Zacks Small-Cap Research

November 15, 2012
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Cytomedix, Inc (CMXI-OTC)

CMXI: Disappointing Third Quarter, But Expecting Much Better Times Ahead…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/30/2011
Current Price (11/15/12)	$0.67
Target Price	**$2.00**

UPDATE

We currently model total revenues in 2012 at $10.3 million, comprised of $7.1 million in products sales coming from $0.6 million in AutoloGel, $6.4 million in Angel, and $0.1 million from research products at Aldagen, and $3.2 million in recognition for the complete recognition of the non-refundable option fee. We do not model any additional upfront or licensing fee with a new partner in 2012.

We think the stock is extremely attractive at today's price. According to management, October Angel sales are the highest since Cytomedix took over the product in April 2010. Management also expects that AutoloGel will be a meaningful contributor to the top-line in 2013. We expect acceleration in the enrollment of the RECOVER-Stroke program, and believe DSMB clearance for the first 30 patients will take place shortly. We see $2.00 as fair-value.

SUMMARY DATA

52-Week High	**$2.28**
52-Week Low	**$0.67**
One-Year Return (%)	**-19.37**
Beta	**0.44**
Average Daily Volume (sh)	**57,601**
Shares Outstanding (mil)	**91**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**4**
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					12.9 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					-$0.10 E

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WHAT'S NEW

Financial Results

On November 14, 2012, Cytomedix reported financial results for the third quarter 2012. Total revenues in the quarter were $1.76 million, comprised of $1.70 million in product sales and $0.06 million in royalties. Revenues increased 15% from the third quarter 2012 but were shy of our forecast for revenues of $1.85 million. Management attributed the short-fall to seasonality in Angel sales and lumpiness in AutoloGel sales. That being said, on the third quarter conference call on November 15, 2012, CEO Martin Rosendale noted that October 2012 was the best recorded sales month in the company's history.

Revenues declined 52% sequentially from the second quarter 2012 when the company recorded $1.82 million in partial (and final) recognition of non-refundable $4.5 million option fee in connection with the company's previous exclusive negotiations with a potential strategic partnership for AutoloGel U.S. chronic wound market.

Product sales were made up of $1.58 million in sales of Angel, up 11% from the third quarter 2011 but declined 3% sequentially from the second quarter 2012. Product sales also included $0.11 million in sales of AutoloGel, up 9% from the third quarter 2011 but down 37% sequentially from the second quarter 2012. Both products came in below our estimates of $1.70 million and $0.15 million, respectively. As noted above, management attributed this to seasonality and lumpiness. We note that royalty revenues of $0.06 million were derived from the company's AldeFluor license and were in-line with expectations.

Net loss for the third quarter 2012 was $3.77 million, or 4 cents per diluted share. Loss was greater than our modeling forecasted based on lower-than-expected revenues and higher-than-expected SG&A. However, we note loss for the third quarter included a $0.69 million non-cash expense for re-valuation of the outstanding warrant and contingent consideration. However, even after backing out non-cash expenses, net loss was still slightly higher than our model based on higher-than-expected consulting expenses and professional fees associated with the acquisition of Aldagen earlier in the year. R&D expense was in-line with expectations. In our view, expenses at Cytomedix are too high – specifically the SG&A line – and breakeven operations seem unlikely without a major upward trajectory in either AutoloGel or Angel, or a partnership for the ALDH pipeline.

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.

We see the current cash balance as sufficient to fund operations through the first quarter 2013. We believe the company will seek to raise capital in the next few months. We note the recent filing of a $35 million mixed S-3 on November 5, 2012 and subsequent EFFECT on November 9, 2012. Cytomedix also has $4.1 million available under its current common stock purchase agreement with Lincoln Park Capital. We would not be surprised to see management raise a few million through LPC here in the fourth quarter 2012, then do a larger secondary offering at hopefully better prices in the first quarter 2013.

