Zacks Small-Cap Research

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: Recovering Nicely From Sales Force Disruption As Product Sales Grow 39%

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (11/17/15)	$6.44
Target Price	**$12.50**

OUTLOOK

CTSO continues to generate clinical outcomes data which is being used to accelerate adoption and utilization. CTSO now also focused in U.S. regulatory approval – either with a cardiac surgery and/or critical care indication (such as sepsis). Just filed for EAP designation for U.S. which could speed time to market at lower cost.

Recent restructuring of sales force caused a hiccup in sales but looks like was only a short-term issue. Product sales grew 39% from Q2 to Q3. CTSO already made replacements to sales force with 2 add'l hires expected by current year-end. Add'l distributors, including Fresenius and add'l geographic territories to come online shortly should further accelerate product sales. Interest in and use of CytoSorb from hospitals and physicians continues to increase.

SUMMARY DATA

52-Week High	**$15.24**
52-Week Low	**$4.40**
One-Year Return (%)	**21.45**
Beta	**-0.24**
Average Daily Volume (sh)	**99,349**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$167**
Short Interest Ratio (days)	**14.33**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**72.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	1062 A	1025 A	1162 A	874 A	4123 A
2015	723 A	964 A	1344 A	1454 E	4484 E
2016					12212 E
2017					20245 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-0.20 A	-0.27 A	-0.22 A	-0.47 A	-1.29 A
2015	-0.19 A	0.06 A	-0.11 A	-0.10 E	-0.35 E
2016					-0.27 E
2017					-0.21 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q3 Financials / Operating Update: *Recovering From Sales Force Disruption With Product Sales Up 39% From Q2….*

CytoSorbents reported financial results for the third quarter ending September 30th. It was a solid quarter and indicated that the company continues a successful recovery from the slowdown in product sales caused by restructuring of the sales force earlier this year. The top-line, product sales and operating expenses all came in better than what we were estimating.

Particularly encouraging as it relates to the recovery from the beginning of 2015 is that product sales, at $1.07M, were the highest in company history and represented sequential growth of 39%. And product sales look to be solid from a qualitative view as well – management noted on the call that reorders (as opposed to new customer sales) made up the majority of product revenue and demand is broadly dispersed across their customer base – both of which support continued sequential growth and limited volatility. And product sales should further benefit from the ever-growing customer count – which increased by over 50% in the last year, as well as incremental additions to the direct sales force – two people added during Q3 and another two expected to be hired before year-end.

And additional impetus's to product sales growth should come online in the near term. That being sales of CytoSorb through Fresenius as well potentially through their (unnamed) cardiac surgery partner. While culmination of both of these events have been drawn out longer than anticipated, management indicated on the call that there has been substantive progress towards those ends.

Fresenius, which will distribute in Denmark, Finland, France, Norway, Poland and Sweden, is now expected to commence launch in Q1 2016. And while we think initial sales through this channel, the game plan for which will largely follow CTSO's direct sales strategy of targeting KOLs, may be somewhat muted on the front-end, this relationship has the potential to be a meaningful contributor to revenue in 2016 and beyond. Relative to CTSO's cardiac surgery partner (top four cardiac surgery company) - they have now completed their evaluation ("went as good as could be expected") - while management did not provide much more in the way of if and when sales could be expected to materialize through this relationship, they did note on the call that they will have an update in the future.

Grants revenue, from the DARPA sepsis project, contributed $272k in the quarter with $537k remaining yet to be billed. And with work beginning immediately under the $1.5M two-year Phase II NHLBI grant related to further development of HemoDefend, grant revenue should remain meaningful in 2016.

CTSO also made strides on the operational side over the last few months, one of the highlights of which was the 2nd international user's meeting where positive results from three separate cardiac surgery studies were presented (more details below). Another significant event was submission of the application to FDA seeking approval for EAP designation. And in parallel, REFRESH I, the 40-patient, 8 site, randomized cardiac surgery clinical trial enrolled the first patient and management anticipates 6 of the 8 sites will have at least one patient enrolled by the end of this month (November).

On the call management highlighted the potential broad utility of the device in applications outside of the forefront indications (such as intra-operatively during cardiac surgery and sepsis). Management summarized three near-fatal cases of critically-ill patients which were failing standard of care but recovered following introduction of CytoSorb; a young girl with toxic shock syndrome, a man that failed traditional liver dialysis and went into severe septic shock, and a man with pyelonephritis (severe kidney infection). These, as well as other critical-care applications, are areas that may present opportunities to exploit in the future.

