Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Product Revenue Sets New Record, Further Growth Expected in 2H

Based on our 10-year DCF model, which uses a 13% discount rate to account for certain risks and uncertainties that CytoSorbents faces, and a 2% terminal growth rate, the shares are valued at approximately $12.

Current Price (08/11/17)	$4.50
Valuation	**$12.00**

OUTLOOK

Management continues to guide for product sales to increase sequentially from 1H to 2H 2017. We think the improved reimbursement picture in Germany, continued robust product sales growth from existing distributors OG (i.e. outside of Germany), recently established distribution in new territories and initial roll-out of the Fresenius co-marketing agreement could all be meaningful catalysts. With ~60 investigator initiated studies either ongoing or planned as well as potential near-term publication of REFRESH I data, there should be a regular flow of additional clinical and outcomes data to help further enhance the marketing message. New CMO came aboard June 1st. Will work to optimize trial design for REFRESH II - commencement of which CTSO still expects to happen this year.

Toxic side effects of cancer immunotherapies could offer another, and potentially very significant opportunity, for CTSO. With FDA likely to approve Novartis' CTL019 later this year (possibly followed by Kite's candidate), the feasibility of CytoSorb as a toxicity-mitigation option for these drugs could soon become more clear.

SUMMARY DATA

52-Week High	**$6.73**
52-Week Low	**$3.45**
One-Year Return (%)	**-4.86**
Beta	**-0.57**
Average Daily Volume (sh)	**139,925**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$127**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**59.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 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)
2016	1810 A	2222 A	2412 A	3083 A	9528 A
2017	3114 A	3566 A	3664 E	3877 E	14221 E
2018					21078 E
2019					30676 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-0.08 A	-0.12 A	-0.11 A	-0.17 A	-0.47 A
2017	-0.05 A	-0.04 A	-0.07 E	-0.09 E	-0.26 E
2018					-0.34 E
2019					-0.20 E

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

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Q2 Financials / Operating Update: *Product Revenue Sets New Record, Further Growth Expected in 2H…*

CytoSorbents reported financial results for their second quarter ending June 30th and provided a business update. Product sales rebounded strongly from the slight (i.e. < 1%) sequential decrease from Q4 to Q1, jumping 17% sequentially and 64% on a yoy basis to just over $3M in Q2. Much of the re-acceleration in product sales growth appears to be related to firming up of reimbursement in Germany.

As a reminder, a dedicated reimbursement code recently became available in Germany but with some hospitals delaying purchasing as they awaited notification regarding payment rates, Q1 product sales were negatively impacted. But, based on a survey (about reimbursement) of some of CTSO's key German accounts as well as the 21% sequential growth in product sales related to that country from Q1 to Q2, that headwind appears to have begun to reverse.

With some hospitals still yet to renegotiate payment rates under the new dedicated code but which could do so throughout the remainder of the year, we think it is likely that additional related benefit shows up in 2H 2017. With Germany accounting for approximately 60% of total product sales, any additional acceleration from that territory could have an outsized positive impact on total revenue. Attractive reimbursement could also facilitate increased utilization from existing customers as well as initial adoption of prospective accounts. Similar reimbursement in other European countries, if eventually established, presents another potential catalyst.

Management continues to guide for product sales to increase sequentially from 1H to 2H. While not providing specifics relative to the expected catalysts, we think the improved reimbursement picture in Germany, continued robust product sales growth from existing distributors OG (i.e. outside of Germany), recently established distribution in new territories and initial roll-out of the Fresenius co-marketing agreement could all be meaningful contributors. With ~60 investigator initiated studies either ongoing or planned as well as potential near-term publication of the REFRESH I data, there should be a regular flow of additional clinical and outcomes data to help further enhance the marketing message.

Financials…

Total revenue was $3.6M, up 61% yoy, up 18% sequentially and 12% higher than our $3.2M estimate. Product revenue came in at $3.0M, up 64% yoy and up 17% sequentially. Grant income was $525k - which is the highest of any quarter since Q4 2013 (i.e. when the DARPA grant was highly active).