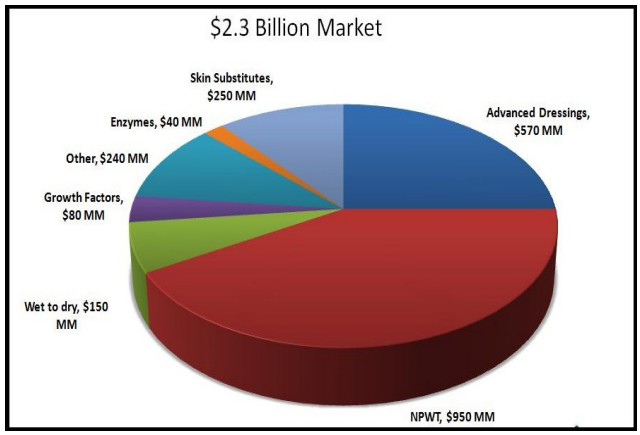
The best near-term non-dilutive option for management would be to secure a new partnership to market AutoloGel in the U.S. On the third quarter call management noted being in active discussions with a number of parties, although no timeframe for a deal was given. Ultimately, management believes they can secure a partner, or partners, on AutoloGel for broad commercialization in 2013. However, we are not anticipating a deal before the end of the year. This could provide some non-dilutive funds to Cytomedix and potentially be a catalyst for the stock in throughout 2013.

CMS Grants AutoloGel Coverage

On August 2, 2012, CMS issued a National Coverage Determination (NCD) for autologous blood-derived products for the treatment of chronic non-healing wounds. The decision reverses nearly 20 years for non-coverage for autologous platelet rich plasma (PRP) treatments, including Cytomedix' AutoloGel – the only FDA approved treatment options. CMS granted coverage to AutoloGel under its Coverage with Evidence Development (CED) program. We encourage investors to view the final memo on CMS' website:

http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=260

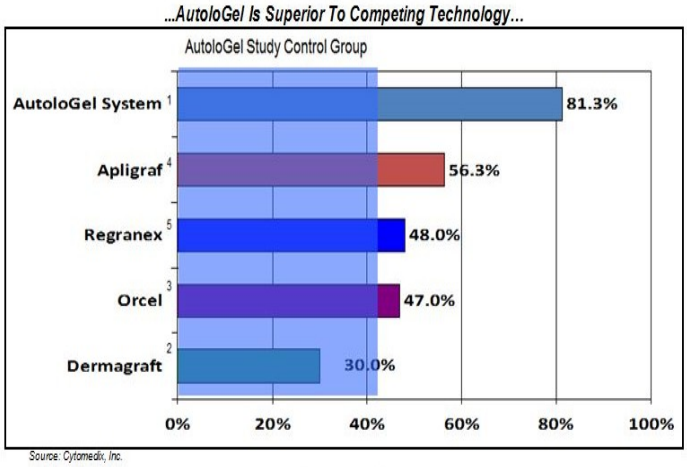
CED is full coverage by the government to Medicare / Medicaid beneficiaries seeking to use AutoloGel for the treatment of chronic non-healing wounds - more specially, diabetic foot ulcers, venous leg ulcers, and pressure ulcers. Frost & Sullivan estimates the U.S. chronic wound care market is $2.3 billion in size, with more than 6 million wounds treatment annually.

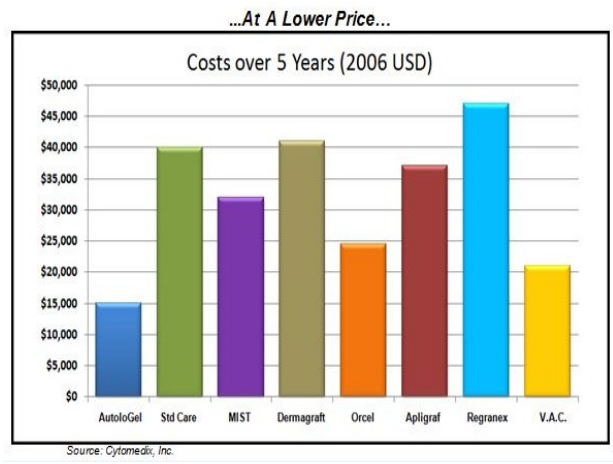


PRP products like AutoloGel represent only a small fraction of the market share. There are dozens of alternative therapies that compete with AutoloGel, some of them commodity types of products that have established habitual use patterns or set provider contracts to encourage standardized use.

