Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTCQX)

CMXI: Setting The Stage For Future Growth…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (04/02/14)	$0.51
Target Price	**$1.00**

UPDATE

On March 31, 2014, Cytomedix, Inc. (CMXI) reported financial results for the fourth quarter and full year ended December 31, 2013. Total revenues in the quarter were $3.5 million, an increase of 65% over the fourth quarter 2012. Revenues were driven by $3.0 million in product sales, $0.3 million in royalties, and $0.2 million in licensing fees and other income. Product sales consisted of $2.8 million in recorded pass-through sales of Angel to Arthrex, Inc. and $0.2 million in sales of AutoloGel.

We believe Cytomedix shares are fairly-valued right now at $1.00. We will adjust this valuation after the RECOVER data in early May 2014. We are eying the company for an upgrade and hope to make a final decision on our recommendation after the first quarter earnings report in about 40-45 days.

SUMMARY DATA

52-Week High	**$0.65**
52-Week Low	**$0.36**
One-Year Return (%)	**6.25**
Beta	**0.17**
Average Daily Volume (sh)	**346,591**
Shares Outstanding (mil)	**107**
Market Capitalization ($mil)	**$55**
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)
2013	2.3 A	2.4 A	3.4 A	3.5 A	11.6 A
2014	3.8 E	4.7 E	7.2 E	10.7 E	26.4 E
2015					45.5 E
2016					71.9 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.05 A	-$0.05 A	-$0.05 A	-$0.05 A	-$0.20 A
2014	-$0.04 E	-$0.03 E	-$0.03 E	-$0.02 E	-$0.11 E
2015					-$0.05 E
2016					$0.01 E

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WHAT'S NEW

Financial Results

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Angel sales increased 48% from the fourth quarter 2012. We remind investors that Cytomedix controls the manufacturing of the Angel device and thus records the associated revenue and expenses from the product on its income statement. Sales of the Angel device are sold at a transfer price to Arthrex, Inc., which we believe amounts to around a 2.5% gross mark-up. The company records the revenue from the transfer of the product but then also records the associated cost of goods below the revenue line. The company then records a low-teens royalty on sales of the device to Arthrex in the royalty line. Cytomedix is also amortizing the $5.0 million upfront payment from the licensing transaction in August 2013 to the tune of around $0.1 million per quarter.

AutoloGel sales in the quarter were up 29% from the fourth quarter 2012. The company began promoting the product to physician's offices after the initial proposed payment options by CMS for the Physicians Fee Schedule (PFS) were put into place in July 2013. Management noted on the fourth quarter earnings call that the Medicare Administrative Contractors (MACs) have been directed to set the payment rates for claims for AutoloGel based on the claims and invoices that are submitted by healthcare providers under the PFS. This effectively allows the individual contractors to determine the level of reimbursement. Management then noted that some of these claims were getting kicked back for incorrect coding or reimbursement protocols during the fourth quarter 2013, so it looks like reimbursement is still a work-in-progress at this stage.

R&D costs totaled $3.8 million in 2013. SG&A costs totaled $17.4 million. Gross margin took a big hit in the second half of the year because of the GAAP accounting noted above on Angel transfer sales to Arthrex, Inc. Management believes that AutoloGel can produce 70% gross margin in time, but we expect overall gross margin to remain in the single-digits for 2014 until royalty payments from Arthrex begin to ramp to substantially higher levels than the $0.3 million recorded in the fourth quarter 2013. Net loss for the fourth quarter and full year 2013 totaled $4.9 million and $20.2 million, respectively. Loss for the full year was similar to the $19.8 million reported in 2012. Loss did improve slightly during each quarter in 2013, but at this stage the company remains a long way from profitability.

Cytomedix exited 2013 with $3.3 million in cash on the books. The company burned approximately $3.5 million in the fourth quarter and $10.0 million during the full year 2013. On March 31, 2014, Cytomedix announced a tiered financing agreement with Deerfield Management Company and Anson Group. We provide a quick summary of the transaction below:

- Deerfield: Under terms of the agreement, Deerfield has agreed to provide up to $35 million in capital to Cytomedix through a senior convertible note. The commitment will be funded in two separate tranches. Deerfield initially provided $9.0 million at the closing of the transaction (which took place on March 31, 2014). The senior note is convertible into Cytomedix common stock at $0.52 per share. This equates to 17.3 million shares. Deerfield also received 25.1 million warrants to purchase Cytomedix common stock at an exercise price of $0.52 per share; these warrants expire on March 31, 2021.