Grant income benefitted in-part from two new awards which both came in May and are funded by the United States Army Medical Research Acquisition Activity (USAMRAA). This includes funding of up to $999k over two years for a phase II contract related to the development of HemoDefend in enabling universal plasma. The other, a phase I contract which will pay up to $719k over four years, relates to novel hemoadsorptive therapies for severe burn injuries. The addition of these two grants has incrementally increased our total modeled through 2021.

As noted, much of the strength in product sales was attributed to improved reimbursement in Germany. And while Germany has been a significant contributor to revenue, that market may still remain relatively untapped given their significant population and large hospital network. Management has indicated that adoption in that country has been brisk and aided by strong support by certain KOLs. One hospital in Germany already generates over $1M in product sales for CTSO. With over 400 mid-to-large hospitals in the country, we think there is considerable near-term upside from that market.

As we explained in our Q1 update, we felt that since we viewed Germany as CTSO's most important territory relative to both near-term sales as well as opportunity for growth, that it was important that any reimbursement-related headwind be rectified so as to not create a long-term hangover. Management's comments on the Q2 call indicating reimbursement there has already significantly increased (and may further broaden throughout additional hospitals), coupled with the strong sequential product revenue growth from that country, is highly encouraging in that regard.

Meanwhile, product margin, at 65% in Q2, was not a particular highlight. This compares to approximately 68% in Q1 of this year and as well as in Q2 2016. The mix of direct versus distributor sales was cited as influencing product margin. The good news is that there is nothing indicating fundamental shrinkage in margins and management is guiding for product margin to potentially grow to 70%. We continue to model incremental widening through the course of the out-years in our model from a combination of opportunistic pricing power and volume-related production efficiencies.

Operating expenses we $4.5M - while this is $1M higher than Q1, almost all ($799k) of the difference relates to non-cash stock compensation - and the increase in stock comp relates to pre-determined operational milestones that were met during the quarter. Excluding the increase in stock comp, operating expenses were $3.6M, marginally lower than our $3.8M estimate.

While R&D expense, at $488k, remains relatively low given the conclusion of REFRESH I, we expect these expenses to climb with commencement of REFRESH II (which could potentially happen prior to current year-end). As it relates to SG&A – we continue to model this line to grow at a lower than historical rate as compared to revenue given leverage of certain fixed costs which should also help to improve profitability.

Cash used in operating activities was $1.9M and $3.9M ($1.6M and $3.1M ex-changes in working capital) in the three and six months ending June 30, 2017. Cash balance, recently bolstered by the $10.3M (net) equity raise in April and the more recent $5M draw on their term loan, was $16.4M at Q2 quarter-end. Management expects cash balance to fund operations through, at least, the end of 2018.

Operational Update: Sepsis On Radar, CAR-T Cancer Opportunity, Optimizing REFRESH II Trial Design…

Sepsis: While we think cardiac surgery is still the initial focus for U.S. development, management spent much of the conference call talking about the potential opportunity CytoSorb may have in the treatment of sepsis, including where other novel drugs and devices have failed. One of possible underlying theme to the high failure rate has been the difficulty in demonstrating consistency in outcomes due to the heterogeneous nature of the condition. As we have indicated in our prior reports, history has shown that a shotgun approach to enrolling a pivotal sepsis study is likely a recipe for a big waste of money - that is something that CTSO recognizes and clearly is committed to avoiding. We have and continue to interpret that management's approach towards sepsis will be very systematic and that they will continue to conduct OUS sepsis-related studies to help flesh out potential patient populations in which CytoSorb appears to be most effective - which would presumably improve the chances of success and which may afford a relatively small (potentiall pivotal sepsis study.

REFRESH: On June 1st, Dr. Eric Mortensen, MD, PhD joined CTSO as their new Chief Medical Officer. He is now in charge of leading the clinical programs including the U.S. cardiac surgery studies. There was not much in the way of an update related to the REFRESH studies on the Q2 call although Dr. Chan did say that they intentionally delayed an IDE submission to FDA for REFRESH II in order for Dr. Mortensen to get up to speed on the REFRESH I data and to optimize the REFERESH II design to increase chances of eventual success. Management noted that they expect to provide more information about the study protocol in the future and still anticipate REFRESH II kicking off before current year-end. For reference, below we have included results of REFRESH I (and our related commentary) that CTSO released earlier this year.