There is virtually no government business for AutoloGel now. Instead, management has been focusing on private pay procedures, long-term acute care hospitals (LTAC), veteran's administration facilities, and certain state Medicaid agencies. However, the lack of a national coverage decision on the product has limited uptake in this area as well. We believe CMS coverage not only kicks open the door to Medicare / Medicaid, it also meaningfully expands private pay coverage as well as many private insurance companies follow the CMS' lead.

AutoloGel, in our view, is a potential significant leap forward in the treatment paradigm. Not only is the product more effective than the more commonly used Dermagraft (~$195M in sales in 2011) and Apligraf (~$125M in sales in 2011), but it costs less. The data below was compiled by B&D Consulting in September 2007. B&D is an independent advisory and advocacy firm located in Washington. The firm completed a cost effectiveness analysis of AutoloGel compared to alternative therapies for patients with diabetic foot ulcers. Results of this study demonstrate AutoloGel offers a lower cost and better healing outcomes than the other therapies analyzed. This study was published in the Journal of Advances in Skin and Wound Care in December 2008.





Cytomedix has conducted its own market research and clinical studies to assess the cost and effectiveness of AutoloGel when compared to readily available and fully-covered, alternative therapies. For example, included in the company's dossier requesting reconsideration on NCD in May 2011 was a number of case studies collected over the previous seven years.

...Market Misconceptions...

Despite the significant advantages of the product on both cost and effectiveness, and massive market opportunity that lies before Cytomedix with AutoloGel, we believe that investors may be misinterpreting the CED decision. CED is not a road-block or hurdle to coverage, nor is it a stepping stone to coverage. CED is coverage. The only difference between CED and final coverage is that CMS would like to monitor the ongoing use of AutoloGel – for a certain period of time – in order to collect additional data to support its decision. This isn't an FDA clinical trial where CMS is asking Cytomedix for an outcome or a primary endpoint. Instead, CMS and Cytomedix will use a registry to monitor patients post use.

For years, Cytomedix has been stuck in the, "How do we generate data without coverage / how do we obtain coverage without data" conundrum. As a result, the data available is limited. CED provides the pathway from CMS provide the coverage in order for Cytomedix to collect additional data. Perfect.

Investors unfamiliar or skeptical of CED might want to view a similar example to what Cytomedix is doing with AutoloGel to Medtronic's efforts to gain CMS coverage for its Transcatheter Aortic Value Replacement (TAVR) procedure. CMS granted CED to Medtronic for TAVR in May 2012. The decision came with similar post-coverage stipulations as the CMS CED decision on AutoloGel. Medtronic has full coverage for the TAVR procedure, but must collect additional data for CMS at qualified hospitals via a patient registry. In October, we learned that Medtronic created the TVT Registry, a benchmarking tool developed to track patient safety and real-world outcomes related to the TAVR procedure. We think this is a good example of the pathway investors can expect Cytomedix to try to replicate with AutoloGel.

It’s important for investors to understand that CED allows Cytomedix to earn a profit as it collects the data and funnels that back to CMS for review. That's different from a traditional clinical trial which normally cost companies money. Cytomedix will be selling AutoloGel with CMS coverage, and booking revenues as it ramps.

...Seeking A Partner…

Management is in the process of engaging with interested parties experienced in wound care to pursue potential partnerships and commercial agreements for AutoloGel. We think the opportunity exists for Cytomedix to sign a deal in the next several months. Given the size of the market and the multiple potential pathways for sales of the AutoloGel device – home care, hospital care, wound centers, skilled nursing – we think Cytomedix may sign more than one partnership.

We think it’s imperative that Cytomedix partners AutoloGel. The opportunity is too big to leave in the hands of half-a-dozen part-time representatives. We think Cytomedix can handle the running of the clinical study, but to truly realize the kind of upside that AutoloGel offers, the product needs to be in the hands of a much larger firm capable of tier-1 promotion. Ideally, we would like to see in the order of 100 full-time representatives promoting the product. Under that scenario, the drug truly is a competitor to Dermagraft and Apligraf.

