Zacks Small-Cap Research

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Cytomedix, Inc (CMXI-OTC)

CMXI: Cytomedix Licenses Angel To Focus On AutoloGel…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	02/14/2013
Current Price (08/08/13)	$0.44
Target Price	**$1.00**

UPDATE

On August 8, 2013, Cytomedix reported financial results for the second quarter 2013. Revenues and expenses were largely in-line with expectations. In fact, sales of both Angel and AutoloGel were dead-on with our forecasts.

Cytomedix announced that it has licensed Angel to Arthrex, Inc. in return for cash and a low-teens royalty on sales. We believe the deal is positive for Cytomedix because it provides the company with much needed cash (estimated at $7.0 million on hand as of today), allows for significantly greater Angel sales in the coming years, and allow for management to shift the company's focus to AutoloGel. We are positive on the Cytomedix story but can't help by remain on the side-line as long as the RECOVER-Stroke trial continues.

SUMMARY DATA

52-Week High	**$1.64**
52-Week Low	**$0.39**
One-Year Return (%)	**-69.92**
Beta	**0.29**
Average Daily Volume (sh)	**75,851**
Shares Outstanding (mil)	**105**
Market Capitalization ($mil)	**$45**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**16**
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 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	3.0 A	3.7 A	1.8 A	2.1 A	10.6 A
2013	2.3 A	2.4 A	1.4 E	0.9 E	7.0 E
2014					6.2 E
2015					10.9 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.07 A	-$0.09 A	-$0.04 A	-$0.04 A	-$0.24 A
2013	-$0.05 A	-$0.05 A	-$0.04 E	-$0.04 E	-$0.18 E
2014					-$0.15 E
2015					-$0.11 E

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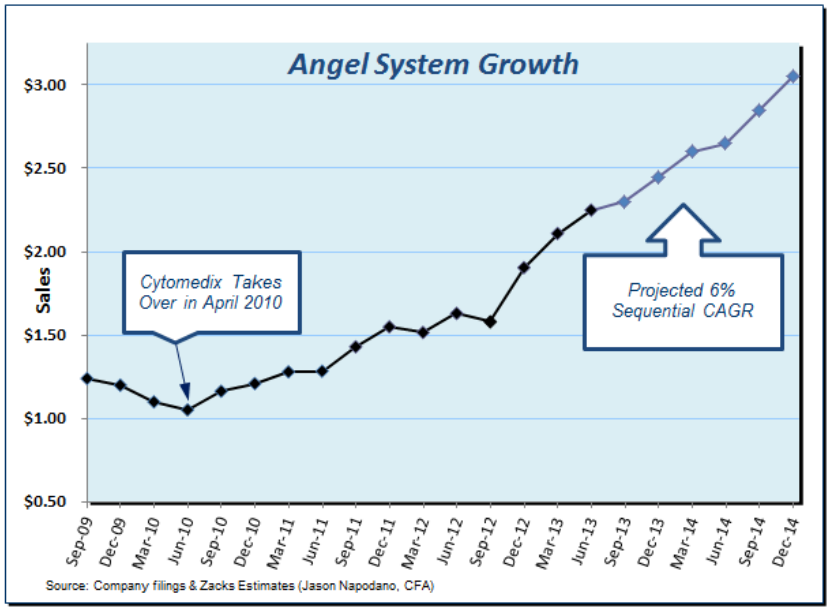
WHAT'S NEW

Angel Licensed To Arthrex, Inc. For Cash & Royalties

On August 7, 2012, Cytomedix announced that it had signed a five-year exclusive worldwide licensing agreement with Arthrex, Inc., for the commercialization of the Angel Concentrated PRP System. Under the terms of the agreement, Cytomedix will retain ownership of Angel, but has granted Arthrex an exclusive worldwide right to develop, manufacture, and commercialize the product. Arthrex paid Cytomedix an upfront payment of $5 million, and will make royalty payments on future sales in the low teen range (we model 13.5%). The term of the agreement is five years, with a three year renewal option.