  Tranche two of the transaction will occur after Cytomedix obtains shareholder approval to increase the authorized share count. We note the current authorized share count is 200 million and as of March 24, 2014, Cytomedix had a basic count of 110.8 million plus another 61.1 million in stock options, warrants, convertible notes, and contingent consideration to Aldagen. That put the fully-diluted number at 171.9 million prior to the Deerfield financing. Including the 42.4 million issuable under the first tranche of the Deerfield transaction, Cytomedix would be at 213.3 million, above the authorized amount by 13.3 million. Therefore, we expect the company to seek approval to increase the authorized amount in the next few months.

  Once the authorized amount has been increased, Cytomedix can collect tranche two of the Deerfield transaction, which includes expanding the senior convertible note by another $26 million. Under the same terms as the first tranche, this equates to 50.0 million shares of common stock when converted and 67.5 million warrants to purchase common stock at $0.52 with seven-year term.

- Anson: Under terms of the agreement with Anson Group, Cytomedix issued 3.846 million shares of common stock at $0.52 per share to raise gross proceeds of $2.0 million. Anson also received 2.884 million warrants to purchase common stock at $0.52 per share. The warrants expire on March 31, 2019.

In conjunction with the Deerfield and Anson financings, Cytomedix paid approximately $3.8 million to extinguish the secured debt (including accrued interest and fees) owed to MidCap Financial originally entered into in February 2013. Summing up the Deerfield, Anson, and MidCap transactions, Cytomedix netted approximately $6.0 million in cash. As of March 31, 2014, we believe the company held just over $7.0 million in cash on the books. We believe this is enough cash to fund operations for another six months. We expect that tranche two from Deerfield will be completed by June or July 2014, which will bring in another $26.0 million to the company.

AutoloGel Update

We believe the new payment rules put into place January 1, 2014 by CMS 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 Hospital Outpatient Prospective Payment System (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 average reimbursement under HOPPS for AutoloGel of $74 in 2013. We believe this represents approximately 65% of the Medicare market for the treatment of chronic wounds. Reimbursement under PFS is being directed by the Medicare Administrative Contractors (MAC) based on claims submitted by individual healthcare providers.

We believe that reimbursement at $411 average per treatment is a highly profitable product to both Cytomedix and the hospital outpatient facility or physician's office. We believe Cytomedix was previously selling AutoloGel "at cost" in 2013, which was around $74. As such, Medicare business prior to 2014 was virtually nil. Instead, the company was focused primarily on the limited number of private payer and long-term acute care facilities that were paying for AutoloGel. In 2013, this business generated $0.6 million in revenues to the company. Today, with national coverage under CED and a dramatically leveled playing field in the wound care market, it's a whole new ballgame for Cytomedix. The focus over the next six to nine months is on execution.

Above we noted how the claims under PFS are getting kicked back from improper coding. It is clear that there are still bumps in the road under both PFS and HOPPS. As such, the company is holding off on hiring and expanding its sales force. Instead, management has brought in talented senior leadership to point the ship in the right direction before they put their foot on the gas pedal. We note two recent hires:

- Dean Tozer: Dean Tozer has been consulting with Cytomedix for the past several months. We actually had he opportunity to sit down with Dean face-to-face with him in January 2014. He brings more than 25 years' experience in the global healthcare industry and has an established track record of successfully launching and marketing wound care products. From 2006 to 2011, he was Senior Vice President at Advanced BioHealing Inc. where he was responsible for the acquisition and reintroduction of Dermagraft into the U.S. market. Subsequently, Mr. Tozer became Vice President of Corporate Development at Shire Regenerative Medicine following the acquisition of Advanced BioHealing, where he led the business development efforts for that division including the 2012 acquisition of Pervasis Therapeutics. Mr. Tozer was also a founding executive and officer of the Alliance for Regenerative Medicine, where he served as Treasurer. He earned a Bachelor of Commerce degree from St. Mary's University in Halifax, Canada and is a Certified Management Accountant.

