Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTC)

CMXI: Focus Turns To AutoloGel and CMS Decision In Two Weeks.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (11/13/13)	$0.36
Target Price	**$1.00**

UPDATE

On or before November 27th, the Center for Medicare and Medicaid Services (CMS) will issue a final decision on reimbursement for advanced wound care products starting in 2014. This has a profound effect on Cytomedix and where sales of AutoloGel head over the next few years. We would view strict packaging laws and a reimbursement price at or around $875 (the preliminary decision proposed price) as enormously positive for driving uptake of AutoloGel. Cytomedix is also waiting for the final payment classification under the Hospital Outpatient Prospective Payment System (HOPPS) that could open up significant doors previously shut to the company's sole remaining product in 2014.

We believe shares of Cytomedix are cheap and attractive, and the final CMS decision in late November could be our catalyst to upgrading the shares – outcome dependent.

SUMMARY DATA

52-Week High	**$0.88**
52-Week Low	**$0.36**
One-Year Return (%)	**-50.07**
Beta	**-0.03**
Average Daily Volume (sh)	**72,405**
Shares Outstanding (mil)	**105**
Market Capitalization ($mil)	**$38**
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	3.4 A	1.9 E	10.0 E
2014					12.6 E
2015					20.9 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	-$0.05 A	-$0.04 E	-$0.18 E
2014					-$0.12 E
2015					-$0.08 E

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WHAT'S NEW

Financial & Business Update

On November 12, 2013, Cytomedix, Inc. (CMXI) reported financial results for the third quarter 2013. Total revenues in the quarter were $3.366 million, up 91% from the third quarter 2012. Revenues were driven by $2.926 million in product sales derived from both Angel and AutoloGel and $0.440 million in licensing fees, royalties, and other revenue related to the company's licensing agreement and commercial partnership with Arthrex, Inc. signed in August 2013. Below we provide a little more granularity on the revenue line:

Product Sales	***$0.116 million in AutoloGel sales (+7% YoY)***
	$0.911 million in Angel sales prior to the Arthrex, Inc. agreement
	$1.294 million in one-time sales to Arthrex, Inc. for existing placed units
	$0.2xx million in new machines sold to Arthrex, Inc. post the agreement
	$0.4xx million in disposables for existing Angel machines post the agreement
Other Revenues	***$0.188 million in royalties on Angel product sales sold to Arthrex, Inc. (~ low teens royalty)***
	$0.129 million in transition revenue related to the August 2013 Arthrex, Inc. agreement
	$0.067 million in licensing fees

Gross margin in the third quarter was only 3.7%, down significantly from the 42.7% reported in the second quarter 2013 and 41.7% reported in the third quarter 2012. Gross margin was negatively impacted by the contractual selling price of Angel products and existing inventory and related equipment to Arthrex, Inc. during the quarter, which the company noted was at book value (zero-margin). Gross margin on the AutoloGel business was consistent with historical averages at around 75%. Going forward, we expect the "at cost" transfer price of Angel equipment to Arthrex, Inc. will continue to negatively impact reported gross margin, although this should be offset more and more each quarter as royalty payments from Arthrex to Cytomedix begin to grow. Despite the reported very low margin in the quarter, we are pleased to see AutoloGel margins remaining high and believe that royalty revenue from Arthrex will help improve overall profitability at Cytomedix starting in 2014.

Operating expenses totaled $5.126 million during the third quarter, consisting of $0.923 million in R&D and $4.203 million in SG&A. Operating expenses have been flat to down over the course of the year. The transition of substantially all of the Angel business to Arthrex, Inc. will help reduce overhead at the company going forward, although we expect this will be offset entirely by management funneling existing resources to AutoloGel. The company currently has 9 full-time sales representatives promoting AutoloGel. Management's goal is to double that number in 2014. We expect R&D expense to drop in 2014 as the company plans to effectively halt the Phase 2 RECOVER-Stroke trial with ALD-401 at roughly 50 patients at the end of the year.