…A Little Background On Angel…

Angel is the company's concentrated PRP device and associated disposable products used in surgical settings for the separation of concentrated platelets from whole blood or bone marrow aspirates. Angel has been the main bright spot for Cytomedix over the past year. In fact, sales have continued their impressive march upwards ever since the company acquired the product from Sorin in April 2010. Angel sales in the second quarter 2013 totaled $2.25 million, up 38 year-over-year and 7% sequentially from the first quarter 2013. Below is a graph depicting the impressive recovery and solid growth Cytomedix has been able to achieve with Angel.

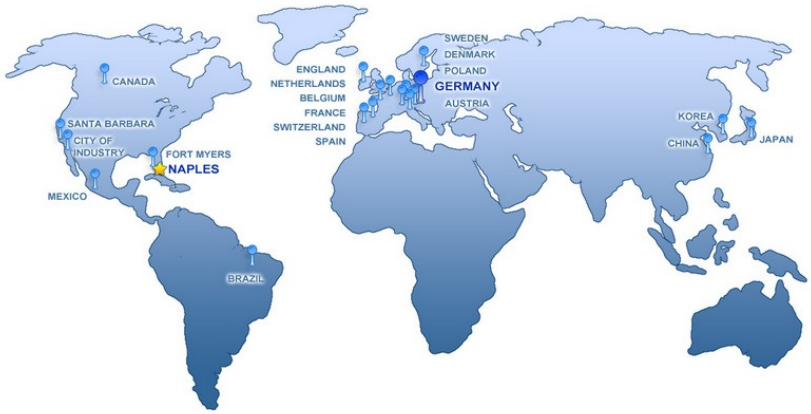


Cytomedix has placed nearly 600 units into the market, that's up nicely from the 500-525 placed at the end of 2012. What's more impressive is that the company has been doing this with only a handful of sales representatives. The company exited 2012 with 8 full-time sales reps, and only recently increased the number to 10 as of May 2013.

Much of the growth is coming from orthopedics (sports medicine). In November 2012, Cytomedix announced U.S. FDA approval 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 such as spinal fusion, healing of nonunion bone fractures and other bone grafting applications. Concentrated PRP produced from blood and bone marrow may be used in up to 90% of spinal fusion procedures. In the U.S., approximately 400,000 spinal fusion procedures are performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard. The U.S. biologics market associated with spinal fusion procedures is approximately $700 million annually. We think an equal opportunity exists in Europe.

…A Little Background On Arthrex…

Arthrex is a global medical device company and leader in new product development and medical education in orthopedics. The company pioneered the field of arthroscopy and developed more than 6,000 innovative products and surgical procedures to advance minimally invasive orthopedics. Arthrex has twenty locations worldwide, with over 60 international distribution locations, shipping products to over 100 countries. As of year-end 2012, Arthrex had more than 1,500 employees in Southwest Florida, 700 national and international employees and about 2,000 sales associates around the world (source: company spokeswoman Lisa Gardiner).



Arthrex, Inc. - National & International Locations

Arthrex has a large commercial infrastructure supporting sales throughout the world and will immediately take responsibility for all sales and marketing activities for Angel. Angel is currently approved in the U.S., and various countries in Europe and in the Middle East, as well as in Canada and Australia.