- Jennifer Linsky: Jennifer Linsky also joins Cytomedix from Shire Regenerative Medicine, where she was a National Accounts Manager and National Manager of Market and Business Development. At Shire, she launched a business development and comprehensive disease management program initiative that increased the diabetic wound market potential nationwide. Ms. Linsky also spent more than 7 years in positions of increasing responsibility at GlaxoSmithKline, culminating in her promotion to a four-year position as a District Sales Manager. Ms. Linsky earned a Bachelor of Science in Nutritional Science/Pre-Medicine and graduated cum laude from Auburn University.

These are great hires by Cytomedix to oversee the re-launch of AutoloGel in 2014. Dermagraft was a product that languished for a period of time prior to CMS reimbursement. However, post national coverage by CMS, Dermagraft sales took off, ramping from under $10 million in 2007 to over $150 million in 2012. The wound care market has changed since Dermagraft was positing sales above $150 million.

In fact, the changes instituted by CMS in late 2013 to the market made Shire divest the product because the sales opportunity has been significantly impaired. Nevertheless, the economics for AutoloGel are attractive under the new payment schedules and we believe the experience of Mr. Tozer and Ms. Linsky will help Cytomedix realize the potential of the product once many of the remaining "kinks" with respect to coding and filing claims gets worked out.

As far as the required clinical programs under CED, all things look to be on track. By the end of the year, management expects to have over 1,000 patients enrolled in all four programs combined. We remind investors that the four CED programs include one randomized clinical trial (RCT) seeking to enroll 280 patients with varied wounds, and then three separate registry programs each seeking to enroll up to 750 patients with diabetic foot ulcers, venous legs ulcers, and pressure ulcers, respectively. Management expects the RCT program to fully enroll in 2013. The other three programs, as well as any new programs the company elects to initiate, will likely take 18 to 24 months to enroll and report data.

…Revenues To Surge…

The company currently has nine sales representatives out in the field promoting the product, with a goal of 20 by the end of the year. We went back and looked at the magnitude of business that Advanced BioHealing (ABH) was doing with Dermagraft in 2012 prior to its acquisition by Shire Pharmaceuticals. ABH had Dermagraft sales near $150 million annualized at the time of the deal, with about 100 full-time representatives. That equates to around $1.5 million per rep. If Cytomedix can match even half that efficiency, with a goal of 20 reps in the field at year-end 2014, Cytomedix could be annualizing at $15 million in revenue with AutoloGel in 2015. That's an incredible ramp!

If we look at the base generated in 2013 of $0.6 million, we think CMS reimbursement kicks open significant opportunity for expanding sales with long-term acute care facilities, non-Medicare patients, and VA hospitals. Specifically, we believe Cytomedix can turn that $0.6 million base business in 2013 into $1.5 to $2.0 million in 2014. Additionally, by just enrolling the four CED programs in 2014, we expect the company to generate $3 to $5 million in revenues. Ultimately, $15 million in sales may be an aggressive assumption for 2015 given that the company does not plan to bring these new reps on until the second half of the year, but with 20 reps to enter 2015 and a long-term goal to get to 60 reps in a few years, AutoloGel sales should surge in 2015 and 2016.

As noted above, priority one is standardizing the policies and procedures under the new CMS payment rules, enrolling the CED trials, and working with PFS and HOPPS groups to iron out and kinks in the process so that when the reps do come on board, or a deal with a pharmaceutical company is struck, the ramp goes smoothly. Given the size of the wound care market at an estimated $3.5 billion, and the fact that AutoloGel has an FDA approved label for all three wound types – diabetic foot ulcers, pressure ulcers, and venous leg ulcers (note: Dermagraft and Apligraf has label indication only for diabetic foot ulcers) – and the favorable economics associated with AutoloGel, we see the product as having speak sales in the $100 million range. We plug this number into our valuation model discussed below.

