Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTCQX)

CMXI: Fundamentals Set To Dramatically Improve… Maintain Buy Rating.

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	04/25/2014
Current Price (08/15/14)	$0.37
Target Price	**$1.50**

UPDATE

On August 14, 2014, Cytomedix, Inc. reported financial results for the second quarter ending June 30, 2014. Second quarter results were nothing to get excited about. In fact, we were disappointed with the revenue line and the net loss was sizable due to non-cash charges associated with closing down the Durham, NC Aldagen R&D facility. That being said, we think that is the last bad quarter Cytomedix will have. The good times start now! Angel sales should begin to dramatically ramp at Arthrex, providing a nice cash royalty to Cytomedix, and AutoloGel should see sales begin to ramp in the second half of the year upon re-branding and re-launch under the CED process. As a result, we are sticking to our 'Buy' rating because we believe fundamentals bottomed and are set to dramatically improve over the next 12 to 18 months. Our target is $1.50 per share.

SUMMARY DATA

52-Week High	**$0.65**
52-Week Low	**$0.36**
One-Year Return (%)	**-9.42**
Beta	**-0.69**
Average Daily Volume (sh)	**76,797**
Shares Outstanding (mil)	**122**
Market Capitalization ($mil)	**$47**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**13**
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 2014 Estimate	**N/A**
P/E using 2015 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	1.9 A	2.3 A	2.9 E	4.6 E	11.6 E
2015					30.2 E
2016					50.6 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	-$0.05 A	-$0.09 A	-$0.03 E	-$0.03 E	-$0.20 E
2015					-$0.05 E
2016					$0.01 E

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WHAT'S NEW

Financial & Business Update

On August 14, 2014, Cytomedix, Inc. (CMXI) reported financial results and filed its Form 10Q for the second quarter ending June 30, 2014. Total revenues in the quarter were $2.33 million, down 4% from the second quarter 2013. Revenues were driven by $1.85 million in product sales derived from both Angel and AutoloGel and $0.48 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. Product sales declined 22% from the second quarter 2013. Gross margin in the quarter was -0.1%. It was ugly, and looks like a big concern for shareholders. But investors need to understand the dynamics of the new income statement at Cytomedix post the Arthrex, Inc. transaction.

…Let's Talk About Angel and The Gross Margin…

The primary reason for the significant decline in product sales in the second quarter 2014 is simple – Cytomedix no longer books product sales on Angel, they book the transfer price on Angel sold to Arthrex. Big difference! Based on historic gross margin, we believe this number is around 60% of the original product sales. That alone explains the year-over-year decline in revenues for Angel. In fact, with Angel revenues down only 23% from the second quarter 2013, it is clear that unit growth is positive. Going forward, we expect Arthrex to grow Angel revenues significantly over the next several years. We expect this ramp to take place starting in the third quarter 2014.

Below the top-line, Cytomedix makes a small mark-up on the transfer price to Arthrex, and books its full cost of goods sold. For the purpose of our model, we assume the transfer price mark-up is 2.5%. This is the reason why gross margin in the quarter looks so terrible. Until AutoloGel takes off or the royalties from Arthrex start rolling in, Cytomedix revenue line and cost of goods sold line are separated by a 2.5% transfer price. Add-in some inventory stocking and some one-time expenses associated with closing the Durham, NC Aldagen facility and gross margin was negative for the quarter. This number does not accurately represent the business. Angel unit sales are clearly growing and with a one-quarter lag on royalties, we believe things will turn around on the P&L soon.

For instance, the company books "low-teens" royalties on end-user product sales of Angel at Arthrex. This number equated to $0.37 million in the quarter, up from $0.26 in the first quarter 2014. Using this number, we can then back-calculate the end-user product sales of Angel in the first quarter by using a best-guess royalty rate of 13%. This number equates to $2.8 million, or up roughly 26% from the $2.25 million Cytomedix did without Arthrex in the second quarter 2013.

On the first quarter call, CEO Martin Rosendale noted that Arthrex just recently launched the product in April 2014 under its own banner. During the entire first quarter 2014, Arthrex was just maintaining the previous in-place business while they worked on developing new kits and new components, all which will includes a higher selling price than what Cytomedix was selling Angel for in 2013. If one visits the Arthrex, Inc. website, several new products packaged with Angel can be seen. These include existing bone marrow aspirate cell suspension products, BioCartilage® matrix, its Autograft osteochondral repair system, and its existing PRP autologous systems. None of these products were active in the first half of the year, but they are now.