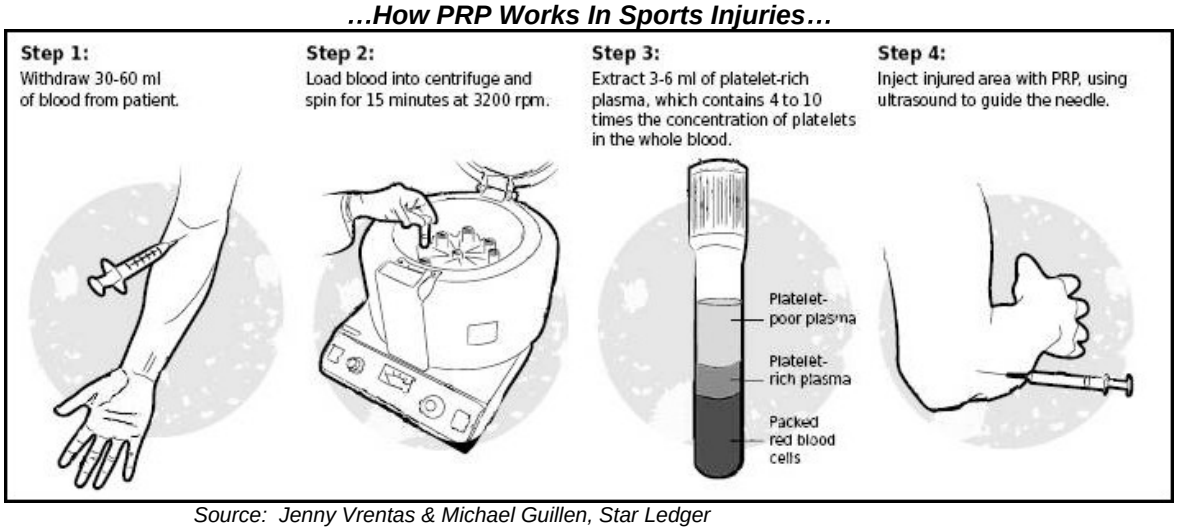
…Why This Makes Sense For Cytomedix…

Above we noted that Cytomedix was able to generate roughly $10 million in annualized revenues from Angel with only 10 full-time sales representatives. Arthrex has 2,000 sales representatives. The company has a core focus on orthopedic products, with a strong emphasis on orthobiologics. A quick trip to the Arthrex website shows key product groups in autologous blood products, bone grafting, cartilage, cellular products, and soft tissue repair. Angel fits right in with this core focus. We can see Arthrex promoting Angel alongside its existing bone marrow aspirate cell suspension products, its BioCartilage® matrix, its Autograft osteochondral repair system, or its existing PRP autologous systems.

There are several things we believe Arthrex can do to drive Angel sales. The first is increase the Angel average selling price. To date, Cytomedix has been focusing on cardiovascular surgery and only just starting to penetrate the orthopedic market. Arthrex, with a strong foothold in orthopedics can co-mingle Angel with existing products to create kits or solutions for orthopedic surgeons. Secondly, we expect Arthrex to dramatically ramp-up the marketing and promotion on Angel – something cash-strapped Cytomedix has been unable to do. Previously, Cytomedix was relying on PRP workshops and peer-to-peer networking to get the word out about Angel. Arthrex can throw significant marketing dollars at the product to drive uptake, both in and outside the U.S. Finally, Arthrex scale dwarfs what Cytomedix had. Even if only 10% of the Arthrex sales force carries Angel, that's still a 200% increase over what Cytomedix was doing.

Angel held about 10% market share in the concentrated PRP market. With sales annualizing around $10 million, that puts the entire market at around $100 million in size. However, this is a market that is growing rapidly. Cytomedix estimates the market was only $40 million in size in 2009. Sales of concentrated PRP devices have been soaring as more data becomes available in orthopedics and sport-related injuries. 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. New York Mets all-star center fielder Carlos Beltran used PRP to aid in his recovery from a bone bruise on his right knee. The LA Dodgers, Seattle Mariners, Denver Nuggets, and Dallas Cowboys have all embraced the use of PRP.

