Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTC)

CMXI: AutoloGel Deal Falls Through, But Core Business Remains Solid…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/30/2011
Current Price (08/15/12)	$1.14
Target Price	**$2.00**

UPDATE

It's been a mixed August for Cytomedix. Earlier in the month the company announced that CMS has granted Coverage with Evidence Development (CED) for AutoloGel for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds. The final proposal memo is very favorable for the company and we believe kicks open a potential multi-million dollar opportunity for the company. On August 14, 2012, the company issued strong financial results for the second quarter highlighted by record sales in both AutoloGel and Angel and meaningful clinical progress with ALD-401. However, the bombshell was the announcement that talks with the company's potential AutoloGel licensing partner, a top-20 global pharmaceutical company, have ended. We see a partnership for AutoloGel as an imperative for future growth of the product. Management does get to keep the $4.5 million non-refundable payment, and already claims to be in talks with potential new partners for the device. Nevertheless, we have revised down our estimates meaningfully given the lack of big pharma promotion we had built into our model prior to the news. As a result, we are reducing our price target to $2 per share. We maintain our optimism on Cytomedix, and believe, in the long run, terminating talks with this partner may work to the company's benefit if they can secure a new partner (or partners) on equal footing.

SUMMARY DATA

52-Week High	**$2.28**
52-Week Low	**$0.30**
One-Year Return (%)	**377.42**
Beta	**0.99**
Average Daily Volume (sh)	**82,229**
Shares Outstanding (mil)	**74**
Market Capitalization ($mil)	**$109**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**20**
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	1.9 E	2.1 E	10.7 E
2013					9.6 E
2014					12.6 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	-$0.02 E	-$0.04 E	-$0.21 E
2013					-$0.13 E
2014					-$0.10 E

WHAT'S NEW

Financial Results

On August 14, 2012, Cytomedix reported financial results for the second quarter 2012. Total revenues in the quarter were $3.69 million, comprised of $1.81 million in product sales, $0.05 million in royalties, and $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. Revenues increased by 164% over the second quarter 2011.

Product sales were made up of $1.63 million in sales of Angel, up 27% from the second quarter 2011 and 7% sequentially from the first quarter 2012 and $0.17 million in sales of AutoloGel, up 55% from the second quarter 2011 and up 5% sequentially from the first quarter 2012. Both products posted record sales in the quarter. Royalties of $0.05 million were derived from the company's AldeFluor license. Licensing fee revenues of $1.82 million completes the full recognition of the $4.5 million non-refundable option fee noted above. We do not longer expect Cytomedix to recognize licensing and collaborative revenue in the second half of 2012.

Net loss for the second quarter 2012 was $7.46 million, or 9 cents per diluted share. This was significantly greater than our modeling forecasted. However, we note several non-cash expenses in the quarter associated with the acquisition of Aldagen in mid-February 2012 and the re-valuation of the outstanding warrant and contingent consideration. Cytomedix recorded nearly $4.4 million in non-cash expense during the quarter. 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, as well as higher-than-expected R&D expense. In our view, expenses at Cytomedix are too high 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 $4.4 million in cash on an operations and investing standpoint. The company raised approximately $4.5 million in cash during the quarter through the issuance of common stock and proceeds from warrant exercises during the quarter. Cytomedix exited the quarter with $8.5 million in cash and investments, up slightly from the $8.4 million reported at the end of March 2012. Within this $8.5 million, management has allocated $4.7 million to the ongoing clinical development of ALD-401 in the RECOVER-Stroke phase 2 trial and related matters.

We see the current cash balance as sufficient to fund operations into the first quarter 2013. We note there are an estimated 800k warrants currently exercisable at $1.00 per share that expire at the end of August 2012. We expect that these will contribute toward the cash balance here in the third quarter. There are an additional 5.5 million warrants exercisable at stock prices ranging from $0.50 to $0.60 we believe management can attempt to encourage the holders to exercise to provide some additional cash to the company. However, we do believe that the company will require some additional regardless later this year or in early 2013.

Previously, our financial model assumed an upfront payment from the "Top-20 global pharma partner" the company was in exclusive negotiations with on the U.S. licensing for AutoloGel in the area of $3 million. We also modeled a $3 million milestone for the filing of the next-generation AutoloGel device ("AutoloGel 2.0") in the first quarter 2013. We believed these two payments could have delayed an offering until the middle of 2013. Management believes they can secure another partner, or partners, on AutoloGel in the next few quarters. This could provide some non-dilutive funds to Cytomedix throughout 2013.