Angel Update

In August 2013, Cytomedix partnered its Angel Concentrated PRP system by licensing the rights to Arthrex, Inc. in return for $5 million in cash and future low-teens royalties (we model 13%). We think this was a wonderful transaction for Cytomedix, and one where the market really hasn't come to grips with the potential upside Arthrex, Inc. brings to the table. For example, based on analysis of previous quarterly reports, we believe Angel delivered around 15-20% net margin to Cytomedix. On sales of around $10 million over the trailing twelve months, that's a net profit of $1.5 to $2.0 million. At 13% royalty, all that needs to happen for Cytomedix to have essentially made a good decision here is for Arthrex, Inc. to do around $15 million in Angel sales. That's only $5 million more than Cytomedix was doing itself, promoting with 10 independent contract sale representatives, and sales in the fourth quarter 2013 were $2.8 million, annualizing at $11.2 million.

Arthrex, Inc. has over 1,500 sales representatives! Arthrex, Inc. also has the potential to package Angel with its existing bone marrow aspirate cell suspension products, its BioCartilage® matrix, its Autograft osteochondral repair system, or its existing PRP autologous systems. Arthrex, Inc. is going to turn Angel from a $10 million product to a $50 million product in our view. Just take a look at the product brochure that Arthrex has prepared on Angel ahead of the official re-launch in April 2014. Not only is this a significant step-up in promotional material, but it seems clear that Arthrex is already attempting to up-sell Angel with existing product-lines noted above. The company has created a bone marrow aspiration kit that sells at nearly double the cost of the stand-alone Angel device. And keep in mind, Cytomedix gets a low-teen royalty on all Angel-related product sales, including these far more expensive kits. That alone could turn the $11 million run-rate into well above the $15 million hurdle for a "good decision" noted above.

The royalties to Cytomedix are going to dwarf the previous sales in a few years. For 2014, we believe Arthrex will post Angel sales in the area of $18 million. In 2015, we believe Arthrex can growth the franchise to over $28 million, peaking at $75 million in the next few years. Similar to AutoloGel, we plug these numbers into our valuation model discussed below.

ALD-401 Update

The company's Phase 2 RECOVER-Stroke clinical study with ALD-401 completed enrollment at 48 patients in January 2014. Originally, the company planned to enroll 100 patients in the study, but based on an interim resizing analysis conducted by the company in January 2014, management concluded that the trial is adequately powered based on pre-specified assumptions at 48 patients. On the fourth quarter update call, management specifically noted this interim analysis determined that the trial was adequately powered to demonstrate a clinically appropriate difference in the primary efficacy endpoint. The previous protocol noted that RECOVER was 90% powered to detect a 0.8 drop in Modified Rankin Scale (MRS) from baseline to recovery at 90 days. We believe at 48 patients, the powering is lower than the 90% original assumption, but still adequate enough to provide evidence of efficacy in this proof-of-concept study.

Data from RECOVER in early May is a major catalyst for Cytomedix. If it is positive – meaning the primary endpoint hits and delivered a >0.8 reduction in mRS at 90 days post treatment – the shares skyrocket. We think they could hit $2.00 on the news. Any reduction vs. the shame procedure and we think the stock still reacts well considering expectations are very low and its clear things like powering assumptions and enrollment can be expanded in later studies. No reduction – a complete failure – and we think the stock maintains current in value because that means Cytomedix will probably be done spending money on the Bright Cell technology. As such, data from RECOVER represents a risk-free call option for Cytomedix investors.

Valuation & Recommendation

To value Cytomedix, we are doing a simple "sum-of-parts" valuation for the three drivers of the top-line: AutoloGel, Angel, and ALD-401. We believe AutoloGel is a $100 million product for Cytomedix. We believe Angel is a $75 million product for Arthrex, Inc., of which Cytomedix gets low-teens royalty. We apply no value for ALD-401.

The wound care market is $3.4 billion in sales, with a dramatic shift towards cheaper, easier to use, more effective products expected in 2014 thanks to a monumental CMS decision in November 2013. AutoloGel is a highly effective product with favorable economics to both payers and providers. The AutoloGel label includes approval for use in all three major wound categories, providing a distinct competitive advantage over completing products looking to crack private formularies and gain use in VA hospitals and long-term acute care facilities. The four CED programs that Cytomedix plans to enroll in 2014 should generate $3-5 million in sales alone in 2014. Assuming modest growth in the base business, AutoloGel sales should eclipse $4 million in 2014. Industry analysis of previous wound care products suggest that with 20 reps, AutoloGel could do $12-15 million in revenues in 2015 and $25 million in 2016. With peak sales in the $100 million range by 2018, an industry average 4x price-to-sale multiple, and a 20% discount rate, AutoloGel alone is worth $200 million in market value.