…How PRP Works In Sports Injuries…



Source: Jenny Vrentas & Michael Guillen, Star Ledger

From a forecasting standpoint, we previously believed that Cytomedix could drive Angel sales to $12.5 million in 2015. We believe Arthrex can double that number. We suspect that Arthrex will eventually take over the manufacturing of Angel as well, reducing overhead cost at Cytomedix. We believe many of the existing 10 sales representatives at Cytomedix previously promoting Angel will be swapped over to AutoloGel. At Cytomedix, Angel was a peak $15 million product. In the hands of Arthrex, sales could easily hit $40 million in five years. Thus, our estimated 13.5% royalty payment on top-line sales from Arthrex to Cytomedix actually equates to greater net cash flow to the company starting in 2015. And finally, it allows Cytomedix to focus on increased promotion of AutoloGel, a product set for a significant re-launch into the market later this year.

AutoloGel Finally Ready For Takeoff

We note that the long-waited finish line for gaining the Centers for Medicare and Medicaid Services (CMS) reimbursement on AutoloGel seems to be in sight. This has been a long and somewhat convoluted process for investors to follow, but it is obvious that the company is making progress based on the history to date:

- 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 reversed nearly 20 years of non-coverage for autologous platelet rich plasma (PRP) treatments, including Cytomedix's AutoloGel - the only FDA approved PRP treatment option for wound care.

- On March 1, 2013, CMS approved the clinical outcomes in the Coverage with Evidence Development (CED) protocols submitted by the company. This approval allowed Cytomedix to begin promoting and rolling out the protocols to physicians and patients for AutoloGel when used to treat Medicare beneficiaries.

- On March 18, 2013, CMS issued temporary reimbursement coding and claims payment instructions to its regional contractors for the use of AutoloGel in chronic non-healing wounds. The assignment of a Healthcare Common Procedure Coding System (HCPCS) code establishes the reimbursement mechanism for physicians and other providers submitting claims for services provided to Medicare beneficiaries.

- On July 10, 2013, Cytomedix, Inc. announced that CMS has issued proposed payment regulations under the Physician Fee Schedule (PFS) and the Hospital Outpatient Prospective Payment System (HOPPS) that include proposed guidelines covering Medicare reimbursement for AutoloGel.

  → With respect to physicians' offices, CMS has proposed that Medicare Administrative Contractors (MACs) determine the payment amount for AutoloGel for claims as they are submitted. Historically, Medicare contractors have paid these types of claims based on product invoices presented by the healthcare provider. Cytomedix will essentially get paid under the Physician Fee Schedule for what they bill - around $450 per single use. This took effect July 1, 2013. As a result, Cytomedix can immediately now go out and promote AutoloGel to physicians, mostly podiatrists and wound-care specialists, for in-office use of AutoloGel and get reimbursed full price for each sales.

→ For hospital outpatient services, CMS has placed the reimbursement code for AutoloGel in an Ambulatory Payment Classification (APC) that provides limited reimbursement for use of the product. Under the HOPPS guideline, AutoloGel will be reimbursed only comparable to a Level-2 debridement product, the reimbursement of which is less than $100 per use. That puts Cytomedix at a significant disadvantage trying to charge $450 for a product hospitals are only authorized to reimburse at around $100 per use. Cytomedix tells us that they are already in communication with CMS on revising the APC listing to authorize reimbursement of AutoloGel similar to a skin substitute, which would put the reimbursement for the product and associated application service in the area of $875 to $1375 per use.

Net-net, the decision in July was a positive for Cytomedix. Prior to that decision, there was virtually no government business for AutoloGel. CMS-NCD provides a pathway for reimbursement of AutoloGel to Medicare and Medicaid beneficiaries, which make up over half of the approximate 2.0 million pressure ulcers, 1.5 million diabetic foot ulcers, and 1.7 million venous leg ulcers treated in the U.S. each year. AutoloGel is the only PRP product FDA-approved for the treatment of these types of chronic wounds.