CMS Grants CED For AutoloGel

On August 2, 2012, the Centers for Medicare & Medicaid Services (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. CMS granted coverage to AutoloGel under its Coverage with Evidence Development (CED) program. CMS noted in its decision to award NCD to autologous PRP, and with it the only FDA approved product, Cytomedix's AutoloGel, that in order to receive the benefits of coverage, patients must be enrolled in a clinical research study. 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

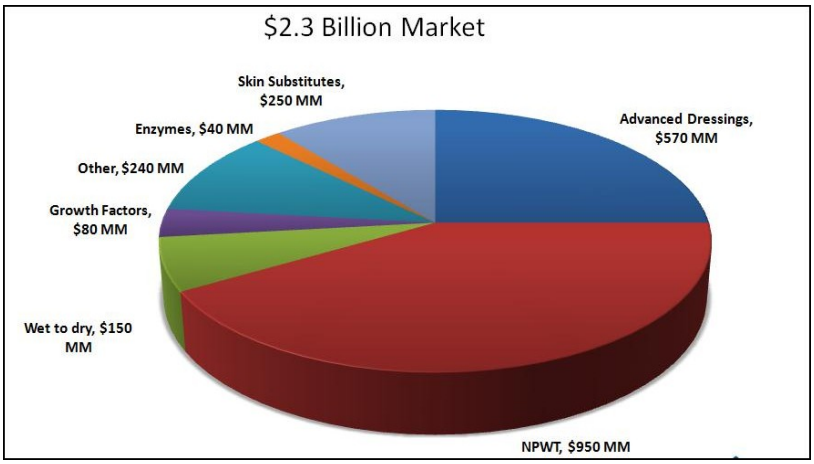
Investors will notice that the final decision memo contains some key changes from the preliminary decision issued by CMS in May 2012. The most obvious change from that preliminary decision is the term randomized clinical trial (RCT) is no longer used by CMS. Instead, CMS notes requiring a clinical research study (CRS). This was key victory for Cytomedix, as the challenges of running a RCT in this indication, outlined by Cytomedix CEO Martin Rosendale in the public comments section of the memo were numerous. Cytomedix even met with CMS in late June 2012 to lobby its case. The meeting seems to have been a successful endeavor for the company. The company called the final memo "a pleasant and unexpected surprised."

With the steep requirement for an RCT a thing of the past, we believe Cytomedix can now effectively, and profitably, design a protocol to address the "evidence development" issue posed by CMS. Management believes the clinical research study can be derived from an existing registry. Management met with CMS as recently has August 14th to discuss the protocol. Management called the initial design suggested by CMS "practical and pragmatic." Cytomedix has already identified key clinical sites to participate in the study and feels as though the cost of enrolling the study and collecting the data is less than the reimbursement that CMS coverage now provides.

…Coverage & Awareness Should Drive Sales…

We believe CED could be a meaningful driver of AutoloGel sales. There are approximately 2.0 million pressure ulcers and 1.5 million diabetic foot ulcers each year in the U.S. where AutoloGel and its physiologically relevant concentration of platelet-rich plasma could be an effective product. However, approximately half of these are in patients covered by Medicare / Medicaid, and non-coverage has been a significant impediment for uptake.

The market for products addressing chronic wounds in the U.S. is estimated to be $2.3 billion annually. There are over 6 million wounds (primarily diabetic foot ulcers, venous leg ulcers, and pressure ulcers) treated each year. Platelet rich plasma (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, but the lack of a national coverage decision on the product has limited uptake in this area as well. CMS coverage not only kicks open the door to Medicare / Medicaid, it also meaningfully expands private pay coverage as well.

...Partnership Falls Through…

August 14, 2012, Cytomedix announced that its ongoing discussions with the "Top-20 Global Pharmaceutical Company" have ceased. On the second quarter call, CEO Martin Rosendale stressed that terminating discussions with the potential partner was in no way related to CMS' decision to provide CED on AutoloGel and that the pharmaceutical company had a "unique circumstance" that was not going to allow the deal to be mutually beneficial. Unfortunately, that's all the information we received. We remind investors that talks initiated back in August 2011 with this partner. The $4.5 million payment that Cytomedix received was non-refundable. Although we are extremely disappointed that the deal fell through, we are pleased that Cytomedix netted $4.5 million in cash for a product that did only $170k in sales in the second quarter 2012.

Management is now free to start re-engaging with other interested parties experienced in wound care to pursue potential partnerships and commercial agreements for AutoloGel. On the second quarter call, Mr. Rosendale noted interest from other potential partners throughout the exclusive negotiation period. In fact, the company reported being on the phone with potential partners immediately following the press release.

We think the opportunity exists for Cytomedix to sign a new partner 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. The previous exclusive negotiations centered on the hospital setting only. Cytomedix was free to engage in talks on the home care and nursing area, and has reported being in talks with partners separate from the exclusive talks for the hospital market.

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. The pharma partner was going to assign 100 full-time representatives to the effort. This is the type of promotion we expect Cytomedix to secure in the coming months from a new partner.