Q3 Results

Q3 total revenue was $1,344k, up 16% yoy and up 39% sequentially. Product sales of $1,072k were ahead of our $961k estimate by about 12% and represented yoy and sequential growth of 4% and 39%, respectively. Also noteworthy is that on a constant-currency basis, yoy product sales would have been ~$1,222k, yoy growth of18%.

Grant revenue was $272k, up from $191k in Q2 of this year. As noted, we expect additional grant revenue coming from the DARPA sepsis contract as well as the newly penned NHLBI Phase II HemoDefend grant.

Product margins remain very healthy, which came in at about 63% in Q3 and 62% through the first nine months of the year. OpEx at $2.9M in Q3 was inline with the average through the first half of this year and was 11% lower than our $3.2M estimate – the difference mostly coming from more moderate SG&A spend as we had expected

higher upfront costs related to new sales rep hires. Nonetheless, we continue to model incremental spend in both SG&A and R&D going forward related to a larger sales force, greater aggregate commissions from growing sales and higher REFRESH clinical trial expenses.

Excluding non-cash change in warrant liability, Q2 net income and EPS were ($2.1)M and ($0.08), compared to our ($2.6)M and ($0.10) estimates. CTSO exited Q3 with $9.3M in cash and short-term investments which they believe will be sufficient to fund operations into 2016.

HemoDefend Awarded $1.5M Ph 2 NHLBI Grant: Should Provide Greater Insight Into Utility/Commercialization
In late October CTSO announced that they were awarded a Phase II grant from the National Heart, Lung and Blood Institute to fund further development of HemoDefend. The 2-year contract, titled, "pRBCs (packed red blood cells) Contaminant Removal with Porous Polymer Beads", began immediately.

This most recent contract follows a Phase I grant from NHLBI in the amount of $203k that CTSO received in September 2013 which encompassed both the in-line filter and "beads in a bag" configurations and focused on increasing the number of blood contaminants that can be captured by the technology as well as determining the quality of the blood following treatment.

Dr. Larry Dumont, from the Geisel School of Medicine at Dartmouth, worked with CytoSorbents on the the Phase I grant and will also be involved in the Phase II contract, which expands the in-line filter testing to human subjects. CTSO also notes in the PR that this will also fund development of new polymers related to blood transufions

As we have noted in our coverage of CTSO, we had yet to model any financial contribution from HemoDefend given the earlier stage of development of the product and little visibility as to potential commercialization timelines. CytoSorbents had not spoken much about HemoDefend in the recent past, although had noted that they had experienced some interest in the technology since introducing it at the October 2011 American Association of Blood Banks conference. With their main focus on the roll-out of CytoSorb, HemoDefend was relegated to somewhat of a back-burner project.

And while the grant likely provides little in the way of financial margin (our model has been updated to reflect the Ph2 award), it has the potential to push development closer towards a feasible commercialization timeline. CTSO has in the past talked about looking for a partner to help in completing development of HemoDefend for one or more applications. This follow-on grant, coupled with additional evidence indicating its effectiveness in cleaning blood – including a poster presentation at AABB 2015 (also in late October) – may help attract additional interest from potential partners. At the very least, it almost certainly will provide additional insight into the effectiveness and potential applications of the technology as well as lending another vote of confidence from the NHLBI, a division of the National Institutes of Health.

2nd Int'l User's Meeting Update: Safety Further Established, Outcomes Lend Add'l Support to REFERSH I U.S. Cardiac Surgery Study…
CytoSorbents announced a summation of their 2nd International User's Meeting, held on Oct 2 in Berlin, Germany. The User's Meeting was held just prior to the 28th European Society of Intensive Care Medicine Conference (ESICM), where CTSO exhibited and, with colleagues, made several presentations covering topics such as CytoSorb's role in controlling deadly cytokine storm and results of users' experience with their flagship device.

CTSO noted that the User's Meeting attracted 100 participants from over 18 countries. Highlights included that CytoSorb has now been used in over 8,000 human treatments (including in more than 1,000 cardiac surgeries) – this is up from 5,500+ as of May of this year (a figure that CTSO provided on the Q1 earnings call). And while the press release summarizing the highlights of the meeting did not provide specifics in terms of efficacy data from users' experiences, which included preliminary results from three cardiac surgery trials, it did offer that CytoSorb's safety profile continues to be excellent which is a clear positive for conducting additional and larger trials, including REFRESH I, the company's U.S. cardiac surgery study.