…Conclusions …

Above we've outlined why we believe CED is so important to AutoloGel. There is virtually no government business for AutoloGel right now, and the lack of government business is impeding uptake in the private pay market. CED is coverage at a profit to the company. Plus, AutoloGel is a superior product. Data from both independent and company sponsored studies shows that AutoloGel works better and costs less than products like Dermagraft and Apligraf. Both these products have CMS coverage and will do over $150 million in revenues in 2012.

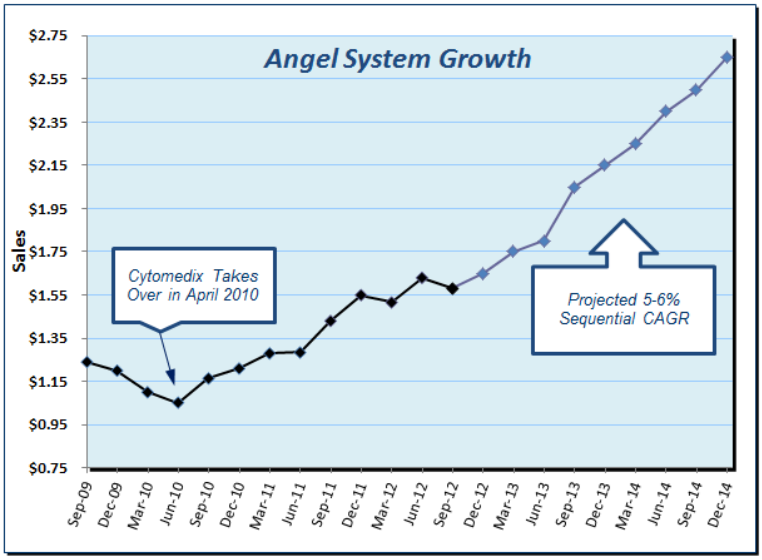
Based on conversations that we are having with investors, there is significant misconception on CED. Cytomedix will do $0.6 million in AutoloGel sales in 2012. It's a non-factor in the company's valuation at this point. Expectations are low due to the previous sales and misconceptions on CED. That will change in 2013. On the third quarter conference call, CEO Martin Rosendale noted that he expects AutoloGel to “contribute meaningfully” to revenues in 2013. As a point of reference, Cytomedix will treat around 300 patients with AutoloGel in 2012. The company’s goal is to increase that number to over 1,000 in 2013.

Angel Keeps Chugging Along

Angel sales were below our expectations in the third quarter 2012, coming in at $1.58 million vs. our estimate of $1.70 million. Sales were up 11% year-over-year but down 3% sequentially. Management attributed the decline to seasonality during the third quarter. We are looking back in our model at previous third quarter results for 2010 and 2011; there was no drop-off in sales. So we are unsure just what seasonality hurt Angel in 2012. That being said, CEO Martin Rosendale noted on November 15, 2012 that October 2012 was Angel's best sales month ever, so perhaps the drop-off will just turn out to be a one quarter phenomenon.

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…



Cytomedix continues to build out its sales infrastructure both domestically and internationally. Earlier in the year the company hired a national sales director to go along with 7 regional sales managers and 20+ independent agents. On the third quarter call on November 15, 2012, management noted hiring 2 additional representatives. We expect management to add new sales managers and field reps in the coming year. The number of independent reps has grown each quarter as Cytomedix expands its network to promote Angel.

…New Indications to Drive Growth…

BMAC: 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.

Angel is intended to be used in the clinic or intraoperatively at the point-of care for the safe and rapid preparation of PRP from a small sample of whole blood or a small mixture of blood and bone marrow. The devices proprietary software automatically adjusts the separation parameters to deliver a consistent, high quality product. We note that in vitro performance testing data with Angel yielded statistically significant improvement in the concentrations of hematopoietic progenitor / stem cells, reduced presence of pro-inflammatory cells, and provided better separation of platelet rich plasma (PRP) and red blood cells compared to alternative devices. We see this as a significant market opportunity for Cytomedix, as management can now position Angel PRP at a "best in class" device that offers meaningful advantages over the competition. These advantages compared with other commercially available systems include: 1) high platelet yields, 2) significant reduction in pro-inflammatory cells, 3) rapid processing time, 4) adjustable hematocrit from 0%-25%, and 5) flexible final concentrated PRP volumes.

