Zacks Small-Cap Research

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Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Cytomedix, Inc (CMXI-OTC)

CMXI: Negotiations Continue For Cytomedix On AutoloGel…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/30/2011
Current Price (07/02/12)	$1.30
Target Price	**$3.00**

UPDATE

On June 8, 2012, Cytomedix submitted a public comment to CMS updating the company's plans to comply with the proposed Coverage with Evidence Development (CED) for AutoloGel for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds. We are expecting the final CED document from CMS on August 7, 2012. In the meantime, negotiations with the potential pharmaceutical partner continue. We expect a short-term distribution agreement to be signed in August 2012, with a larger licensing and supply agreement in September / October 2012. We remain optimistic on the Cytomedix story and think the recent stock pull-back represents an attractive entry point. Our target is $3 per share.

SUMMARY DATA

52-Week High	**$2.28**
52-Week Low	**$0.28**
One-Year Return (%)	**395.45**
Beta	**1.29**
Average Daily Volume (sh)	**323,178**
Shares Outstanding (mil)	**57**
Market Capitalization ($mil)	**$125**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**3**
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	3.5 E	1.9 E	2.3 E	10.8 E
2013					12.6 E
2014					25.1 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	-$0.01 E	-$0.03 E	-$0.03 E	-$0.12 E
2013					-$0.07 E
2014					$0.02 E

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WHAT'S NEW

Meeting With CMS

On June 8, 2012, Cytomedix submitted a public comment to the Centers for Medicaid & Medicare Services (CMS) updating the company's plans to comply with the proposed Coverage with Evidence Development (CED) for AutoloGel for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds. In this comment, CEO Martin Rosendale outlined the challenges to running a randomized clinical trial (RCT) in wound care, and the desire to obtain the necessary evidence for final reimbursement of AutoloGel through an observation study (a registry).

…A Little Background…

As a reminder, on May 9, 2012, CMS issued a preliminary decision proposing that platelet-rich plasma (PRP) will be covered for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds. In the National Coverage Determination (NDC) memo, CMS proposes coverage of AutoloGel through its Coverage with Evidence Development (CED) program. To demonstrated the evidence development, CMS proposes the requirement that all patients receiving AutoloGel be enrolled in a randomized clinical trial (RCT) that addresses the following questions (below) using validated and reliable methods of evaluation:

Prospectively, do Medicare beneficiaries that have chronic non-healing diabetic, venous and/or pressure wounds who receive well-defined optimal usual care along with PRP therapy, experience clinically significant health outcomes compared to patients who receive well-defined optimal usual care for chronic non-healing diabetic, venous and/or pressure wounds as indicated by addressing at least one of the following:

- ✓ *Complete wound healing?*
- ✓ *Ability to return to previous function and resumption of normal activities?*
- ✓ *Reduction of wound size or healing trajectory which results in the patient's ability to return to previous function and resumption of normal activities?*

The preliminary NDC notes that while CMS found no conclusive evidence to support Medicare coverage for AutoloGel, there was also no conclusive evidence that the product lacked a benefit. CMS then emphasized that the safety of AutoloGel was not in question. Therefore, CMS requested "additional data gathered in the context of clinical care" to "further clarify the impact of these items and services on the health of Medicare beneficiaries." CMS outlined the strict requirements for the RCT in the preliminary NDC proposal found on the www.cms.gov website.

…What's RCT To CMS (vs. FDA)…

The key question that remains with respect to the final NDC-CED document, expected on or before August 7, 2012, is what exactly a RCT means in the eyes of CMS. We remind investors that AutoloGel has already received FDA approval. A randomized controlled trial in the eyes of CMS is not the same as in the eyes of the FDA. Cytomedix already answered the FDA's question of, "Does it work and is it safe?" CMS is now asking, "Should it be covered for Medicare beneficiaries?"

The nuance is important for investors to understand. CMS wants to know how AutoloGel compares to the current (reimbursed) standard-of-care for chronic non-healing wounds. They are interested in seeing if AutoloGel improves the quality of life of Medicare patients beyond what's currently available under national coverage. Finally, CMS wants to know if it returns people to normal activities at a faster / earlier rate than current therapies. These are not the same sort of efficacy questions the FDA asked, and Cytomedix answered a decade ago.