Arthrex Inc. should be able to turn Angel into a $75 million product by 2018. They will accomplish this through a combination of dramatically increasing the sale and promotional effort, raising the price of the device, and coupling Angel with other Arthrex products and developing custom kits for things like bone marrow aspiration. Cytomedix received a low-teen royalty on sales of all Angel and Angel-coupled products at Arthrex, plus a small low-single digit mark-up on finished goods transfer. With $75 million in peak sales and 13% royalty, applying the same valuation measures as noted above with AutoloGel, Angel is worth $25 million in market value.

ALD-401 remains a wild-card in our valuation model. At this point, we place no value on the program. Data from RECOVER-Stroke is expected in early May 2014. Once the data is out, we will reassess our valuation. If Cytomedix kills the program, there should be no change to our current valuation. If the trial succeeds, ALD-401 could be worth another $100 to $200 million in immediate value.

We believe Cytomedix shares are fairly-valued right now at $1.00. We will adjust this valuation after the RECOVER data in early May 2014. We believe there is tremendous value here and certainly not oppose to buying ahead of the data. We are eying the company for an upgrade and hope to make a final decision on our recommendation after the first quarter earnings report in about 40-45 days.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2012 A	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Med Product Sales	**$7.24**	**$10.50**	**$3.18**	**$4.00**	**$6.25**	**$9.50**	**$22.93**	**$40.50**	**$65.00**
Aldagen Pipeline	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Royalties & Collabs	**$3.32**	**$1.07**	**$0.62**	**$0.70**	**$0.92**	**$1.22**	**$3.46**	**$4.98**	**$6.88**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$11.57**	**$3.80**	**$4.70**	**$7.17**	**$10.72**	**$26.39**	**$45.48**	**$71.88**
YOY Growth	45.8%	9.5%	64.0%	93.7%	113.0%	209.5%	128.0%	72.4%	58.0%
Cost of Royalties	$0.02	$0.09	$0.05	$0.05	$0.05	$0.05	$0.20	$0.25	$0.25
Cost of Sales	$3.90	$8.36	$2.98	$3.56	$5.25	$7.58	$19.37	$31.05	$46.50
Product Gross Margin	46.2%	20.3%	6.3%	10.9%	16.0%	20.3%	15.5%	23.3%	28.5%
R&D	$3.39	$3.80	$0.80	$0.85	$0.90	$0.95	$3.50	$3.75	$4.00
% R&D	32.1%	32.8%	21.1%	18.1%	12.6%	8.9%	13.3%	8.2%	5.6%
SG&A, Other Fees	$16.16	$17.41	$3.70	$3.95	$4.10	$4.25	$16.00	$17.50	$18.50
% G&A	152.9%	150.5%	97.4%	84.1%	57.2%	39.6%	60.6%	38.5%	25.7%
Operating Income	($12.88)	($18.10)	($3.73)	($3.72)	($3.13)	($2.11)	($12.68)	($7.07)	$2.63
Operating Margin	-121.9%	-156.4%	-98.1%	-79.2%	-43.7%	-19.6%	-48.1%	-15.5%	3.7%
Interest & Other Income	($6.89)	($2.13)	($0.50)	($0.50)	($0.50)	($0.50)	($1.00)	($1.00)	($1.00)
Pre-Tax Income	($19.76)	($20.23)	($4.23)	($4.22)	($3.63)	($2.61)	($13.68)	($8.07)	$1.63
Taxes	$0.02	$0.009	$0	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%
Preferred A, B, D, E	$0.01	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($19.80)	($20.24)	($4.23)	($4.22)	($3.63)	($2.61)	($13.68)	($8.07)	$1.63
Net Margin	-187.4%	-174.9%	-111.3%	-89.8%	-50.6%	-24.3%	-51.9%	-17.7%	2.3%
Reported EPS	**($0.24)**	**($0.20)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.11)**	**($0.05)**	**$0.01**
YOY Growth	217.7%	-19.2%	-27.0%	-29.9%	-47.2%	-65.9%	-44.0%	-57.9%	-117.7%
Weighted Ave. Shares Out	81.9	103.6	107.5	125.0	145.0	165.0	125.0	175.0	200.0

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

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