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.

Reinfusion: Before Cytomedix took over, Sorin was already seeing real-world use of the Angel device during surgery for total blood management. Cytomedix is looking to file a 510(k) application to expand the label to include the reinfusion of packed red blood cells separated during the bone marrow processing procedure. The company needs to conduct a small human study prior to filing the 510(k). We think this opens the door for potential use in the surgical setting by cardiologists potentially for initiations such as critical leg ischemia (CLI). If Angel can deliver real-time highly viable stem cells along with PRP, this could be an enormous revenue opportunity for Cytomedix. We note that some clinicians are already successfully using Angel in this indication today. Cytomedix plans to help facilitate investigator sponsored trials (ISTs) in this area.

This is where a potential marriage of Angel and Aldagen gets interesting. We see synergies in the manufacturing debulking progress and the potential for Angel's PRP (or even platelet poor plasma) to be used as the delivery vehicle for ALD-201 or ALD-301. Angel separates the red blood cells in as little as fifteen minutes. Incorporating Angel into Aldagen's process could save four hours on the processing time. And using AutoloGel to treat chronic wounds in patients with CLI could improve the outcome of the trial when used with $ALDH^{br}$ Cells.

Aesthetic Applications: 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.

Sports Medicine: 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. Tiger Woods was reported to use PRP to shorten his recovery time after his ACL tear in 2008. Pittsburgh Steelers' Hines Ward and Troy Polamalu both used PRP to recover from an injury during the 2008 NFL season in which the team won the Super Bowl. The use of PRP is clearly on the rise in professional sports. The LA Dodgers, Seattle Mariners, Denver Nuggets, NY Mets, and Dallas Cowboys have all embraced the use of PRP. In fact, we are now beginning to see use in college and amateur athletics. Standards have yet to be set however, and some sports purists are bringing up ethical questions regarding the use of PRP. In fact, the World Anti-Doping Agency, as of January 1, 2010, has banned the use of PRP in international competition when injected directly into muscle. The agency continues to allow PRP use for tendon, bone, and ligament injuries. Nevertheless, for the non-professional athlete, PRP could represent a cheap and quick alternative to a lengthy recovery processes following orthopedic surgery or a minor injury such as a muscle sprain or strain.

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. We think the product offers doctors and trainers excellent characteristics, including improved processing time, greater sterility, and enhanced administration. Cytomedix continues its efforts to use peer-to-peer networking and webinars to help drive use of the Angel device in orthopedics / sports medicine. As noted above, we see this as the "Holy Grail" for Angel.

DSMB Clearly Expansion of RECOVER-Stroke

On May 16, 2012, Cytomedix announced that an independent data safety monitoring board (DSMB), after reviewing the safety data from the first 10 patients in the ongoing RECOVER-Stroke program, has recommended that the phase 2 trial continue as designed. Enrollment of these 10 patients took place at three clinical sites in the U.S. (Duke University Medical Center, the Los Angeles Brain and Spin Institute, and the University of Texas Health Science Center). This safety data was just recently presented at the World Stoke Congress in Brazil in October 2012 by Sean Savitz, M.D., a professor of neurology and director of the stroke program at the University of Texas. Safety of the procedure was assessed by laboratory studies, neurological examinations and serial neuroimaging. No serious adverse events were reported.

Following the DSMB review of the first 10 patients, the trial has been allowed to expand to the next 90 patients. Management has opened enrollment at an additional 6 sites around the U.S. to date. As of November 15, 2012, four sites are actively enrolling patients and another five have just begun screening. Management expects that a total of 10 to 15 sites will be online by the end of the year. We note there is a second DSMB review after a total of 30 patients have been enrolled. We expect these results to be announced in the first quarter 2013.