…Challenges of RCT…

We see a number of challenges to running a post-marketing RCT in chronic non-healing wounds. Firstly, CMS has outlined CED on three wounds types – diabetic ulcers, venous ulcers, and pressure ulcers. Cytomedix believes these biologically distinct wounds have differing etiologies and behaviors, and that it would not make sense to run one RCT to include all three wound types. Secondly, the standards of care, which include use of antibiotics or other systemic drugs, and wound cleanings and dressings, differ between the three wound types. As such, projected outcomes for the three wound types also differ.

Cytomedix also outlines potential challenges to constraining the baseline population for the RCT. A typical RCT for pivotal phase 3 or PMA study might incorporate substantial inclusion and exclusion criteria. Typical exclusion criteria may include age (too old or too young), co-morbidities (peripheral arterial disease, infection, osteomyelitis, cellulitis, corticosteroid treatment, hyperglycemia, liver impairment, renal impairment, bleeding disorders, cancer, renal dialysis, gastrointestinal disease, respiratory disease, severe cardiac disease, diabetes, etc…) wound size and grade (too severe, too large), or use of concomitant medications (immunosuppressive drugs, alcohol/drug abuse, anticoagulants, antiplatelet drugs, vasoactive drugs). However, for CMS, these sort of "real-world" patients should be included in the RCT.

The final challenge that Cytomedix sees with respect to an RCT is defining the endpoints. A typical phase 3 or PMA program will look at a specific primary endpoint at a specific time – for example, complete wound healing at 24 weeks. However, for CMS and "real-world" patients, this may not be practical. As noted above, CMS has suggested that returning to previous function and/or improving quality of life are acceptable endpoints for coverage. For patients with significant wounds and co-morbidities, setting a defined stopping time point may not make sense.

…Ironing Out The Details…

In late June 2012, Cytomedix met with CMS face-to-face to iron out these details. Cytomedix would like to conduct the RCT in the form of an observations study – essentially a registry. Observation studies can be large, have wide inclusion criteria, include all patient types, and still be well-controlled and designed. In fact, an extensive, validated registry in wound care already exists and can be adapted to a CED decision. We believe that Cytomedix is in the process of incorporating these changes and plans to present to CMS in August 2012. This may come after the final CMS decision on CED set for August 7th. However, August 7th is just when CMS plans to tell Cytomedix "Yes or No", there is no set timeframe on "How". The finalized protocol for the observation-RCT may not be finalized until September or October 2012.

A Partner Waiting

Many, if not all, of the questions raised above as to what the final NCD-CED document will look like in August, and what the final protocol for the observational-RCT will look like in September / October, are the same questions that Cytomedix's undisclosed "Top-20 Global Pharmaceutical company" would like answers to before they enter into a broad licensing and supply agreement for AutoloGel. Accordingly, on July 2, 2012, Cytomedix announced that the exclusivity period for negotiating a deal on AutoloGel, which was set to expire on June 30, 2012, has been extended to August 30, 2012. This is the second time the exclusivity period has been extended. To date, Cytomedix has received $4.5 million in non-refundable exclusive negotiation payments from this yet undisclosed partner.

We expect that many of the above questions will be answered after the CED document comes out on or before August 7, 2012. Cytomedix notes that current negotiations with the Pharma partner are centered on the material terms and provision of a distribution agreement. This would be a short-term agreement for the simple distribution of AutoloGel through the partner's sales force. We expect this deal will be signed in late August 2012, and that Cytomedix will immediately look to distribute AutoloGel through the partner's sales force once signed. Under this initial distribution agreement, Cytomedix will retain control of AutoloGel and book all revenues. Cytomedix will pay the partner a royalty based on sales made using their hospital-based sales force of approximately 100 full-time representatives. This will be a significant step-up in promotion for AutoloGel, as Cytomedix currently promotes the product with six part-time representatives.

