Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTC)

CMXI: Cash Position and LT Growth Prospects Becoming A Concern…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (02/14/13)	$0.71
Target Price	**$1.50**

UPDATE

We currently model total revenues in 2013 at $9.35 million, comprised of $1.5 million in products sales coming from AutoloGel and $7.75 million from Angel. We model a net loss of $14.6 million for 2013, with cash burn around $12 to $14 million for the full year. We do not model upfront or licensing fees in 2013. We have lowered our rating to 'Neutral' and adjust our target to $1.50 (from $2.00) to account for the expected dilution from a financing and the longer enrollment time on RECOVER-Stroke (higher costs).

The single biggest catalyst for the shares in 2013 would be a deal for AutoloGel. If the company and strike a deal that puts AutoloGel back on the map, that might be the boost in both cash and revenues the company needs to power forward with Angel and keep placing shots on goal with ALD-401, ALD-451, and ALD-301.

SUMMARY DATA

52-Week High	**$2.28**
52-Week Low	**$0.57**
One-Year Return (%)	**-38.79**
Beta	**0.29**
Average Daily Volume (sh)	**69,933**
Shares Outstanding (mil)	**92**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**15**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	1.4 A	1.4 A	1.5 A	3.0 A	7.3 A
2012	3.0 A	3.7 A	1.8 A	1.9 E	10.3 E
2013					9.4 E
2014					11.6 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.03 A	-$0.02 A	-$0.04 A	$0.01 A	-$0.08 A
2012	-$0.07 A	-$0.09 A	-$0.04 A	-$0.03 E	-$0.22 E
2013					-$0.13 E
2014					-$0.11 E

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WHAT'S NEW

Lowering Rating To 'Neutral'

We are lowering our rating on shares of Cytomedix to 'Neutral' – something we should have done several months ago – given the mounting near-term overhang around the cash position, slow enrollment in the phase 2 RECOVER-Stroke trial, and the long-term growth concerns for AutoloGel. We believe the company needs to secure funding in the next month, and based on the lack of near-term catalysts and investors questions that remain ahead of both the registry program on AutoloGel and the ongoing phase 2 RECOVER-Stroke trial, we believe an impending raise may be on "not so shareholder friendly" terms. We believe the stock remains meaningfully undervalued, but are nervous about the slow enrollment and outcome of the RECOVER-Stroke trial and the company's ability to grow AutoloGel as a standalone entity.

…AutoloGel Drifts Along…

In June 2012, things seemed to be going very well for Cytomedix and AutoloGel. The company was in exclusive negotiations with a major pharmaceutical company for the licensing and distribution of AutoloGel to the hospital market; a deal that would have surely brought significant upfront cash and accelerating sales of the device, and nice royalty payments to Cytomedix. But the pharmaceutical company walked away for undisclosed reasons in August 2012, despite the fact that the Center for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) for AutoloGel only weeks before. Right or wrong, the market interpreted the deal falling through as a sign that CMS granting coverage under its Coverage with Evidence Development (CED) program was disappointing or carried undue burden.

AutoloGel is a product that generated only $53k for the twelve months ended September 30, 2012. And despite the fact that we believe CED is not limiting to AutoloGel growth, and is on the contrary a potential major catalyst for the sales in 2013 and beyond, investors we speak with remain highly skeptical that an acceleration is coming. For example, on the company's third quarter conference call in August 2012, CEO Martin Rosendale noted that he expects AutoloGel to "contribute meaningfully" to revenues in 2013. As a point of reference, Cytomedix treated around 300 patients with AutoloGel in 2012. The company's goal is to increase that number to over 1,000 in 2013. Despite this bullish guidance, the stock continued its precipitous decline, hitting a low of $0.57 in December 2012.

We believe Cytomedix needs to out-license AutoloGel to a major player in the chronic wound market. The company's part-time sales effort of seven regional sales managers and 20+ independent agents will never bring AutoloGel to the sales level comparable with competing technologies like Dermagraft (~$195M in sales in 2011) and Apligraf (~$125M in sales in 2011), despite the fact that AutoloGel looks to be more effective and cheaper than both products. The U.S. chronic wound market is an estimated $2.3 billion opportunity; and despite solid data, differentiating characteristics, and coverage under Medicare, AutoloGel is not even a drop in this bucket. The promotion effort around AutoloGel needs to be quadrupled, at a minimum. Until the company can strike an out-licensing or co-promotion agreement to make this happen, AutoloGel remains an after-thought in the Cytomedix investment story.