…Changes To Our Model…

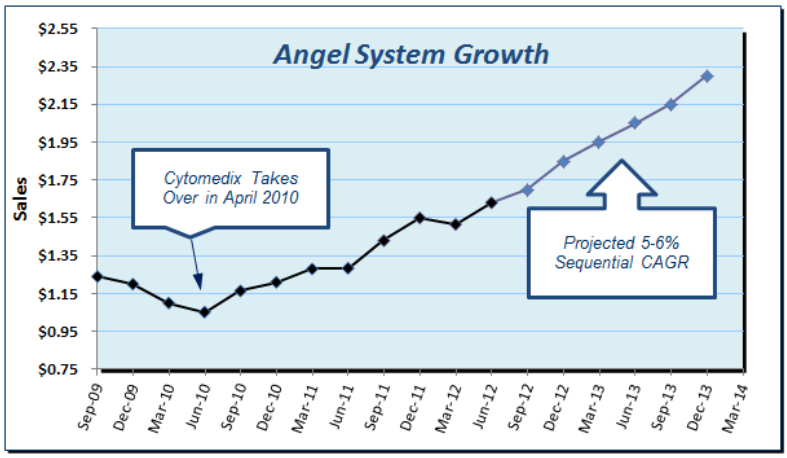
AutoloGel sales are almost immaterial at this point, coming in at $0.17 million in the second quarter 2012. We note this level of sales is being generated with little to no promotion by the company. The lack of reimbursement on the Medicare / Medicaid side put up significant road-blocks on the private pay market. Almost all the business was cash pay to date. Now that CED is available, the floodgates should open. All that remains is promotion.

Unfortunately, we expected the big pharma partner to be the engine that drove the ramp in sales. Management is confident that they can find a new partner, or partners, over the next few quarters. For the purposes of our model, we have removed all partnering revenue and the "hockey stick" like ramp we expected in AutoloGel sales following signing of the big pharma partner. We see an uptick in AutoloGel sales based on CED, but for us to really start getting aggressive with the ramp we will need to see signed agreements for promotion with larger organizations.

Angel Keeps Chugging Along

Angel sales were just above our expectations in the second quarter 2012, coming in at $1.63 million vs. our estimate of $1.60 million. Sales were up 27% year-over-year and 7% sequentially. Unit placements have really increased nicely over the past few months. The company started the year with roughly 350 units out in the market between the U.S. and Europe. As of the end of July 2012, the company has around 475 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 500 units placed. There is usually a lag between when units are placed and when they start generating meaningful revenues from consumables, but we are clearly encouraged by the traction management is gaining with respect to building the business. We note that greater than 90% of the business is still in the U.S. and that Europe represents a significant opportunity for expansion in the coming years.

…Angel Ramp Continues…



Cytomedix continues to build out its sales infrastructure both domestically and internationally. The company just recently hired a national sales director to go along with 7 regional sales managers and 20+ independent agents. 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 September 1, 2011, Cytomedix announced that it had filed a 510(k) application to the U.S. FDA for use of the Angel Whole Blood Separation System for the processing of bone marrow aspirate. The expanded indication includes processing a mixture of blood and bone marrow, a rich source of stem cells, to create a bone marrow aspirate concentrate (BMAC). *In vitro p*erformance testing 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.

Angel has the potential to deliver RPR with highly viable bone marrow stems cells in a real-time, point-of-care setting for use in orthopedic or cardiovascular indications. There are approximately 500,000 spinal fusion procedures performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard to support effective fusion. The biologics market associated with spinal fusion procedures is approximately $800 million annually. We note that some clinicians are already successfully using Angel in this indication today. However, FDA clearance will allow Cytomedix to market the Angel System for this significant opportunity. The ease-of-use, separation efficiencies, and high quality output, are of notable benefit and competitive advantage compared with other commercially available systems.

Cytomedix noted on its second quarter call that they will be in position to respond to the FDA's request for information around platelet function by the end of the third quarter. We expect the FDA to make a decision on expanding the label to include BMAC early in 2013. Once approved in the U.S., we think management will look to follow a similar road-map in Europe to expand the CE Mark on the device.

