, we are not surprised by the announcement yesterday to wind the study down and seek alternatives to fund the Aldagen pipeline. The market simply was not assigning any value to this program and it was burning valuable cash that could be re-prioritized to AutoloGel.

In the end, ALD-401 may be a breakthrough cell therapy candidate for stroke. That still remains to be seen. But 50 patients (give-or-take a few) should be enough to get a clear picture on whether or not it is worth continuing to spend money in this area. If RECOVER-Stroke fails, like the market seems to think it will, then cutting the size of the trial in half will prove to be a wise decision. If it succeeds, Cytomedix will still be able to reap the rewards and big pharma partners will come knocking.

From a go-forward standpoint, the deal to partner Angel makes sense. Although Angel was the primary driver of the top-line over the past two years, we believe that Arthrex can take the product to levels far beyond what Cytomedix can obtain in-house. The sales force promoting Angel at Arthrex will be, at a minimum, ten-fold to where it was prior to the deal. Thus, although Cytomedix will only collect low-teens royalties on gross sales, by 2015 we believe the net cash flows from the deal will be positive compared to if Cytomedix continued to promote Angel alone.

The light at the end of the tunnel seems to have finally emerged for AutoloGel, so much so that management feels confident enough to monetize Angel, wind-down Aldagen, and go all-in from a commercial standpoint. With favorable reimbursement, AutoloGel goes from near zero sales to potentially tens of millions. And with CMS about to dramatically change the entire wound care landscape in 2014, Cytomedix might just be sitting on pocket aces.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E
Med Product Sales	**$7.24**	**$2.25**	**$2.36**	**$0.95**	**$0.20**	**$5.76**	**$3.00**	**$6.00**
YOY Growth	22.7%	33.6%	27.0%	-44.2%	-90.1%	-20.4%	-47.9%	100.0%
Aldagen Pipeline	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Royalties & Collabs	**$3.32**	**$0.06**	**$0.06**	**$0.49**	**$0.66**	**$1.27**	**$3.21**	**$4.43**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$2.32**	**$2.42**	**$1.44**	**$0.86**	**$7.03**	**$6.21**	**$10.43**
YOY Growth	45.8%	-23.2%	-34.2%	-18.4%	-59.3%	-33.5%	-11.7%	67.9%
Cost of Sales	$3.90	$1.27	$1.35	$0.43	$0.08	$3.13	$1.20	$2.28
Product Gross Margin	46.2%	43.8%	42.7%	55.0%	58.0%	45.6%	60.0%	62.0%
R&D	$3.39	$0.90	$1.23	$1.25	$1.30	$4.68	$5.50	$6.00
% R&D	32.1%	38.9%	50.6%	87.0%	152.0%	66.5%	88.6%	57.6%
SG&A, Other Fees	$16.16	$5.15	$4.50	$3.80	$3.85	$17.30	$17.00	$18.00
% G&A	152.9%	222.1%	185.7%	264.6%	450.3%	246.1%	273.8%	172.7%
Operating Income	($12.88)	($5.00)	($4.66)	($4.05)	($4.39)	($18.11)	($17.53)	($15.89)
Operating Margin	-121.9%	-	-	-	-	-257.6%	-282.3%	-152.4%
Interest & Other Income	($6.89)	($0.33)	($0.37)	($0.35)	($0.30)	($1.35)	($1.00)	($1.00)
Pre-Tax Income	($19.76)	($5.33)	($5.03)	($4.40)	($4.69)	($19.46)	($18.53)	($16.89)
Taxes	$0.02	$0.00	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0.0%	0.0%
Preferred A, B, D, E	$0.01	$0	$0	$0	$0	$0	$0	$0
Net Income	($19.80)	($5.34)	($5.03)	($4.40)	($4.69)	($19.46)	($18.53)	($16.89)
Net Margin	-187.4%	-	-	-	-	-276.8%	-298.4%	-162.0%
Reported EPS	**($0.24)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.18)**	**($0.15)**	**($0.11)**
YOY Growth	217.7%	-	-	-	-	-26.8%	-16.2%	-24.1%
Weighted Ave. Shares Out	81.9	99.1	104.6	107.0	109.0	110.0	125.0	150.0

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

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