So what we think is going to happen is a significant ramp in the end-user revenues associated with Angel in the very near future. Angel was a $10 million product at Cytomedix promoted by a handful of part-time representatives. Arthrex is going to turn it into a $75 million product thanks to higher ASP's, bundling with new products, and 1,500 full-time sales reps beating down the doors of orthopedic and cardiovascular surgeons. As a result, we believe that royalties to Cytomedix are going to dwarf the previous sales Cytomedix booked rather quickly. As royalties grow with 100% gross margin, the gross profit margin reported should also dramatically recover in the coming quarters.

…Focus Now On AutoloGel…

With Arthrex now handling Angel, and Aldagen shut down, Cytomedix is squarely focused growing AutoloGel. AutoloGel sales in the second quarter 2014 totaled $0.120 million. This was a disappointment, as sales have not yet accelerated due to logistical issues associated with implementing the Coverage with Evidence Development (CED) process. That being said, we think management is doing the necessary things to iron-out the process and we anticipate a meaningful ramp in revenues coming in the third quarter 2014.

Gross profit on AutoloGel in the quarter totaled $0.029 million, or 24%. Clerarly this is nothing to get terribly excited about. But similar to Angel, investors need to understand what's going on here. Cytomedix just received reimbursement under HOPPS and PFS effective January 1, 2014. These new payment rules are going to take a few quarters to funnel their way through the system. However, the important thing to understand is that these new payment rules have dramatically enhanced the commercial viability of the product.

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 the Physician's Fee Schedule (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.

Earlier in the year, the company noted that 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 (and even re-brand) of AutoloGel in 2014. Dermagraft was a product that struggled 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. But now the wound care market share changed. Dermagraft is no longer advantaged. In fact, the changes instituted by CMS in late 2013 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 to being enrollment later this year. In the next 2-3 quarters, we expect the company 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 2014. The other three programs, as well as any new programs the company elects to initiate, will likely enroll and report data in 2015. Similar to any clinical program, implementing the protocol includes obtaining IRB approval at each site. The company is targeting 120 sites right now. As such, enrollment is 2-4 months behind the schedule that was laid-out earlier in the year. We do not see this as a major concern. We think that once implemented the ramp in enrollment will be expeditious. We continue to believe by 2015 Cytomedix will have one of the largest data sets in the entire wound care market. We recommend investors view our Zacks Report from April 2014 for an update on what we saw at the Symposium on Advanced Wound Care (SAWC) in Orlando, FL.

…Sales Expansion Coming…

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. That's clearly not enough to target all 2,000 specialty wound care centers in the U.S., but it's a nice start. 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 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 $3.4 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, nine peer-reviewed publications, massive data to be in hang in 2015, CMS clearly on the company's side with respect to low-cost / effective pricing, we see Cytomedix as uniquely well-positioned in this market. In our view, AutoloGel is looking like it has peak sales in the $100 million range.

…Not Profitable, Yet…

Net loss for the second quarter 2014 totaled $11.32 million, or $0.09 per share. Operating burn in the quarter totaled only $4.84 million, as much of the expenses were non-cash. Non-cash charges in the quarter totaled $4.7 million associated with closing down the Durham, NC Aldagen R&D operation. There was another $0.5 million in severance packages associated with reducing headcount from Aldagen. Cytomedix has since sub-let the facility to a new company, so ongoing cash lease obligations in Durham, NC will be negligible. We expect a small $0.5 million charge in the third quarter associated with this transaction, but going forward we do not anticipate significant write-downs or impairment charges prior to the completion and data from the Phase 2 PACE study with ALD-301.

Assuming sales ramp of AutoloGel and Angel in-line with our expectations, we think it is possible the company can achieve positive cash flow from an operating basis in 2016. As a result, we acknowledge that our recent upgrade of our rating to 'Buy' in April 2014 is early. However, with the fundamental improvement we expect to occur over the next several quarters we believe downside is limited and upside is tremendous.

…Finally, The Cash To See Things Through…

On March 31, 2014, Cytomedix announced a tiered financing agreement with Deerfield Management Company and Anson Group. 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.