…RECOVER-Stoke: Slow Enrollment and High Risk…

Roughly a year ago, Cytomedix made the transformational decision to acquire privately-held Aldagen, and with it the company's ALDH bright cell technology. Impetuous for the deal was to boost the company's focus on regenerative medicine and create what management referred to as the "three pillars of generative medicine" – scaffolds, signals, and cells. Aldagen had candidates ALD-201 for ischemic heart failure, ALD-301 for critical limb ischemia, and ALD-401 for ischemic stroke in the clinical pipeline.

The lead program was a recently initiated phase 2 study, dubbed RECOVER-Stoke, with ALD-401. At the time of the deal (February 2012), six of the targeted 100 patients had been enrolled in the study. In May 2012, Cytomedix announced that an independent data safety monitoring board (DSMB), after reviewing the safety data from the first 10 patients, had recommended that the phase 2 trial continue as designed. Enrollment of these 10 patients took place at three clinical sites in the U.S. Safety data presented in October 2012 at the World Stoke Congress in Brazil showed procedure was safe and yielded no serious adverse events. Following the DSMB review of the first 10 patients, the trial has now been allowed to expand to the next 90 patients. Management opened enrollment at an additional 6 sites around the U.S., with an ultimate goal of 10 to 15 sites.

There is a second DSMB review after a total of 30 patients have been enrolled. But it is now February 2013, over a year since the acquisition of Aldagen, and we are still waiting for the DSMB to clear the 30th patient. At this pace, full enrollment of 100 patients will not take place until 2014. We do not know the reasons why enrollment in RECOVER-Stroke is taking so long. Stroke is an enormous market opportunity. Each year, some 700,000 American's suffer an ischemic stroke. Finding patients should not be an issue.

We can only surmise that either the enrollment criteria is too strict or that the trial protocol is simply not attractive to physicians or patients. We note that trial is a double-blind, placebo-controlled design, with a 60/40 randomization between drug and control. ALD-401 will be administered to the patient via a single injection (3 ml) directly into the carotid artery approximately two weeks (13 to 19 days) following the stroke. Athersys is conducting a competing phase 2 trial in stroke with its MultiStem cell therapy, targeting 140 patients. However, the Athersys trial is enrolling at 20+ sites and seeks to dose patients 24 to 36 hours after the stroke. We question why Cytomedix elected to wait 13 to 19 days before dosing in its study.

Stroke has been a minefield for drug development over the past decade. Small molecules and biologics tested in late-stage trials for acute ischemic stroke – eliprodil, selfotel, aptiganel, enlimomab, LeukArrest, nimodipine, fosphenytoin, maxipost, tirilazad, citocline, disutenton, diazepam, repinotan, nalmefene, and gangloside-GM1 to name a few – have all failed for one reason or another.

One thing to note about all the above failures is that they are all one molecule going after one target. Cell therapy has the potential to use multiple mechanisms of action with multiple pathways for success. So we are keen to see the outcome of both phase 2 trials being conducted by Cytomedix and Athersys. That being said, these are clearly high risk studies and we would not recommend investors get aggressive ahead of the data.

We note that Cytomedix is also in phase 1 studies with ALD-451, a formulation of the company s ALDH bright cells, designed to test the feasibility and safety when administered intravenously in World Health Organization (WHO) grade IV malignant glioma patients following surgery, radiation therapy and treatment with temozolomide. The trial is being run in collaboration with Duke University Medical Center and expected to enroll up to 12 patients in an open-label design.

Cytomedix also recently announced the signing of an agreement with the NIH to collaborate on a phase 2 clinical study in patients with intermittent claudication (IC) and ALD-301. The study is being funded by NHLBI/NIH and managed by the Cardiovascular Cell Therapy Research Network (CCTRN). The phase 2 study, called "PACE" (Patients with Intermittent Claudication Injected with ALDH Bright Cells) is expected to enroll 80 patients in a double-blind, placebo-controlled design. The primary endpoints of the study are safety and the change in peak walking time at 6 months compared to baseline.