CTSO hopes to be able to make the study presentations publicly available and is seeking permission from the studies' investigators (i.e. CTSO did not sponsor the studies and therefore does not "own" the data) to do so. Of particular interest may be the preliminary data from three cardiac surgery studies, including two randomized and one three-arm study. These are:

- *Reduction of Inflammation Reaction to Extracorporeal Circulation in Cardiac Surgery by Interleukin Dialysis*, conducted at the University of Hamburg-Eppendorf in Germany. The study, which is now completed, used CytoSorb in the cardiopulmonary circuit in patients undergoing elective coronary bypass and heart valve

surgery. 20 patients randomized with and without use of CytoSorb. Primary outcome is change in levels of cytokines during the procedure as compared to baseline. Cytokines measured are IL-6, IL-8, IL-10 and TNF-alpha

- *Effect of Cytokine Removal in Cardiopulmonary Bypass Patients Using the CytoSorb Filter*, conducted at the Medical University of Vienna. The study, which has also now completed, used CytoSorb cardiopulmonary circuit in patients undergoing elective cardiac surgery (which may include valve surgery, CABG or a combination of the two). 37 patients randomized to CytoSorb installed in the circuit or to a control group where CytoSorb is not used. Primary outcome is evolution of cytokines IL-1β, IL-6, IL-18, TNF-alpha and IL-10.

- *Removal of Cytokine on Cardiopulmonary Bypass with CytoSorb Compared to On- and Off-pump Myocardial Revascularization*, being conducted at the University Hospital of Cologne. This is a three-arm study (with two controls) with targeted enrollment of 300 patients undergoing elective myocardial revascularization. Patients are assigned to one of three cohorts; 1) use of cardiopulmonary bypass with CytoSorb in the circuit , 2) use of cardiopulmonary bypass without CytoSorb in the circuit (control arm) and 3) no pump used (control arm). Primary outcome is evolution of the inflammatory response as measured by change from baseline in cytokine level. Cytokines measured are IL-6, IL-8, TNF-alpha and C3/C4-complement leukocytes CRP. Preliminary data, from 142 patients, was presented.

CTSO noted that results of the studies showed that "some cytokines are removed in CytoSorb treat patients" – but qualified that these are shorter studies with relatively 'healthier' patients and that the risk of adverse events and mortality were low in both the CytoSorb and control cohorts. These studies are expected to include more complex cardiac procedures where risk of inflammation is higher – and which might presumably show a more definitive difference in outcomes of CytoSorb versus control patients.

A couple of key takeaways of the results were mentioned in CTSO's press release; that they support feasibility and safety of REFRESH I (patient screening is now underway) and safety, ease of use and feasibility are expected to increase confidence of using CytoSorb in a range of cardiac surgery procedures.

And in addition to cardiac surgery, as well as other conditions such as sepsis, pancreatitis, lung injury (and others), CTSO noted that CytoSorb has now also been used for treatment of certain tropical diseases such as Dengue Fever and Scrub Typhus. So the conditions and illnesses where CytoSorb may have utility continues to grow, which further expands the aggregate size and total value of the device's target markets.

Recent Points-of-Interest

- Distribution of CytoSorb now covers over 30 countries. Recent additions have been Saudi Arabia (distributed by Techno Orbits), Australia/New Zealand (distributed by TekMed), Italy (via Aferetica SRL) and Israel (via AlphaMedix). Other territories, including Russia (awaiting regulatory approval) and other areas in the GCC could come onboard over the near-term
- International CytoSorb registry went live in Q4 2014. Sponsored by Jena University Hospital (Germany), the registry will collect data from users of CytoSorb. CTSO noted on the Q4 call that as many as 1,000 patients may be included in the registry by current year-end. The registry is listed on clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT02312024)
- CytoSorb.com website also recently launched – which includes list of investigator initiated studies which are underway or in the planning phase. Website also includes case reports, many of which have been published in peer-reviewed journals. We expect the clinical experience documented in case reports, studies and through the registry to be key components of driving awareness and facilitating marketing efforts
- First international users meeting held in March 2015 at the International Symposium on Intensive Care and Emergency Medicine in Belgium. Second users meeting held in October 2015 in Berlin. These user meetings are another significant part of CTSO's marketing and awareness efforts and are expected to provide valuable feedback from early adopters. The company noted that both users meetings were very well attended
- Agreement with Biocon, CTSO's distributor in India, was expanded whereby Biocon agreed to increase the minimum purchase agreement and will be funding and publishing results from their own investigator initiated and patients case studies. Biocon now also has distribution rights of CytoSorb for all critical care illnesses in India and certain emerging countries. As we have noted in the recent past, Biocon has been a key ally of CTSO and, while CTSO does not disclose sales per revenue channel, we think Biocon has been a material contributor to product sales growth and has the potential to increase further