Cash as of June 30, 2014 was $25.0 million. Based on the current burn rate and minimum cash-balance requirements under the company's convertible note obligation with Deerfield, we see this level of cash as sufficient to fund operations into the second half of 2015.

Attractive Valuation

To value Cytomedix, we are doing a simple "sum-of-parts" valuation for the two drivers of the top-line: AutoloGel sales and Angel royalties. 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 ongoing clinical programs with ALD-301 in peripheral arterial disease or ALD-351 in glioblastoma.

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 a few million in sales alone in 2014. Assuming modest growth in the base business, AutoloGel sales should eclipse $3 million in 2014. Industry analysis of previous wound care products suggest that with 20 reps, AutoloGel could do $12.5 million in revenues in 2015 and $25 million in 2016. With peak sales in the $100 million range by 2018, a premium 5x price-to-sale multiple, and a 20% discount rate, AutoloGel alone is worth $235 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 (netting around 15% all-in economics). With $75 million in peak sales and 15% economics, applying the same valuation measures as noted above with AutoloGel, Angel is worth $30 million in market value.

Summing these parts two parts together and we believe Cytomedix shares are fairly-valued right now at a market value of $265 million, or around $1.50 per share. We fully understand the stock is in "show-me" mode and that the top-line probably will not take off meaningfully until 2015. That being said, we now finally expect the financial results to start showing meaningful improvement starting with the third quarter numbers in October 2014. Accordingly, we are sticking to our 'Buy' rating because we believe fundamentals bottomed and are set to dramatically improve over the next 12 to 18 months.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2012 A	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
Med Product Sales	**$7.24**	**$10.50**	**$1.42**	**$1.85**	**$2.45**	**$4.00**	**$9.72**	**$27.50**	**$47.00**
YOY Growth	22.7%	45.0%	-36.8%	-21.7%	-16.3%	35.3%	-7.4%	182.8%	70.9%
Royalties & Collabs	**$3.32**	**$1.07**	**$0.42**	**$0.48**	**$0.45**	**$0.62**	**$1.88**	**$2.65**	**$3.61**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$11.57**	**$1.85**	**$2.33**	**$2.90**	**$4.62**	**$11.60**	**$30.15**	**$50.61**
YOY Growth	45.8%	9.5%	-20.3%	-4.0%	-13.8%	33.2%	0.2%	159.9%	67.9%
Cost of Royalties	$0.02	$0.09	$0.04	$0.04	$0.05	$0.05	$0.19	$0.25	$0.25
Cost of Sales	$3.90	$8.36	$1.41	$1.85	$2.25	$3.56	$8.82	$18.38	$28.95
Product Gross Margin	46.2%	20.3%	1.0%	-0.1%	8.0%	10.9%	9.3%	33.2%	38.4%
R&D	$3.39	$3.80	$0.95	$0.96	$0.65	$0.50	$3.06	$2.50	$2.50
% R&D	32.1%	32.8%	51.7%	41.2%	22.4%	10.8%	26.4%	8.3%	4.9%
SG&A, Other Fees	$16.16	$17.41	$4.09	$9.29	$3.25	$3.15	$19.78	$15.00	$16.50
% G&A	152.9%	150.5%	221.5%	399.5%	112.0%	68.3%	170.5%	49.8%	32.6%
Operating Income	($12.88)	($18.10)	($4.65)	($9.82)	($3.30)	($2.65)	($20.25)	($5.98)	$2.41
Operating Margin	-121.9%	-156.4%	-251.9%	-422.3%	-113.7%	-57.4%	-174.6%	-19.8%	4.8%
Interest & Other Income	($6.89)	($2.13)	($0.98)	($1.49)	($1.00)	($1.00)	($4.47)	($2.00)	($1.00)
Pre-Tax Income	($19.76)	($20.23)	($5.63)	($11.32)	($4.30)	($3.65)	($24.72)	($7.98)	$1.41
Taxes	$0.02	$0.009	$0.005	$0.005	$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)	($5.63)	($11.32)	($4.30)	($3.65)	($24.72)	($7.98)	$1.41
Net Margin	-187.4%	-174.9%	-305.2%	-486.7%	-148.2%	-79.0%	-213.1%	-26.5%	2.8%
Reported EPS	**($0.24)**	**($0.20)**	**($0.05)**	**($0.09)**	**($0.03)**	**($0.03)**	**($0.20)**	**($0.05)**	**$0.01**
YOY Growth	217.7%	-19.2%	-6.0%	93.5%	-28.0%	-41.6%	2.5%	-77.2%	-115.5%
Weighted Ave. Shares Out	81.9	103.6	111.2	121.6	126.0	135.0	123.5	175.0	200.0