…Need For Cash…

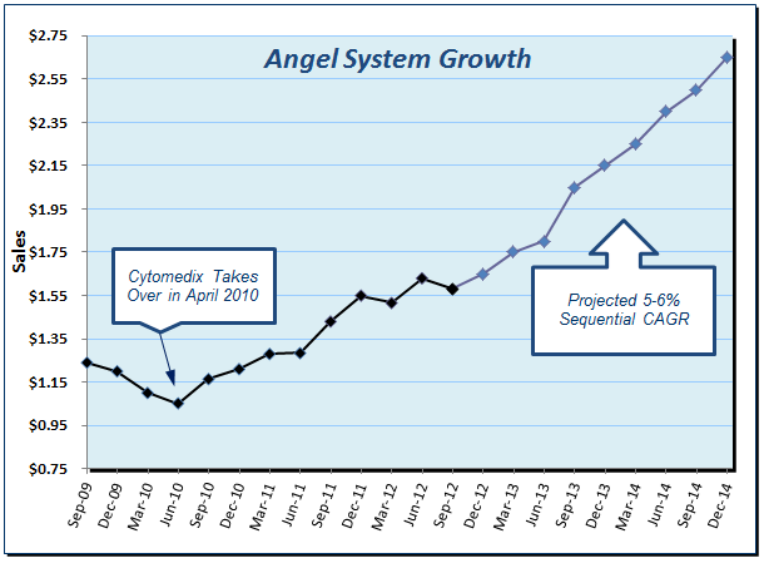
On November 14, 2012, Cytomedix reported financial results for the third quarter 2012. During the quarter, Cytomedix burned roughly net $2.7 million in cash. This includes burning $3.6 million on an operating and investing standpoint and generating $0.9 million from financing activities. Cytomedix exited the quarter with $5.9 million in cash and investments, down $2.7 million from the $8.5 million reported at the end of June 2012. Of this $5.9 million, the company has allocated $3.2 million to continuing the ALD-401 phase 2 RECOVER-Stroke trial currently enrolling patients.

Based on a similar estimated burn in the fourth quarter 2012, we forecast that Cytomedix exited 2012 with roughly $3.0 million in cash on the books. This is enough cash to fund operations through the March / April 2013, assuming the company had not been accessing capital through its common stock purchase agreement with Lincoln Park Capital in the fourth quarter 2012 ($4.1 million remained as of September 30, 2012). We note the recent filing of a $35 million mixed S-3 on November 5, 2012. We suspect that the company will seek to raise capital in the next few weeks. With the stock at $0.71 and catalysts lacking, we are concerned about the size and pricing of the deal. We believe the company may need to include full warrant coverage to attract investors to the story. We would not be buyers of the stock ahead of this potential highly dilutive offering.

…Angel Remains The One Bright Spot…

Despite the fact that Angel sales were below our expectations in the third quarter 2012, coming in at $1.58 million vs. our estimate of $1.70 million, CEO Marty Rosendale noted that October 2012 was the best month in the company's history for Angel. And, despite the slow quarter, unit placements have really increased nicely in 2012. The company started the year with roughly 350 units out in the market between the U.S. and Europe. As of the end of October 2012, the company has around 450 units out in the market, of which around 50 are in Europe. We note there are an additional 25+ units in the hands of distributors around Europe that should be placed in the next few months. Back in the U.S., we think management can be at or near 450 units placed by the end of the year.

…Angel Ramp Continues…



We expect that new markets will continue to drive growth of Angel in the near-term. On November 8, 2012, Cytomedix announced that the U.S. FDA had granted clearance for the use of Angel for processing a small sample of blood or a mixture of blood and bone marrow aspirate (BMAC). The 510(k) approval now allows for PRP produced from either blood or a mixture of bone marrow aspirate to be combined with bone graft material and used in appropriate orthopedic procedures as deemed necessary by a clinician, such as spinal fusion, healing of nonunion bone fractures and other bone grafting applications. In the U.S., approximately 500,000 spinal fusion procedures are performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard. Concentrated PRP produced from blood and bone marrow may be used in up to 90% of spinal fusion procedures. The U.S. biologics market associated with spinal fusion procedures is approximately $700 million annually. We think an equal opportunity exists in Europe.

Angel is being used in the U.K. for aesthetic applications, where physicians are injecting PRP under the skin to facilitate skin rejuvenation. Angel PRP is also being used in fat transfer procedures to improve graft survival and aesthetic outcomes. These innovative applications represent development opportunities for future Angel indications. It places Angel squarely in competition with Cytori's PureGraft and Celgraft products for these aesthetic and plastic surgery market.

That being said, sports medicine remains the "Holy Grail" for Angel. Evidence that using PRP to shorten and improve healing with knee, ankle, elbow, or an ACL or MCL sprains is growing rapidly. We have seen clinical data demonstrating PRP is effective at treating chronic tennis elbow, severe Achilles tendonitis and osteoarthritis of the knee. In the next few months we expect Cytomedix to see additional data on the use of PRP in treating sports injuries. Cytomedix is working with Dr. Peter H. Edwards, Jr, a board certified orthopedic surgeon with a fellowship trained specialty in Sports Medicine. Dr. Edwards practice has an emphasis on arthroscopic surgery of the knee and sports injuries of the lower extremity. He is a team physician for the U.S. Men's and Women's National Soccer Teams. Dr. Edwards has amassed data from roughly 60 patients with Achilles tendonitis, and plans to present the data at an upcoming medical meeting. Cytomedix is also working with an Angel customer in the Northeast that plans to look at the use of PRP in 20 patients with plantar fasciitis. We view teaming up with cutting-edge physicians like this as key to the company's strategy to grow Angel in this potentially enormous market opportunity.