CAR-T Cell Cancer Therapy Opportunity: the feasibility of CytoSorb as a treatment for cytokine release syndrome (CRS) could soon become more clear given the impending PDUFA date (Sept / Oct) of CTL019, Novartis' CAR-T cell candidate for the treatment of an aggressive form of leukemia. In July an FDA advisory panel voted unanimously to approve the immunotherapy which demonstrated such extraordinarily efficacy in clinical studies that a member of the panel noted that it was the most exciting thing he had seen in his career. The compromise, however, was that clinical studies also showed the drug elicited severe CRS (i.e. severe inflammatory response with excessive and harmful levels of cytokines) in up to 47% of patients. CRS can result in serious complications and lead to organ failure and death. While we think it is almost a certainty that FDA will approve CTL019, NVS will still need to have a toxicity-mitigation strategy.

While corticosteroids and tocilizumab have been used with some success in controlling CRS, there are drawbacks. This includes that corticosteroids are suspected of potentially comprising immunotherapy efficacy. Relative to tocilizumab, researchers have noted that its use should be avoided if macrophage activating syndrome (MAS) is suspected.[1] Interestingly, CytoSorb has been used successfully in several patients with a condition called hemophagocytic lymphohistiocytosis (HLH) - one of these was the subject of a case report published in early March 2017 in the Journal of Clinical Immunology. Studies have shown that subjects with secondary HLH, which is often caused by virologic infection and characterized by a strong and sometimes uncontrollable immune response including CRS, can exhibit responses similar to cancer patients treated with certain immunotherapies. The similarity in CRS response in HLH and cancer patients treated with immunotherapies and CytoSorb's early success in treating HLH patients (via reduction in inflammatory markers) is encouraging, particularly as it may relate to mitigating the toxicity of CTL019 and similar therapies that could come to market (Kite's KTE-C19 is also awaiting FDA approval). Another factor that could play in CTSO's favor is the fact that Dr. June Carter, who recently joined

[1] Shannon L. Maude, MD, PhD,* David Barrett, MD, PhD,* David T. Teachey, MD,* and Stephan A. Grupp, MD, PhD. Managing Cytokine Release Syndrome Associated With Novel T Cell-Engaging Therapies. Cancer J. 2014 Mar-Apr; 20(2): 119 122.

CytoSorbents' scientific advisory board, also led the CTL019 program at the University of Pennsylvania. 'Next-steps' towards pursuit of this potential opportunity may become more clear following FDA approval of CTL019. Given the extraordinary efficacy already seen with CTL019 and the recent and growing massive inflow of investment dollars targeting immunotherapy development, this is an application that we think, if validated, could hold enormous growth potential for CTSO. Stay tuned.