- Fresenius partnership announced in December 2014 whereby Fresenius has distribution rights of CytoSorb for critical care applications in France, Sweden, Norway, Finland, Denmark and Poland. We think this deal with Fresenius, which is the world leader in dialysis, provides not only substantial distribution reach, it also provides a significant vote of credibility to CytoSorb and CytoSorbents. Fresenius-related sales are expected to commence in Q1 2016
- Recently announced partnership with "top four" (unnamed) medical device company for use of CytoSorb in France for cardiac surgery. Evaluation by this company of CytoSorb, although delayed, was finally completed during Q3 2015. Assuming all goes well the parties will collaborate on a broader marketing message and promote the product - initially at the KOL level and then drive down into hospitals and individual physicians levels. CTSO will update on next steps
- FDA approval to commence U.S. feasibility study of CytoSorb came in early February. The study, named REFRESH (Reduction in FREe Hemoglobin), was original designed as a 20-patient, three center, single arm study which would compare CytoSorb in cardiac surgery to a non-interventional trial. FDA subsequently approved an amendment to the study converting it to a 40-patient, eight site, randomized controlled study. So the amendment consolidates the non-interventional arm directly into the study. The study will evaluate CytoSorb's ability to actively remove plasma free hemoglobin and cytokines, among other inflammatory markers. These toxic substances, which are produced during cardiac surgery, can lead to serious complications including kidney injury / failure. The study will provide a comparison of how well CytoSorb was able to reduce toxic substances and related adverse events between the active study patient population and those undergoing cardiac surgery where CytoSorb was not used. Enrollment at one site has now begun and management expects 6 of the 8 sites to have commenced enrollment by the end of this month (November). While initial expectations were that if all went well that the study could wrap up by Q1 2016, this will likely be a later event in 2016 as a result of slight delays in starting enrollment.

- In April 2015 CTSO announced they would investigate the Expedited Access Pathway for U.S. regulatory approval. CTSO filed their EAP application in Q3. The application includes protocol of proposed premarket and postmarket studies. While management did not disclose specifically what they expect to pursue as endpoints in either of the studies, they indicated premarket could be metrics such as days in the intensive care unit, days on the ventilator, hemodynamic stability or use of vasopressors. Standard primary endpoint for a sepsis indication has been 28-day all-cause mortality, which is what was used in CTSO's European Sepsis Trial and which is being used in Spectral Medical's EUPHRATES trial (and which was used by Eli Lily to gain approval of Xigirs – which was removed from the market). So this is presumably the primary endpoint that CTSO would use in a postmarket study.
- German dosing study progressing well with over 100 of the planned 300 patients currently enrolled.
- Recently restructured direct sales team, with four of the ten reps fired in Q1 2015. Two additional full-time direct reps and a contract cardiac surgery rep were brought on in Q3. Another two are expected to come onboard before year-end. The new reps will likely take several months to get fully productive but with revenue continuing to be driven by a mix of both reorders from existing customers as well as from new accounts and with the new territories that just came online, we continue to think product sales will show a meaningful yoy and sequential increase. Additional catalysts to product sales growth could also come online in the near-term including initiation of sales by Fresenius as well as CTSO's cardiac surgery partner.

Outlook and Model Update

We view 2015 as somewhat of a re-grouping year on the income statement - although "regrouping" should be put into context as we still model better than 20% yoy product sales growth. But, for comparison, 2013 saw product sales up almost 300%. And on the positive side, we expect CTSO to continue to make major strides on the operational front and think recent developments such as the Fresenius deal and expanded agreement with Biocon can be significant contributors to revenue in 2016. We think the company has done an impressive job in recovering from the relative slump caused by the sales force reshuffling, which is highlighted by the almost 40% product sales growth from Q2 to Q3 of this year. And with much of the growth coming from reorders and revenue spread broadly across the customer base, we think this provides support for expectations of continued sequential revenue growth and limited volatility.