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 Medical School). Now that the DSMB has allowed the expansion of the trial to the remaining 90 patients we expect that management will open enrollment at an additional 12 sites around the U.S. In fact, as of early August 2012, five new sites have come online. Enrollment at 100 patients should be completed early in the second quarter 2012. We expect data around June / July 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. 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 30 patients in October or November 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 around the summer of 2013. We expect data about three to four month later, or early 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 late 2013. A positive outcome from the phase 2 program forms the basis for a pivotal registration program to start 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 $10.6 million, comprised of $7.5 million in products sales coming from $0.7 million in AutoloGel, $6.7 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 see a number of catalysts coming later this year. These include:

Upcoming Events	Time
Millennia Holdings to publish AutoloGel data from Japan	April 2012
Present data on AutoloGel at Advanced Wound Care symposium	April 2012
Preliminary decision from CMS on National Coverage	May 9, 2012
DSMB clearance to move into part-2 of the RECOVER-stroke	May 16, 2012
Final decision from CMS on National Coverage	August 2, 2012
Roll out "peer-to-peer" webinar strategy to maximize Angel orthopedic sales	Ongoing
Sign distribution / licensing agreements for AutoloGel	Ongoing
File BMAC applications for EU CE Mark	Q3-2012
Meet with CMS to finalize protocol for clinical study program	September 2012
File U.S. 510(k) application for "next-gen" AutoloGel 2.0 product	Q4-2012
Initiation of phase 2 program by outside investigators in PAD	Q4-2012
Facilitate ISTs on PRP with Angel	2H-2012
Facilitate ISTs using ALDH-br+ cells	2H-2012
Decision from U.S. FDA on Angel 510(k) BMAC application	Q1-2012
Complete enrollment in RECOVER-stroke	1H-2013
Data from phase 1 clinical trial in glioma	1H-2013
Data from RECOVER-stroke	2H-2013
U.S. FDA approval of "next-gen" AutoloGel 2.0 product	2H-2013
Enter into collaboration agreement for Phase 3 stroke trial with ALD-401	2H-2013

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2010 A	2011 A	Q1 A	Q2 A	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Med Product Sales	**$3.79**	**$5.90**	**$1.69**	**$1.86**	**$1.89**	**$2.06**	**$7.48**	**$9.60**	**$12.60**	**$16.50**
YOY Growth	1574.5%	55.8%	23.5%	33.5%	23.6%	28.0%	26.8%	28.3%	31.3%	31.0%
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**	**$0**	**$3.15**	**$0**	**$0**	**$0**
YOY Growth	-100.0%	992.9%	-	-	-	-	-	-	-	-
Total Revenues	**$3.91**	**$7.25**	**$3.02**	**$3.69**	**$1.89**	**$2.06**	**$10.64**	**$9.60**	**$12.60**	**$16.50**
YOY Growth	89.3%	85.3%	120.9%	164.3%	23.3%	-30.3%	46.8%	-9.8%	31.3%	31.0%
Cost of Sales	$1.80	$2.73	$0.85	$0.98	$0.85	$0.93	$2.54	$2.88	$3.40	$4.46
Product Gross Margin	52.5%	53.8%	49.7%	47.3%	55.0%	55.0%	66.0%	70.0%	73.0%	73.0%
R&D	$0.42	$0.10	$0.36	$1.09	$1.05	$1.10	$3.60	$5.00	$5.00	$5.00
% R&D	10.6%	1.4%	11.8%	29.6%	55.6%	53.4%	33.8%	52.1%	39.7%	30.3%
SG&A, Other Fees	$7.29	$7.94	$4.53	$3.96	$3.75	$3.60	$15.84	$16.00	$17.00	$18.00
% G&A	186.3%	109.5%	150.2%	107.5%	198.4%	174.8%	148.9%	166.7%	134.9%	109.1%
Operating Income	($5.40)	($3.51)	($2.72)	($2.35)	($3.76)	($3.57)	($11.35)	($14.28)	($12.80)	($10.96)
Operating Margin	-138.1%	-48.5%	-	-	-	-	-106.7%	-148.8%	-101.6%	-66.4%
Interest & Other Income	($1.40)	$0.02	($2.00)	($5.10)	$2.00	$0.00	($5.10)	($0.15)	$0.20	$0.35
Pre-Tax Income	($6.80)	($3.49)	($4.72)	($7.45)	($1.76)	($3.57)	($16.45)	($14.43)	($12.60)	($10.61)
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)	($1.76)	($3.57)	($16.47)	($14.43)	($12.60)	($10.61)
Net Margin	-231.1%	-53.2%	-	-	-	-	-154.8%	-150.3%	-100.0%	-64.3%
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.09)**	**($0.02)**	**($0.04)**	**($0.21)**	**($0.13)**	**($0.10)**	**($0.07)**
YOY Growth	150.7%	-67.4%	-	-	-	-	172.9%	-36.8%	-23.1%	-29.9%
FAS-123R Expense	$0.41	$0.31	$1.22	$0.31	$0.12	$0.15	$1.80	$0.60	$0.75	$0.75
EPS Impact of FAS-123R	*($0.01)*	*($0.01)*	*($0.02)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.02)*	*($0.01)*	*($0.01)*	*($0.01)*
Weighted Ave. Shares Out	38.7	50.7	63.3	80.9	83.0	90.0	79.3	110.0	125.0	150.0

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

HISTORICAL ZACKS RECOMMENDATIONS

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