Net loss for the third quarter ended September 30, 2013 totaled $4.975 million, or $0.05 per share based on 104.9 million shares outstanding. Net loss as improved slightly each quarter in 2013. From an operations standpoint, the company burned only $8.087 million in cash during the nine months ended September 30, 2013. We note this includes the $5.000 million upfront payment from Arthrex, Inc. to Cytomedix in August 2013.

As of September 30, 2013, the company held cash and short-term investments of approximately $4.697 million. We see the existing cash position as sufficient to fund operations into January 2014. Accordingly, we believe the company will require new capital prior to the end of the year to fund operations in 2014. As of October 31, 2013, the basic share count stood at 105.4 million, with another 8.7 million in stock options (at $1.28 per share) and 17.9 million warrants (the large majority well below strike). We believe the company needs to secure between $5 and $10 million to fund operations comfortably in 2014.

We remind investors that the company has a $15 million common stock purchase agreement (CSPA) active with Lincoln Park Capital Fund, LLC. However, the minimum floor price for this transaction has been set to $0.45 per share, so this is not a current option for the company.

INVESTMENT THESIS

Will AutoloGel Go From 'Zero' to 'Hero' With CMS Decision?

The two strategic decisions made by management in August (to out-license Angel) and September 2013 (to wind-down Aldagen) 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. As a reminder, the process for reimbursement and granting of National Coverage Determination (NCD) starts with the granting of the temporary reimbursement coding and claims payment instructions. CMS put this memo out in March 2013. The assignment of a Healthcare Common Procedure Coding System (HCPCS) establishes the reimbursement mechanism for physicians and other providers submitting claims for services provided to Medicare beneficiaries. The next step after that is the payment procedure. This is what Cytomedix released in July 2013. The press release was a bit of a mixed-bag:

- With respect to physicians' offices, CMS has proposed that Medicare Administrative Contractors (MACs) determine the payment amount for AutoloGel for claims as they are submitted. Historically, Medicare contractors have paid these types of claims based on product invoices presented by the healthcare provider. That's perfect! Cytomedix will essentially get paid under the Physician Fee Schedule for what they bill - around $450 per single use. This took effect July 1, 2013. That means that Cytomedix can immediately now go out and promote AutoloGel to physicians, mostly podiatrists and wound-care specialists, for in-office use of AutoloGel and get reimbursed full price for each sales.

- For hospital outpatient services, CMS has placed the reimbursement code for AutoloGel in an Ambulatory Payment Classification (APC) that provides limited reimbursement for use of the product. Therefore, under the HOPPS guideline, AutoloGel will be reimbursed only comparable to a Level-2 debridement product, reimbursement of which is less than $100 per use. That puts Cytomedix at a significant disadvantage trying to charge $450 for a product hospitals are only authorized to reimburse at around $100 per use. Over the past few months, Cytomedix has been in active discussion with CMS to revise the APC listing to authorize reimbursement of AutoloGel similar to a skin substitute, which would put the reimbursement for the product and associated application service in the area of $875 to $1375 per use.

Earlier in the year, CMS proposed switching wound care reimbursement from the current pay-for-service model, in which the treating physician bills the government based on the number and type of procedures performed, to a pay-for-performance model in which reimbursement is fixed for a given diagnosis. This change, intended to incentivize physicians to pursue the most cost-effective treatment modalities and minimize the nation's health bill, will dramatically change the wound care market by shifting market share away from high-tech products with little demonstrated therapeutic benefit to those with more cost-effective solutions.

In 2014, CMS is proposing packaging skin substitutes with their associated surgeries, similar to how implantable biologics were bundled with surgery in 2009. The agency states, *"We see no reason to distinguish skin substitutes from implantable biologics for OPPS packaging purposes based on the clinical application of individual products."* Packaging payments for skin substitutes into the APC payment for the related surgical procedures would result in a total prospective payment that is more reflective of the average resource costs of the procedures because prices for these products vary significantly from product to product. Packaging would also promote more efficient resource utilization by hospitals and would be more consistent with the treatment of similar products under the OPPS. The total reimbursement for skin substitutes and the procedure has been proposed at $874.