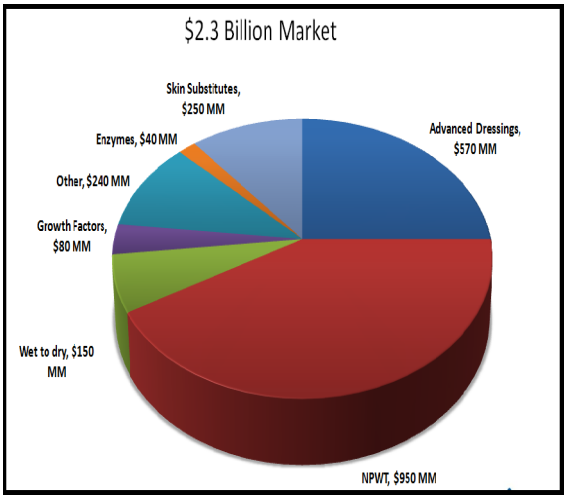
The sort of tier-1 promotion that the pharmaceutical partner could bring coupled with CMS reimbursement could cause AutoloGel sales to soar in the coming years. AutoloGel posts sales of only $390K in the 2011. With significant promotion and CMS coverage, peak sales could eclipse $50 million.

This initial period will give Cytomedix a chance to continue working with CMS to finalize the design protocol for the observations-RCT. Once the final protocol for the observational-RCT has been set, we expect that the deal will move to a full licensing and supply agreement, where the pharmaceutical partner will take over booking revenues of AutoloGel and pay Cytomedix a profit-share (royalty) on sales. We expect that this agreement will come with a modest upfront payment (we model $3 million), plus development milestones relating to the second-generation AutoloGel device (U.S. 510(k) application planned during the second half of 2012).

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.

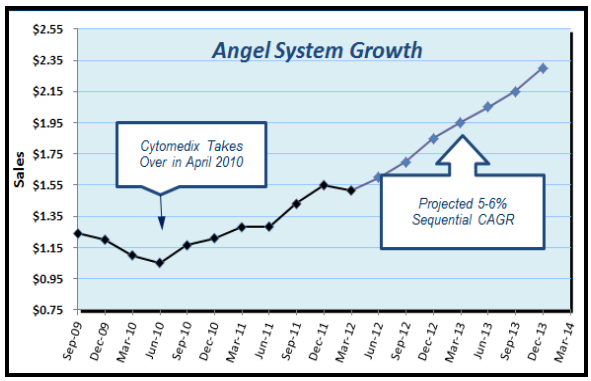
Cash

Cytomedix exited the second quarter 2012 with $8.4 million in cash and equivalents. The company has allocated $4.7 million of this cash to fund the clinical development of ALD-401 in the active RECOVER-Stroke phase 2 trial and related matters. We have confirmed with management that enrollment in RECOVER-Stroke remains on track. We see the current cash balance as sufficient to fund operations well into 2013.

As noted above, if a licensing deal with a larger pharmaceutical company is signed for AutoloGel, it would come with a modest upfront payment. We currently model $3.0 million, which would bring the total upfront consideration for AutoloGel to $7.5 million. Management has noted the deal will also include a “significant milestone payment” for the approval of the next-generation AutoloGel device. Cytomedix is nearing the filing of a 510(k) application for AutoloGel 2.0 in the U.S. The potential addition of $3.0 million in cash sometime over the next 2 to 3 months will further strengthen the company’s cash balance. The potential for another milestone (our guess is $5 million) for AutoloGel 2.0 in 2013 or 2014 should help reduce the company’s need for future dilutive financings.

Angel Just Getting Started

Angel sales were essentially in-line with expectations in the first quarter 2012, coming in at $1.52 million vs. our estimate of $1.55 million. Sales were up 19% year-over-year and flat sequentially. Management noted some lower-margin sales to international distributors during the quarter. Essentially, management was looking to place the units for a small profit, but then generate high margin revenues on the single consumable set use in the future. We note approximately 60 of the nearly 300 units (~20%) are overseas in Europe.



Despite 20% of the systems being in Europe, 95% of the revenues are from the U.S. So management is looking to expand into Europe throughout 2012. We believe a significant opportunity exists for management to expand use of the device at the smaller perfusionist practices where Angel system utilization is low.

Cytomedix continues to build out its sales infrastructure both domestically and internationally. The company employs 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 first quarter call that they have been working with the U.S. FDA on the questions receive with respect to the 510(k) application. We are expecting a decision out of the FDA by the end of the year.

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 plans 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. 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. Enrollment at 100 patients should be completed in about 12 months from today. 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 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.

…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.

Expectations For 2012

We currently model total revenues in 2012 at $10.8 million, comprised of $7.7 million in products sales coming from $0.9 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 remaining non-refundable option fee from the potential strategic supply and distribution partnership on AutoloGel.