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

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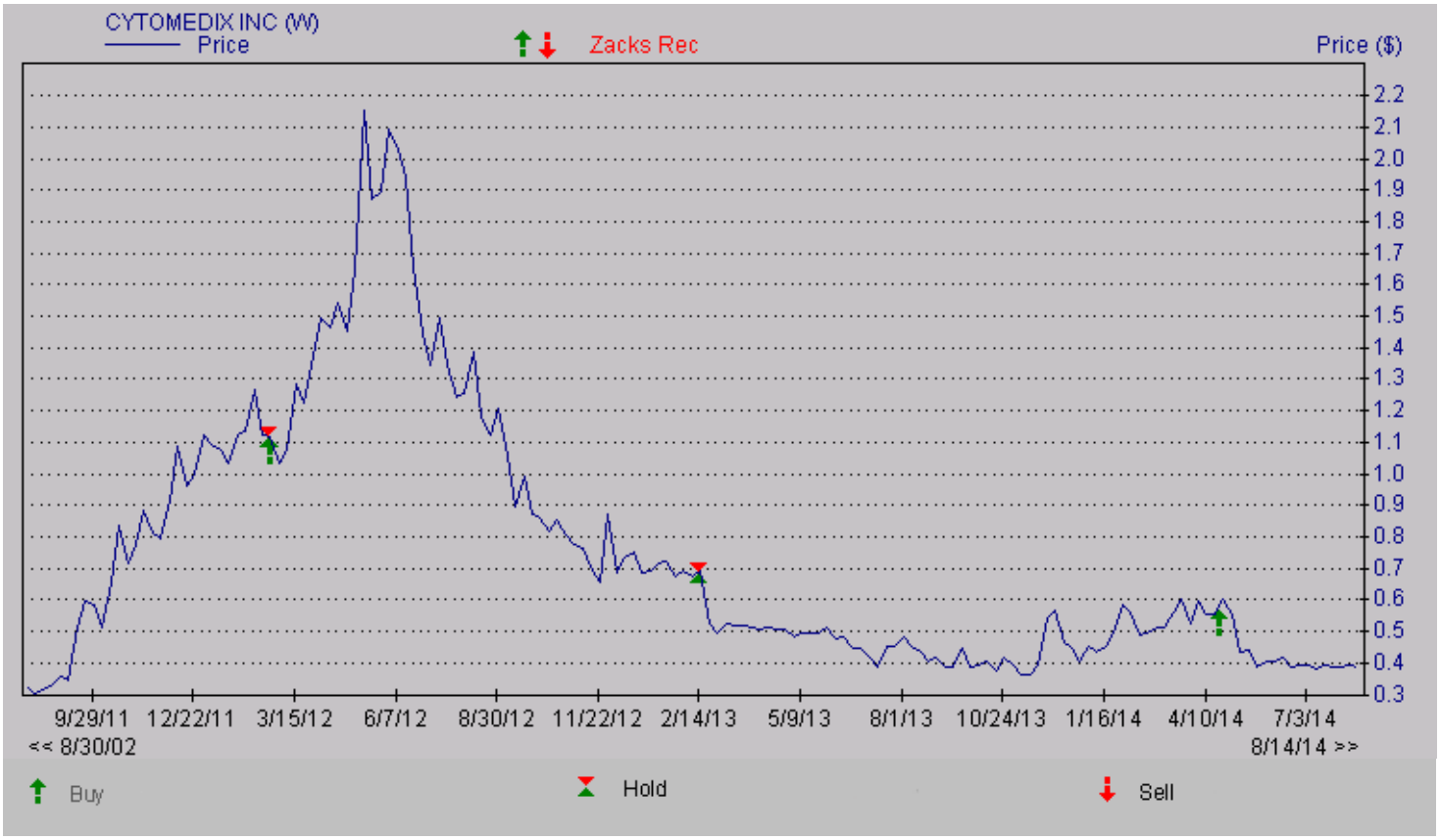

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