Therefore, Under CMS' proposal for packaging, far more expensive products like Dermagraft (Shire Pharma), Apligraf (Organogenesis), and new products like Grafix (Osiris Therapeutics), will become significantly disadvantaged, as all these products cost $1,500 or more. Under the current reimbursement system, hospitals are reimbursed $250 to $500 for the cost of the medical procedure, and are separately reimbursed for the cost of the graft for a total reimbursement of $2,000 to $2,225. The proposed bundled payment of $874 falls far short of the cost of the graft alone. We believe it will be difficult for these manufacturers to reduce their prices sufficiently to be attractive to caregivers in a bundled care environment. Two dermatology KOLs we've spoken with believe that the cost of manufacturing these grafts is in excess of $1,000. As we see it, that's going to create a very challenging sales environment for these products, and a major shift toward cheaper and similar efficacy products.

Finally, CMS moving to a "pay for performance" model could eventually cap the entire reimbursement for "healing a diabetic foot ulcer or venous leg ulcer to something like $3,000 or $4,000. Above we noted that Apligraf is eligible for reimbursement up to six times in the course of treating a VLU. Things are going to change in our view. The leading products are on their way out. A final decision from CMS is expected on or before November 27, 2013. If the final decision is consistent with the preliminary decision, and the reimbursement under HOPPS is revised to a more competitive classification, then AutoloGel immediately jumps from "extremely disadvantaged" on a reimbursement standpoint to "extremely advantaged" given the cost of only $450 per use and the potential for reimbursement at twice that level. We have always noted that 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% 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 in September 2013 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 poised to dramatically change the entire wound care landscape in 2014, Cytomedix might just be sitting on a winner.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
Med Product Sales	**$7.24**	**$2.25**	**$2.36**	**$2.93**	**$1.20**	**$8.74**	**$9.40**	**$16.50**
YOY Growth	22.7%	33.6%	27.0%	71.8%	-40.6%	20.7%	7.6%	75.5%
Aldagen Pipeline	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Royalties & Collabs	**$3.32**	**$0.06**	**$0.06**	**$0.44**	**$0.67**	**$1.24**	**$3.21**	**$4.43**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$2.32**	**$2.42**	**$3.37**	**$1.87**	**$9.98**	**$12.61**	**$20.93**
YOY Growth	45.8%	-23.2%	-34.2%	91.3%	-11.0%	-5.6%	26.4%	65.9%
Cost of Sales	$3.90	$1.27	$1.35	$2.82	$1.05	$6.49	$7.15	$11.63
Product Gross Margin	46.2%	43.8%	42.7%	3.7%	12.5%	25.7%	23.9%	29.5%
R&D	$3.39	$0.90	$1.23	$0.92	$1.30	$4.35	$3.00	$3.25
% R&D	32.1%	38.9%	50.6%	27.4%	69.4%	43.6%	23.8%	15.5%
SG&A, Other Fees	$16.16	$5.15	$4.50	$4.20	$3.85	$17.70	$16.50	$17.00
% G&A	152.9%	222.1%	185.7%	124.9%	205.7%	177.4%	130.8%	81.2%
Operating Income	($12.88)	($5.00)	($4.66)	($4.61)	($4.34)	($18.62)	($14.08)	($10.98)
Operating Margin	-121.9%	-	-	-	-	-186.6%	-111.7%	-52.5%
Interest & Other Income	($6.89)	($0.33)	($0.37)	($0.36)	($0.30)	($1.36)	($1.00)	($1.00)
Pre-Tax Income	($19.76)	($5.33)	($5.03)	($4.97)	($4.64)	($19.98)	($15.08)	($11.98)
Taxes	$0.02	$0.005	$0	$0.000	$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)	($4.97)	($4.64)	($19.98)	($15.08)	($11.98)
Net Margin	-187.4%	-	-	-	-	-200.2%	-119.6%	-57.3%
Reported EPS	**($0.24)**	**($0.05)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.18)**	**($0.12)**	**($0.08)**
YOY Growth	217.7%	-	-	-	-	-24.9%	-33.6%	-33.8%
Weighted Ave. Shares Out	81.9	99.1	104.6	104.9	109.0	110.0	125.0	150.0

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

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