INVESTMENT UPDATE

Expectations For 2013

We currently model total revenues in 2013 at $9.35 million, comprised of $1.5 million in products sales coming from AutoloGel and $7.75 million from Angel. We model a net loss of $14.6 million for 2013, with cash burn around $12 to $14 million for the full year. We do not model upfront or licensing fees in 2013. We have lowered our rating to 'Neutral' and adjust our target to $1.50 (from $2.00) to account for the expected dilution from a financing and the longer enrollment time on RECOVER-Stroke (higher costs). The single biggest catalyst for the shares in 2013 would be a deal for AutoloGel. If the company and strike a deal that puts AutoloGel back on the map, that might be the boost in both cash and revenues the company needs to power forward with Angel and keep placing shots on goal with ALD-401, ALD-451, and ALD-301.

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2010 A	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E	2015 E
Med Product Sales	**$3.79**	**$5.90**	**$1.69**	**$1.86**	**$1.70**	**$1.86**	**$7.08**	**$9.35**	**$11.60**	**$14.10**
YOY Growth	1574.5%	55.8%	23.5%	33.5%	11.4%	15.5%	20.0%	32.0%	24.1%	21.6%
Drug Pipeline	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Royalties & Collabs	**$0.12**	**$1.35**	**$1.33**	**$1.82**	**$0.1**	**$0**	**$3.21**	**$0**	**$0**	**$0**
YOY Growth	-100.0%	992.9%	-	-	-	-	-	-	-	-
Total Revenues	**$3.91**	**$7.25**	**$3.02**	**$3.69**	**$1.76**	**$1.86**	**$10.29**	**$9.35**	**$11.60**	**$14.10**
YOY Growth	89.3%	85.3%	120.9%	164.3%	14.8%	-37.1%	42.0%	-9.2%	24.1%	21.6%
Cost of Sales	$1.80	$2.73	$0.85	$0.98	$0.99	$0.84	$2.41	$2.81	$3.13	$3.81
Product Gross Margin	52.5%	53.8%	49.7%	47.3%	41.7%	55.0%	66.0%	70.0%	73.0%	73.0%
R&D	$0.42	$0.10	$0.36	$1.09	$1.01	$1.05	$3.50	$5.00	$5.00	$5.00
% R&D	10.6%	1.4%	11.8%	29.6%	57.2%	56.5%	34.1%	53.5%	43.1%	35.5%
SG&A, Other Fees	$7.29	$7.94	$4.53	$3.96	$3.96	$3.90	$16.36	$16.00	$17.00	$18.00
% G&A	186.3%	109.5%	150.2%	107.5%	225.3%	209.7%	158.9%	171.1%	146.6%	127.7%
Operating Income	($5.40)	($3.51)	($2.72)	($2.35)	($4.20)	($3.93)	($11.98)	($14.46)	($13.53)	($12.71)
Operating Margin	-138.1%	-48.5%	-	-	-	-	-116.4%	-154.6%	-116.7%	-90.1%
Interest & Other Income	($1.40)	$0.02	($2.00)	($5.10)	$0.43	$1.00	($5.67)	($0.15)	$0.20	$0.35
Pre-Tax Income	($6.80)	($3.49)	($4.72)	($7.45)	($3.77)	($2.93)	($17.65)	($14.61)	($13.33)	($12.36)
Taxes	$0.01	$0.0	$0	$0.00	$0	$0	$0.0	$0	$0	$0
Tax Rate	0%	0%	0%	0.0%	0%	0%	0%	0%	0.0%	0.0%
Preferred A, B, D, E	$2.22	$0.35	$0.01	$0	$0	$0	$0.01	$0	$0	$0
Net Income	($9.04)	($3.86)	($4.73)	($7.46)	($3.77)	($2.93)	($17.67)	($14.61)	($13.33)	($12.36)
Net Margin	-231.1%	-53.2%	-	-	-	-	-171.7%	-156.2%	-114.9%	-87.6%
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.09)**	**($0.04)**	**($0.03)**	**($0.22)**	**($0.13)**	**($0.11)**	**($0.08)**
YOY Growth	150.7%	-67.4%	-	-	-	-	183.2%	-38.4%	-19.7%	-22.8%
FAS-123R Expense	$0.41	$0.31	$1.22	$0.31	$0.31	$0.35	$2.20	$0.60	$0.75	$0.75
EPS Impact of FAS-123R	*($0.01)*	*($0.01)*	*($0.02)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.03)*	*($0.01)*	*($0.01)*	*($0.01)*
Weighted Ave. Shares Out	38.7	50.7	63.3	80.9	91.2	92.5	82.0	110.0	125.0	150.0

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

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