The market for products addressing chronic wounds in the U.S. is estimated to be $2.3 billion annually. Prior to CMS reimbursement, AutoloGel was significantly disadvantaged compared to competing products with full coverage, including Dermagraft (~$153M in sales in 2012) and Apligraf (~$125M in sales in 2011). Instead of going after CMS beneficiaries, management had been focusing on private pay procedures, long-term acute care hospitals (LTAC), veteran's administration (VA) 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. So the CMS coverage decision not only kicks open the door to Medicare and Medicaid, it also meaningfully expands private pay coverage as well as many private insurance companies follow the CMS's lead. The assigning of a reimbursement code for AutoloGel is important because the "G" code facilitates reimbursement in the hospital outpatient setting, skilled nursing facilities, rural health clinics, comprehensive outpatient rehabilitation facilities, federally qualified health centers, and critical access hospitals for non-healing chronic wounds.

If this can be accomplished by January 1, 2014, which Cytomedix management thinks it can, then AutoloGel immediately jumps from "extremely disadvantaged" on a reimbursement standpoint to "extremely advantaged" given the cost of only $450 per use and the potential for reimbursement at 2-3x that level. Products like Dermagraft and Apligraf cost $1500 or more per use, so wide-scale implementation of these new procedural codes could have a profound impact on the chronic wound market in 2014.

…Registry Program Underway…

Cytomedix has already announced they are working with wound care centers around the country to build the registry program. The company will be using Intellicure to aid in the collection and analysis of the data as it is being generated. Management tells us that each use of AutoloGel will generate a profit to the company. That's important for investors to understand. 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.

Back in May 2013, when Cytomedix held its first quarter 2013 conference call, CEO Martin Rosendale said he expects to be able to treat 1,000 patients with AutoloGel in 2013. That's a significant acceleration from the approximate 300 patients treated in 2012. We wouldn't be surprised to see Cytomedix either expand their sales force to start actively promoting AutoloGel, something they have not been doing prior to this year, or strike a co-promotional agreement with a larger organization in the chronic-wound market.

…Final Thoughts On AutoloGel…

We estimate greater than 50% of the market is Medicare beneficiaries. But besides missing out on these patients, private payors were also disadvantaging AutoloGel. With CMS now on board, we expect private payors to follow suit. The economics around AutoloGel should be dramatically improved by the second half of 2013. For example, the company tells us it treated roughly 300 patients to generate $0.55 million of sales in 2012. That came with little marketing and promotional effort by the company. With CED now in place, the company expects to dramatically step-up the marketing efforts. Above we noted that some of the 10 sales representatives previously promoting Angel will be moved over to AutoloGel. On the second quarter call, management noted they would like to see 8-10 sales reps in-house by the end of the year, and then perhaps double that number again in 2014.

In the meantime, Cytomedix is focusing on driving enrollment and treating patients in one of the four CMS-approved trials to collect the data necessary under the CED pathway. These four trials include one randomized efficacy program with Grade 1 or 2 diabetic foot ulcer (DFU) patients vs. a standardized (usually and customary) care and three outcome assessment studies in broader patient populations, such as DFU patients with Grade 3 and 4, venous leg ulcers, and pressure ulcers. The primary efficacy study will seek to enroll 260 patients. In total, the company plans to enroll and treat over 2,400 patients between all four studies to compile data for CMS under the CED pathway.

The goal for 2013 is to exit the year with over 1,000 patients enrolled. This would be a three to four fold increase in sales from 2012, or to around $1.5 million. It's been a rocky-road for AutoloGel, but the potential for significant acceleration in sales in 2013 and beyond is clearly one of the company's biggest opportunities.

The company continues to look for distribution partners for AutoloGel. After the "Big Pharma" partner walked away earlier in 2012 the company immediately began conversations with new potential partners. The timing of a deal remains a wildcard, but any transaction that provides increased sales and promotion, upfront cash, royalties on sales, and the potential for backend milestones would be a big win for management. A partnership remains another, albeit more difficult to forecast, potential opportunity for Cytomedix.