We note our published model does not include the remaining modest upfront payment from the potential AutoloGel partner in 2012, despite our belief that a deal will get done by the end of the year. We've stated that $3.0 million is our best guess for the payment. We model a net loss in 2012 of approximately $9.8 million, or 12 cents per share, although we expect that net cash burn for the year will be less than $4million. We continue to be positive on the Cytomedix story, and have recently raised our target to $3.00 per share.

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 7, 2012
Sign distribution agreement with "Top-20 global pharma company" on AutoloGel	August 2012
Roll out "peer-to-peer" webinar strategy to maximize Angel orthopedic sales	Ongoing
File BMAC applications for EU CE Mark	Q3-2012
Decision from U.S. FDA on Angel 510(k) BMAC application	Q3-2012
File U.S. 510(k) application for "next-gen" AutoloGel 2.0 product	Q3-2012
Meet with CMS to finalize protocol for observational-RCT program	September 2012
Sign licensing agreement with "Top-20 global pharma company" on AutoloGel	October 2012
Facilitate ISTs on PRP with Angel	2H-2012
Facilitate ISTs using ALDH-br+ cells	2H-2012
Complete enrollment in RECOVER-stroke	1H-2012
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 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Med Product Sales	**$3.79**	**$5.90**	**$1.69**	**$1.73**	**$1.92**	**$2.33**	**$7.67**	**$12.60**	**$25.10**	**$43.50**
YOY Growth	1574.5%	55.8%	23.5%	24.1%	25.6%	44.7%	29.9%	64.4%	99.2%	73.3%
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**	**$3.55**	**$1.92**	**$2.33**	**$10.82**	**$12.60**	**$25.10**	**$43.50**
YOY Growth	89.3%	85.3%	120.9%	154.9%	25.3%	-21.2%	49.3%	16.4%	99.2%	73.3%
Cost of Sales	$1.80	$2.73	$0.85	$0.78	$0.86	$1.05	$2.61	$3.78	$6.78	$11.75
Product Gross Margin	52.5%	53.8%	49.7%	55.0%	55.0%	55.0%	66.0%	70.0%	73.0%	73.0%
R&D	$0.42	$0.10	$0.36	$0.50	$0.75	$1.00	$2.61	$3.50	$4.00	$4.50
% R&D	10.6%	1.4%	11.8%	14.1%	39.1%	42.9%	24.1%	27.8%	15.9%	10.3%
SG&A, Other Fees	$7.29	$7.94	$4.53	$3.00	$2.75	$2.75	$13.03	$12.00	$12.50	$13.00
% G&A	186.3%	109.5%	150.2%	84.4%	143.2%	118.0%	120.4%	95.2%	49.8%	29.9%
Operating Income	($5.40)	($3.51)	($2.72)	($0.72)	($2.44)	($2.47)	($7.42)	($6.68)	$1.82	$14.26
Operating Margin	-138.1%	-48.5%	-	-	-	-	-68.6%	-53.0%	7.3%	32.8%
Interest & Other Income	($1.40)	$0.02	($2.00)	($0.05)	($0.05)	($0.05)	($2.15)	($0.15)	$0.20	$0.35
Pre-Tax Income	($6.80)	($3.49)	($4.72)	($0.77)	($2.49)	($2.52)	($9.57)	($6.83)	$2.02	$14.61
Taxes	$0.01	$0.0	$0	$0	$0	$0	$0	$0	$0.2	$3.7
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	10.0%	25.0%
Preferred A, B, D, E	$2.22	$0.35	$0.01	$0.09	$0.09	$0.09	$0.28	$0.20	$0.10	$0.05
Net Income	($9.04)	($3.86)	($4.73)	($0.86)	($2.58)	($2.61)	($9.86)	($7.03)	$1.72	$10.90
Net Margin	-231.1%	-53.2%	-	-	-	-	-91.1%	-55.8%	6.9%	25.1%
Reported EPS	**($0.23)**	**($0.08)**	**($0.07)**	**($0.01)**	**($0.03)**	**($0.03)**	**($0.12)**	**($0.07)**	**$0.02**	**$0.09**
YOY Growth	150.7%	-67.4%	-	-	-	-	57.3%	-38.2%	-122.1%	478.6%
FAS-123R Expense	$0.41	$0.31	$1.22	$0.12	$0.12	$0.15	$1.61	$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	87.1	89.0	90.0	82.3	95.0	105.0	115.0

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

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