Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTCQX)

CMXI: CMS Payment Rules Open Doors For AutoloGel…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (12/02/13)	$0.54
Target Price	**$1.00**

UPDATE

On December 2, 2013, Cytomedix, Inc. (CMXI) announced that the Centers for Medicare & Medicaid Services (CMS) has issued final Medicare payment regulations for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (PFS) that will take effect on January 1, 2014. We believe these new payment rules dramatically enhance the commercial viability of Cytomedix' AutoloGel (autologous platelet-rich plasma) for the treatment of chronic wounds, including diabetic foot ulcers, venous leg ulcers, and pressure ulcers.

We believe shares of Cytomedix are cheap and attractive. We remain Neutral on the shares until a final decision is made on the RECOVER-Stroke trial with ALD-401, but our target is $1.00 per share.

SUMMARY DATA

52-Week High	**$0.88**
52-Week Low	**$0.36**
One-Year Return (%)	**-37.50**
Beta	**-0.20**
Average Daily Volume (sh)	**162,703**
Shares Outstanding (mil)	**105**
Market Capitalization ($mil)	**$58**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**14**
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

CMS Payment Rules Open Key Doors For AutoloGel

On December 2, 2013, Cytomedix, Inc. (CMXI) announced that the Centers for Medicare & Medicaid Services (CMS) has issued final Medicare payment regulations for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (PFS) that will take effect on January 1, 2014. These regulations were published to the federal register website on November 27, 2013. Below we link these final regulations for both HOPPS and PFS.

- ⇨ CMS-1601-FC: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System (PDF, 2.6MB, 1281 pages)

- ⇨ CMS-1600-FC: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and Other Revisions to Part B (PDF, 3.6MB, 1369 pages).

We believe these new payment rules dramatically enhance the commercial viability of Cytomedix' AutoloGel (autologous platelet-rich plasma) for the treatment of chronic wounds, including diabetic foot ulcers, venous leg ulcers, and pressure ulcers. For example, under the new classification in HOPPS as a Level-2 skin substitute (APC-0327), AutoloGel will be reimbursed at an average rate of $411 per treatment encounter. This is roughly a five-fold increase from the proposed $83 per treatment encounter under the proposed guidelines that came out earlier in the year that incorrectly classified AutoloGel as a Level-2 debridement product, and a greater-than five-fold increase over the average reimbursement under HOPPS of $74 in 2013. We believe this represents approximately 60% of the Medicare market for the treatment of chronic wounds.

Under the PFS, the remaining 40% of the Medicare market, AutoloGel will reimbursed and claims will be paid based on charges submitted by physician offices. We suspect that most physicians will claim between $425 and $450 per treatment encounter. This is an enormous improvement in reimbursement from AutoloGel's status at the beginning of 2013 when most claims for the product were denied. We remind investors that this change in policy took place on July 10, 2013, and on Cytomedix' third quarter earnings call, CEO, Marty Rosendale, noted the company has already begun wound care physicians in their offices, as well as previous efforts to promote the product at Long Term Acute Care Facilities and with Veteran's Health Administration Hospitals.

Efforts will now be expanded to promote AutoloGel into the hospital outpatient market and free-standing wound care clinics in 2014. Cytomedix continues to develop launch strategies by focusing on key high density markets that management believes will offer the greatest revenue generating options. The company has nine people in its specialty sales force, which includes one newly hired marketing director, seven account executives, and one VA specialist. Cytomedix expects to double the size of its sales force during 2014 to accommodate the growing number of AutoloGel treatment sites. Additionally, management continues to note being in specialized partnership discussions and we anticipate the signing of key strategic relationships shortly.

CMS Moves Toward Packaging, But Less Boldly Than Predicted

In October 2013, we wrote an article for Seeking-Alpha noting that, "Big Changes" were coming to the wound care market in 2014. We based this belief on the proposed payment rules that CMS published in July 2013. The proposed rules made it clear that CMS was moving toward packaging the product cost in with the application payment to create one bundled payment. It was a move we applauded, and the first step is moving the U.S. healthcare system 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 protocol, intended to incentivize physicians to pursue the most cost-effective treatment modalities and minimize the nation's health bill, is how much of Europe and the rest of the world reimburse things like chronic wounds. The change shifts the market share away from expensive or high-tech products with little demonstrated therapeutic benefit to those with more cost-effective solutions.

Under the proposed guidelines, CMS proposed packaging skin substitutes with their associated surgeries similar to how implantable biologics were bundled with surgery in 2009. 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 HOPPS. The total reimbursement for skin substitutes and the procedure has been proposed at $874.