Aldagen Pipeline: High Risk / High Reward

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

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

As of early August 2013, enrollment has been open to a total of 15 sites. Unfortunately, enrollment is only up to 36 patients – six higher than when the company held its year-end call in early May 2013. The average has been only around 2 patients per month. At that pace, it will take 30+ months to complete enrollment at 100 patients. It looks as though the changes made to the study earlier in the year (increasing the age and easing the inclusion / exclusion criteria based on location of the stroke in the brain) have had little impact on the enrollment pace. At this pace, we believe it might be wise for management to adjust the size of the trial down from 100 patients to 50-60 patients. RECOVER-Stroke is a phase 2 study with a primary focus on demonstrating proof-of-concept and safety. We believe this can be effectively accomplished at 50-60 patients, albeit with meaningfully less power, than the planned 100 patients. Nevertheless, 100 patients seem unobtainable at this point so a change needs to be made.

We note that Cytomedix is also in phase 1 studies with ALD-451, a formulation of the company s ALDH bright cells, designed to test the feasibility and safety when administered intravenously in World Health Organization (WHO) grade IV malignant glioma patients following surgery, radiation therapy and treatment with temozolomide. The trial is being run in collaboration with Duke University Medical Center and expected to enroll up to 12 patients in an open-label design. The primary outcome will be in looking for improvement in cognitive function in patients post treatment with ALD-451. Data from this trial may provide excellent insight into the RECOVER-Stroke trial.

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

PROJECTED FINANCIALS

Cytomedix, Inc.
Income Statement

Cytomedix, Inc.	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E
Med Product Sales	**$7.24**	**$2.25**	**$2.36**	**$0.95**	**$0.20**	**$5.76**	**$3.00**	**$6.00**
YOY Growth	22.7%	33.6%	27.0%	-44.2%	-90.1%	-20.4%	-47.9%	100.0%
Aldagen Pipeline	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Royalties & Collabs	**$3.32**	**$0.06**	**$0.06**	**$0.49**	**$0.66**	**$1.27**	**$3.21**	**$4.43**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$2.32**	**$2.42**	**$1.44**	**$0.86**	**$7.03**	**$6.21**	**$10.43**
YOY Growth	45.8%	-23.2%	-34.2%	-18.4%	-59.3%	-33.5%	-11.7%	67.9%
Cost of Sales	$3.90	$1.27	$1.35	$0.43	$0.08	$3.13	$1.20	$2.28
Product Gross Margin	46.2%	43.8%	42.7%	55.0%	58.0%	45.6%	60.0%	62.0%
R&D	$3.39	$0.90	$1.23	$1.25	$1.30	$4.68	$5.50	$6.00
% R&D	32.1%	38.9%	50.6%	87.0%	152.0%	66.5%	88.6%	57.6%
SG&A, Other Fees	$16.16	$5.15	$4.50	$3.80	$3.85	$17.30	$17.00	$18.00
% G&A	152.9%	222.1%	185.7%	264.6%	450.3%	246.1%	273.8%	172.7%
Operating Income	($12.88)	($5.00)	($4.66)	($4.05)	($4.39)	($18.11)	($17.53)	($15.89)
Operating Margin	-121.9%	-	-	-	-	-257.6%	-282.3%	-152.4%
Interest & Other Income	($6.89)	($0.33)	($0.37)	($0.35)	($0.30)	($1.35)	($1.00)	($1.00)
Pre-Tax Income	($19.76)	($5.33)	($5.03)	($4.40)	($4.69)	($19.46)	($18.53)	($16.89)
Taxes	$0.02	$0.00	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0.0%	0.0%
Preferred A, B, D, E	$0.01	$0	$0	$0	$0	$0	$0	$0
Net Income	($19.80)	($5.34)	($5.03)	($4.40)	($4.69)	($19.46)	($18.53)	($16.89)
Net Margin	-187.4%	-	-	-	-	-276.8%	-298.4%	-162.0%
Reported EPS	**($0.24)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.18)**	**($0.15)**	**($0.11)**
YOY Growth	217.7%	-	-	-	-	-26.8%	-16.2%	-24.1%
Weighted Ave. Shares Out	81.9	99.1	104.6	107.0	109.0	110.0	125.0	150.0

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

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