We continue to look for sales to maintain a recovery through the early part of 2016 – reflecting contribution from newly hired reps, related productivity gains and incremental additional ordering from distributors. And fuel for future growth, including new distribution agreements, regulatory approvals in additional territories (many of which could come in fairly short order and which CTSO already has distribution lined up) and further build-out of the direct team all remain very viable to make a more substantial impact over the longer term.

Important to recognize and the reason we continue to reiterate this, is that we believe management is wisely navigating and executing the roll-out of CytoSorb. Unlike a shotgun approach and "just trust us that our novel product works" followed by many inexperienced med-tech start-ups, CTSO is following a game plan that puts clinical experience and positive outcomes first in order to drive demand and is targeting KOL's (i.e. those who have the most influence). While this strategy can take time, we already see early successes with growth in product sales, a growing list of KOLs using or interested in using CytoSorb as well an increasing number of investigator initiated studies coming online. Many of the user experiences are also being documented in peer-reviewed journal articles which, now with the patient registry live, may expand further and facilitate even greater awareness and resultant adoption.

We are maintaining our Buy recommendation as well as our $12.50/share price target.

FINANCIAL MODEL

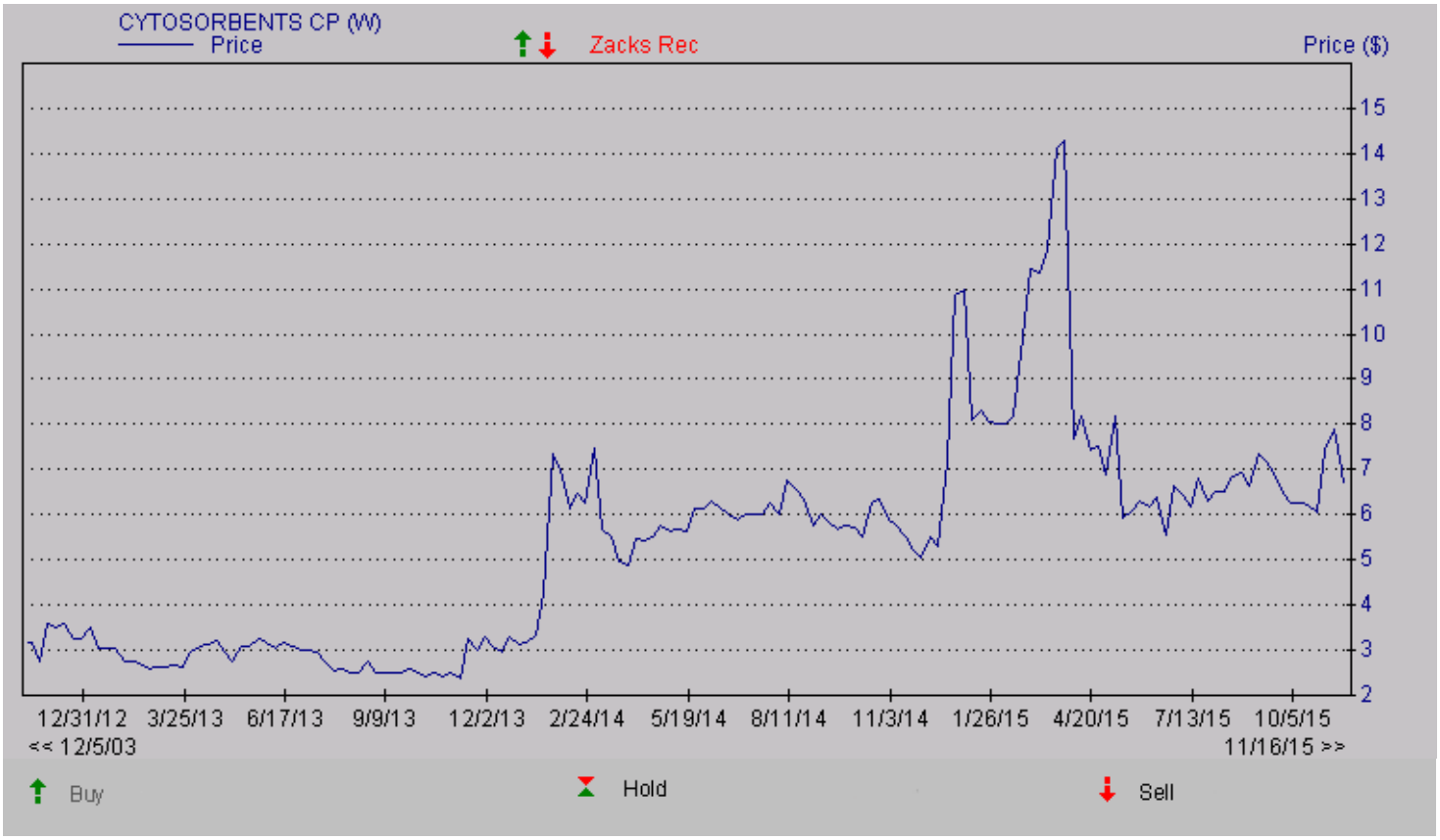
CytoSorbents Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
CytoSorb Sales	$3,135.4	$703.7	$773.1	$1,071.5	$1,242.7	$3,790.9	$11,030.0	$19,580.0	$28,010.0
y-o-y growth	*281.5%*	*23.6%*	*16.6%*	*3.8%*	*42.6%*	*20.9%*	*191.0%*	*77.5%*	*43.1%*
Total Royalties/Grants/Other	$987.5	$19.4	$190.8	$272.2	$211.1	$693.5	$1,181.8	$665.0	$0.0