If all goes well, enrollment at 100 patients should be completed by the third quarter 2012. We expect data around late 2013. As a reminder, the trial is a double-blind, placebo-controlled design, with a 60/40 randomization between drug and control. In the trial 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. The primary objective is to evaluate the safety of ALD-401 evaluated by the occurrence of adverse events in the two groups, as well as post-procedural changes in the diffusion-weighted MRI scan of the brain. Efficacy will be evaluated by change from baseline in the modified Rankin Scale (mRS) three months and changes from baseline in the NIH stroke scale and Barthel Index at three and six months.

Aldagen shareholders can earn a 1.015 million share milestone for enrollment of the first 60 patients with DSMB clearance and a 3.046 million share milestone for completion of enrollment on or before May 31, 2013 (which we see as unlikely given the current pace). Positive data from the phase 2 trial that results in progression towards a phase 3 program (successful end-of-phase 2 meeting with the U.S. FDA) can earn Aldagen shareholders another 16.248 million shares of common stock.

We are relatively confident that the safety endpoint after the first 60 patients enrolled will be met. Data published in the Annals of Neurology,2005;57-6:874-882, concludes that autologous mesenchymal stem cells can be safely administered without inducing serious adverse events, and may improve functional recovery in stroke patients. We expect DSMB clearance of the first 60 patients in March / April 2012.

…A High Risk / High Reward Program…

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 – 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. The most similar path to Aldagen's ALD-401 would be neural stem cells or neurotrophic factors.

- Neurotrophic Factors are a group of proteins involved in cell proliferation, migration, and differentiation. Preclinical studies demonstrate that neurotrophic factors such as nerve growth factor, BDNF, ciliary neurotrophic factor, glial-derived neurotrophic factor, vascular endothelial growth factor, and insulin-like growth factor (IGF)-1 can reduce infarct size in animal models. Phase 1 studies with basic fibroblast growth factor (bFGF) were encouraging, but all programs have been halted prior to phase 3 due to a lack of efficacy seen in mid-stage clinical trials.
- Neural Stem Cells, mainly found in the developing brain, are able to differentiate and regenerate in response to both internal and external stimuli. Research suggests that neural stem cells may be able to regenerate and restore loss of brain function in injuries such as stroke. This has been confirmed by numerous preclinical trials. A similar belief exists for bone marrow stromal cells, which have been shown to develop into neuroectodermal cells including neurons. Companies such as Neuralstem, San-Bio, and ReNeuron are pioneering this field. However, the clinical data remains early-stage.

The other aspect of RECOVER that is different from the above failed programs is the timing of the dose. ALD-401 will be dosed 13 to 19 days after the stroke. In most stroke trials, there is a rush to deliver within that three to six hour window. The only approved medication, tPA, must be dosed within three hours of the event. This has lead most companies to believe the window for an effective product is inside three hours. However, new evidence of stroke research shows that inflammation in the brain persists for two weeks after a stroke. There is also significant variability in baseline around the first few days after a stroke (with respect to mRS and NIH score) as the brain recovers. By allowing the inflammation to subside and the patient to stabilize, Aldagen believes dosing 13 to 19 days after the stroke gives ALD-401 a better chance to succeed.

We view the ALD-401 phase 2 program as different from many of the above failures. It's a novel approach, but the preclinical data looks encouraging. Work out of San-Bio, Neuralstem, and ReNeuron seems to confirm the theory behind the mechanism of action and the trial design. RECOVER is high risk, but given all the above failures and the wide-open market opportunity, it's all high reward.

Management estimates the annual patient population eligible for treatment with ALD-401 is between 176,000 and 265,000 patients (commissioned study by Trinity Partners). Trinity also estimates that the annual nursing home and in-home costs of the post-acute treatment of an ischemic stroke patient is approximately $30,000. The American Heart Association estimates the mean lifetime cost of ischemic stroke in the U.S. to be approximately $140,000. At an estimated price of $20,000 per ALD-401 treatment, with only 5% market share, ALD-401 has peak sales between $200 and $250 million.

We estimate the direct cost of the ongoing phase 2 RECOVER-stroke trial with ALD-401 is roughly $6 to $8 million. We are expecting enrollment to complete in the third quarter 2013. We expect data about three to four month later, or in the fourth quarter 2013. If positive, we expect that management will be in position to meet with the U.S. FDA for the end-of-phase 2 meeting early 2014. A positive outcome from the phase 2 program forms the basis for a pivotal registration program to start late in 2014. We expect management to quickly seek a development and commercialization partner for ALD-401 if the data are positive.