But significantly lobbying and political pressure, mostly from companies with high-priced skin substitute products or physician's organizations racking in big bucks under the "pay for service" plan forced CMS to acquiesce. Instead of one proposed payment of $874 per treatment procedure, CMS gave us a tiered-system of "low-priced" and "high-priced" products, classified into Level-2 and Level-3 categories. Level-2 skin substitutes, which include the aforementioned AutoloGel, as well as the Oasis Wound Matrix, and Theraskin products, are reimbursed at $411 per procedure. Level-3 skin substitutes, which include market leaders Shire's (SHPG) Dermagraft and privately-held Organogenesis' Apligraf, are reimbursed at $1371 per procedures.

These reimbursement levels are up to 100 cm^2 of product. This encompasses an estimated 90% of the wound care market, as products like Dermagraft and Apligraf are typically supplied in 37.5 cm^2 or 44 cm^2 sheets, respectively. When greater than 100 cm^2 of product is required, the reimbursement is increased to $2,260.

Economics Favor AutoloGel

Despite not being reimbursed on an equal level with Dermagraft or Apligraf, we think the economics imposed by the new CMS payment rules dramatically favor Cytomedix and AutoloGel. For example, in our conversations with Cytomedix CEO, Marty Rosendale, he tells us that Cytomedix can achieve 70% or greater gross margin under the new HOPPS and PFS combined payment system. Baked into the new packaged payment rules are the application cost. This is the reimbursement to the physician for their time and doing the procedure. So the wholesale cost from Cytomedix to the physician's office or wound care center must be low enough that the physician or center can maintain profitability at the current payment, but still high enough that the manufacturer has an economically viable business model. If Cytomedix thinks it can still achieve 70% or greater gross margin under this new system, it tells us the cost-of-good on AutoloGel is less than $100.

Counter that incredible low cost versus products like Dermagraft and Apligraf which may cost $1,000 or more and investors can get a sense of where the market will shift starting in 2014. Under the old model, Shire charged roughly $1,620 for Dermagraft. Organogenesis charged even more for Apligraf at around $1,675. Physcians were typically claiming $250 per applications, putting the total cost of the product to CMS at between $1,870 and $1,930. Under the new model, this is capped at $1,371. If physicians still want to make $250 for a Dermagraft or Apligraf procedure, this means Shire and Organogenesis will have to wholesale the product for $1,120 or less. That's an estimated 33% price drop. It remains to be seen if either product is economically viable at this level. Keep in mind that products like Dermagraft must be keep in -75° C freezer, so physicians have added carrying costs when they use the product. If Shire plays hardball with the physicians on Dermagraft price, the physicians will migrate to products that provide better profits to the facility or practice. If Shire caves and allows the physicians or center to earn a handsome profit, their gross margins plummet.

We have heard that Osiris Therapeutics' (OSIR) Grafix has costs-of-good well in excess of $1,000 per unit. Grafix received a two-year pass through on the new CMS payment rules, but Grafix has no national coverage determination that we could find, so the pass through is moot. We continue to believe Grafix will be a commercial flop for Osiris. The future of MiMedx' (MDXG) Epifix, which received a one-year pass through on the CMS payment rules, also remains in-doubt. Contrast this to use of AutoloGel that allows the physician the added reimbursement of the phlebotomy, on top of standard debridement procedures, and we think Cytomedix is in a good position right now. We think Cytomedix has the flexibility in its manufacturing and pricing to allow the physician or center to earn a net $200 profit on each application, and still have handsome economics themselves.

From 'Zero' to 'Hero' With CMS Decision

We have always noted that the data suggest AutoloGel compares well, if not superior to market leading products, Dermagraft and Apligraf. The issue in the past has always been reimbursement. Until recently, the majority of physician's claims under PFS have been denied, and reimbursement under HOPPS was barely sufficient to cover the manufacturing cost of the product. This forced Cytomedix to focus attention on the cash-pay or private insurance market. Only private insurance typically follows Medicare's lead, and cash-pay represents less than 10% of the entire market for chronic wounds. In fact, Medicare is approximately two-thirds of the market. Cytomedix just had two significant doors kicked-open for them by CMS and the new payment rules to take effect January 1, 2014. Not only are there now pathways for reimbursement under both PFS and HOPPS, but AutoloGel might have one of the best economics in the industry under the new rules.

Investors may have noticed that on November 21, 2013, Cytomedix entered into a convertible note transaction to raise $3.0 million in cash. The company also has a $15 million common stock purchase agreement (CSPA) active and accessible with Lincoln Park Capital Fund, LLC. With the new CMS payment rules now finalized, we believe Cytomedix is in a much better strategic position to negotiate with potential partners. The debt offering and CSPA provide some flexibility to the company during negotiations.

Keep in mind, skin substitutes did approximately $600 million in sales in 2012. AutoloGel has less than 0.1% market share. The changes we've outlined above could get AutoloGel to 5% market share in the next few years. That's a $20 to $25 million product, with 70% gross margin. We think larger players in the wound care market, including Shire, Kinetic Concepts, Organogenesis, or Smith & Nephew will take notice.

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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