y-o-y growth	*-38.3%*	*-96.1%*	*-47.2%*	*108.4%*	*8217.6%*	*-29.8%*	*70.4%*	*-43.7%*	*-100.0%*
Revenue	$4,122.9	$723.1	$963.9	$1,343.6	$1,453.8	$4,484.4	$12,211.8	$20,245.0	$28,010.0
YOY Growth	*70.2%*	*-31.9%*	*-5.9%*	*15.6%*	*66.4%*	*8.8%*	*172.3%*	*65.8%*	*38.4%*
Cost of Goods Sold	$2,133.9	$304.5	$465.4	$638.8	$667.6	$2,076.3	$5,225.4	$8,005.7	$10,643.8
Gross Income	$1,989.0	$418.6	$498.5	$704.8	$786.2	$2,408.1	$6,986.4	$12,239.4	$17,366.2
Gross Margin	*48.2%*	*57.9%*	*51.7%*	*52.5%*	*54.1%*	*53.7%*	*57.2%*	*60.5%*	*62.0%*
SG&A	$6,836.2	$2,179.2	$1,924.3	$1,988.8	$2,334.0	$8,426.3	$9,654.0	$13,237.0	$14,341.1
% SG&A	*165.8%*	*301.4%*	*199.6%*	*148.0%*	*160.5%*	*187.9%*	*79.1%*	*65.4%*	*51.2%*
R&D	$2,431.7	$951.0	$801.7	$866.3	$1,035.0	$3,654.0	$4,694.0	$4,902.0	$4,915.0
% R&D	*59.0%*	*131.5%*	*83.2%*	*64.5%*	*71.2%*	*81.5%*	*38.4%*	*24.2%*	*17.5%*
Operating Income	($7,278.9)	($2,711.6)	($2,227.5)	($2,150.3)	($2,582.8)	($9,672.2)	($7,361.6)	($5,899.7)	($1,889.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$2,428.5	$2,005.3	($3,661.8)	$697.1	($3.0)	($962.3)	$0.0	$0.0	$0.0
Pre-Tax Income	($9,707.4)	($4,716.9)	$1,434.3	($2,847.4)	($2,579.8)	($8,709.8)	($7,361.6)	($5,899.7)	($1,889.9)
Taxes (benefit)	($385.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*4.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividend	$9,266.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($18,588.4)	($4,716.9)	$1,434.3	($2,847.4)	($2,579.8)	($8,709.8)	($7,361.6)	($5,899.7)	($1,889.9)
Net Margin	-	*-652.3%*	*148.8%*	*-211.9%*	*-177.4%*	*-194.2%*	*-60.3%*	*-29.1%*	*-6.7%*
EPS	($1.29)	($0.19)	$0.06	($0.11)	($0.10)	($0.35)	($0.27)	($0.21)	($0.07)
YOY Growth	-	-	-	-	-	-			
Diluted Shares O/S	14,441	24,394	24,769	25,038	25,350	24,888	27,000	27,700	28,200

Brian Marckx, CFA

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 25.5%, Hold/Neutral- 55.2%, Sell/Underperform – 15.5%. Data is as of midnight on the business day immediately prior to this publication.