Phase 1 Initiated In Patients With Glioma

In July 2012, Cytomedix announced the initiation of a phase 1 clinical study with ALD-451, a formulation of the company's ALDH bright cells, designed to test the feasibility and safety of ALD-451 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. The trial is expected to enroll up to 12 patients in an open-label design. Besides feasibility and safety, the trial will assess the initial description of the effects of ALD-451 on neuro-cognition.

Malignant glioma patients who undergo surgery, radiation therapy and temozolomide treatment oftentimes experience deterioration of neuro-cognition and have poor patient-reported outcomes. Earlier studies suggest that ALDH bright cells may repair neural brain damage. Management is looking to confirm these results in a phase 1 trial, and then seek to move into a larger phase 2 trial in 2013.

Expectations For 2012

We currently model total revenues in 2012 at $10.3 million, comprised of $7.1 million in products sales coming from $0.6 million in AutoloGel, $6.4 million in Angel, and $0.1 million from research products at Aldagen, and $3.2 million in recognition for the complete recognition of the non-refundable option fee. We do not model any additional upfront or licensing fee with a new partner in 2012.

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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
Med Product Sales	**$3.79**	**$5.90**	**$1.69**	**$1.86**	**$1.70**	**$1.86**	**$7.08**	**$9.35**	**$12.90**
YOY Growth	1574.5%	55.8%	23.5%	33.5%	11.4%	15.5%	20.0%	32.0%	38.0%
Drug Pipeline	**$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**
YOY Growth	-100.0%	992.9%	-	-	-	-	-	-	-
Total Revenues	**$3.91**	**$7.25**	**$3.02**	**$3.69**	**$1.76**	**$1.86**	**$10.29**	**$9.35**	**$12.90**
YOY Growth	89.3%	85.3%	120.9%	164.3%	14.8%	-37.1%	42.0%	-9.2%	38.0%
Cost of Sales	$1.80	$2.73	$0.85	$0.98	$0.99	$0.84	$2.41	$2.81	$3.48
Product Gross Margin	52.5%	53.8%	49.7%	47.3%	41.7%	55.0%	66.0%	70.0%	73.0%
R&D	$0.42	$0.10	$0.36	$1.09	$1.01	$1.05	$3.50	$5.00	$5.00
% R&D	10.6%	1.4%	11.8%	29.6%	57.2%	56.5%	34.1%	53.5%	38.8%
SG&A, Other Fees	$7.29	$7.94	$4.53	$3.96	$3.96	$3.90	$16.36	$16.00	$17.00
% G&A	186.3%	109.5%	150.2%	107.5%	225.3%	209.7%	158.9%	171.1%	131.8%
Operating Income	($5.40)	($3.51)	($2.72)	($2.35)	($4.20)	($3.93)	($11.98)	($14.46)	($12.58)
Operating Margin	-138.1%	-48.5%	-	-	-	-	-116.4%	-154.6%	-97.5%
Interest & Other Income	($1.40)	$0.02	($2.00)	($5.10)	$0.43	$1.00	($5.67)	($0.15)	$0.20
Pre-Tax Income	($6.80)	($3.49)	($4.72)	($7.45)	($3.77)	($2.93)	($17.65)	($14.61)	($12.38)
Taxes	$0.01	$0.0	$0	$0.00	$0	$0	$0.0	$0	$0
Tax Rate	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
Net Income	($9.04)	($3.86)	($4.73)	($7.46)	($3.77)	($2.93)	($17.67)	($14.61)	($12.38)
Net Margin	-231.1%	-53.2%	-	-	-	-	-171.7%	-156.2%	-96.0%
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.09)**	**($0.04)**	**($0.03)**	**($0.22)**	**($0.13)**	**($0.10)**
YOY Growth	150.7%	-67.4%	-	-	-	-	183.2%	-38.4%	-25.4%
FAS-123R Expense	$0.41	$0.31	$1.22	$0.31	$0.31	$0.35	$2.20	$0.60	$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)*
Weighted Ave. Shares Out	38.7	50.7	63.3	80.9	91.2	92.5	82.0	110.0	125.0

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

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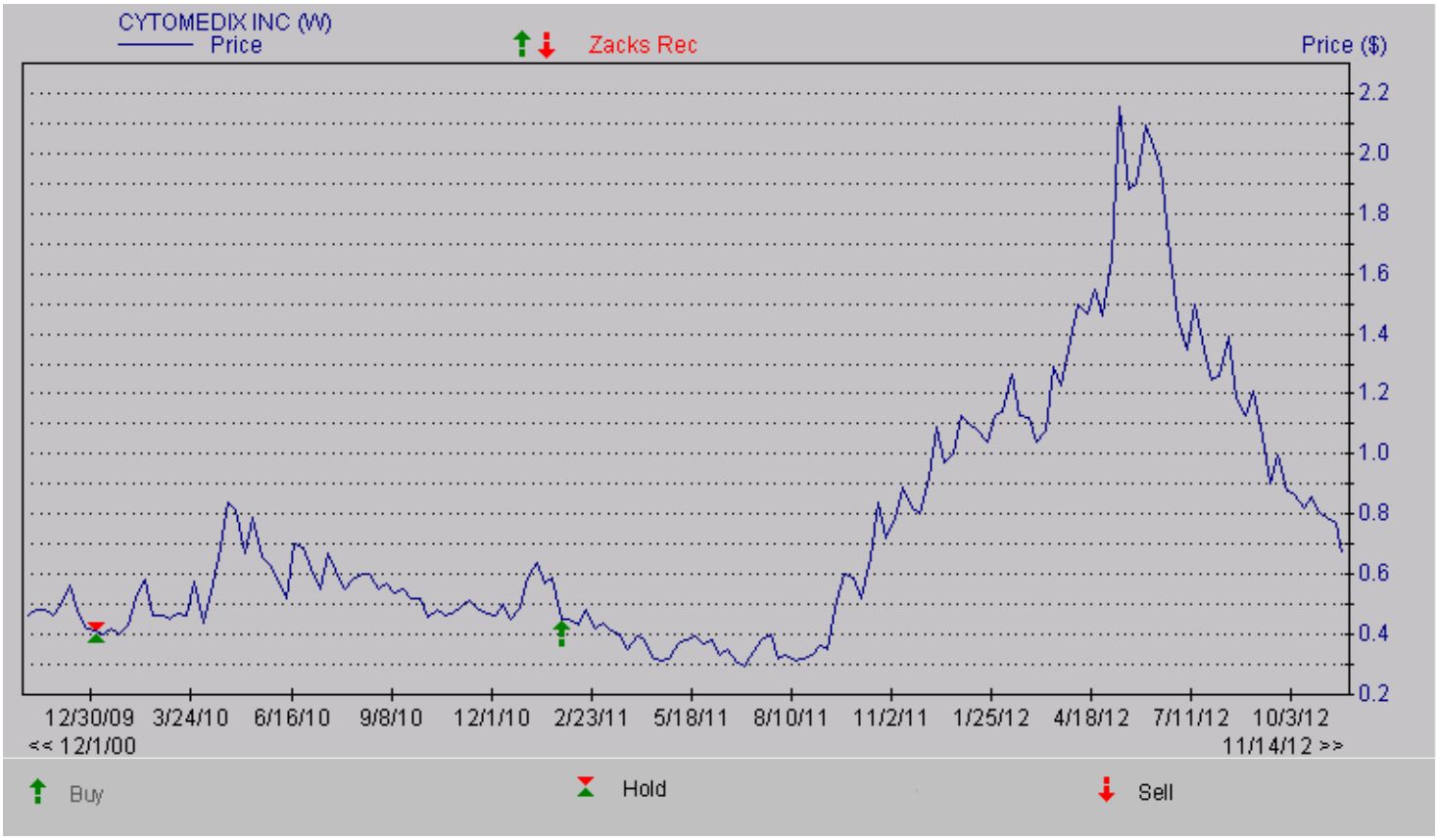

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