REFRESH Refresher…

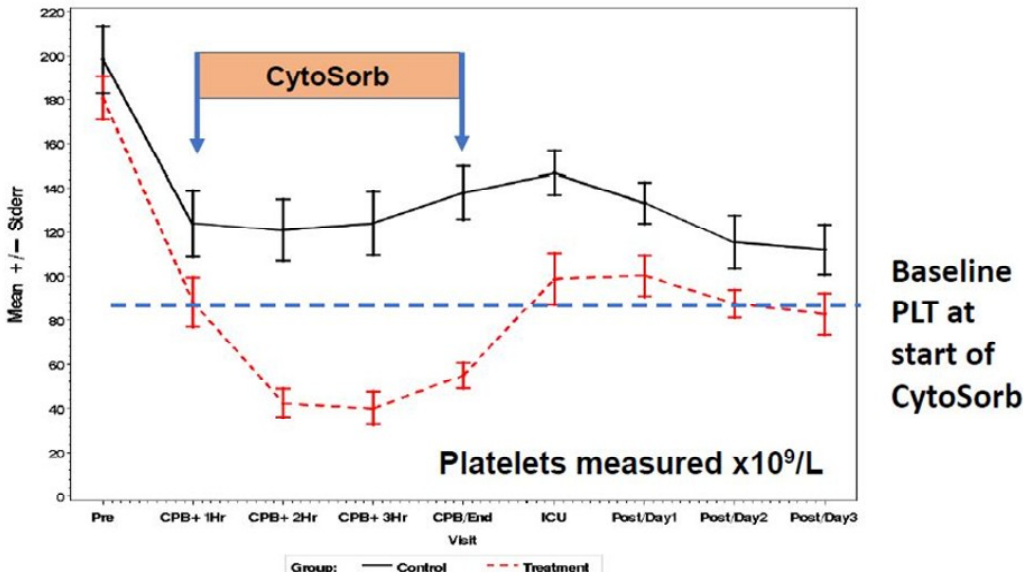
As a reminder, REFRESH I was a multi-site 40+-patient randomized study comparing CytoSorb plus standard-of-care (SOC) to SOC alone (1:1) in the reduction of free hemoglobin in patients undergoing elective complex cardiac surgery requiring cardiopulmonary bypass with anticipated duration of more than 180 minutes. 46 patients (23 each arm) were assessed in the safety population while 38 (18 CytoSorb, 20 control) were assessed in the efficacy population.

In October 2016 CTSO announced positive **safety-related information** and released additional information on the Q1 call. Both the number of total adverse events as well as number of serious adverse events was similar between the treatment and control arms. While there were two deaths in the CytoSorb group (8.7%), this was not statistically different than the one (4.3%) in the control group. Of the 121 adverse events in the CytoSorb arm, two were related to the device – with both related to a drop in platelets.

	Control (N = 23)	CytoSorb (N = 23)
Total Number AEs	137	121
Total Number SAEs	43	44
Mortality	1 (4.3%)	2 (8.7%)
Device Related AEs		2

SOURCE CytoSorbents

Of the 121 adverse events in the CytoSorb arm, two were related to the device – with both related to a drop in platelets. A decrease in platelets (i.e. cells that help blood clot) is not unexpected given that patients undergoing these procedures must be highly anticoagulated and CPB in itself causes a drop in platelets. The chart below illustrates a drop in platelets in both cohorts even prior to introduction of the CytoSorb therapy in the treatment group. Nonetheless, the platelet level in the CytoSorb arm continues to drop with introduction of that therapy while the control group exhibits more of a leveling off. While the decrease in platelets, per management, was not associated with any serious device-related events and post-op coagulation and bleeding parameters as well as transfusions were not different between the two groups, the greater decrease in platelets among the treatment cohort is something that investigators will look at in more detail.



SOURCE CytoSorbents

REFRESH I Efficacy: CytoSorb More Effectively Reduces PfHB Which Is Associated With Kidney Injury….
A clinical study by Windsant, et al. indicated that hemolysis (including plasma free hemoglobin) during cardiac surgery is a contributor to postoperative kidney injury.[2] Plasma free hemoglobin can be dangerous, particularly at relatively high levels. While levels at or below 60 mg/dL have been found to be generally safe, levels over 120 mg/dL have been associated with acute kidney injury (AKI). As it relates to efficacy, there appears to be an association between the type of cardiac surgery and how much plasma free hemoglobin is generated. Specifically, valve replacement surgery (either in isolation or in combination with other cardiac surgery procedures) appears to be associated with higher levels of plasma free hemoglobin.

The average peak plasma free hemoglobin level of the nine patients in the control group (efficacy population) in REFRESH I that underwent valve replacement surgery was 121 mg/dL (median was 123 mg/dL) – or, at potentially dangerously-high levels.

Control group only: Peak PfHb in Different Surgical Procedures (mg/dL)

Procedure	N	Mean	Std	Median	Min	Max
All	20	104.0	58.54	101	23	245
Valve Replacement	9	121.0	46.57	123	57	204
Non-valve Replacement	11	90.1	65.60	61	23	246

CPB Length (median control): 2.8h (Valve) vs 4.0h (Non-valve), p=0.03

SOURCE CytoSorbents

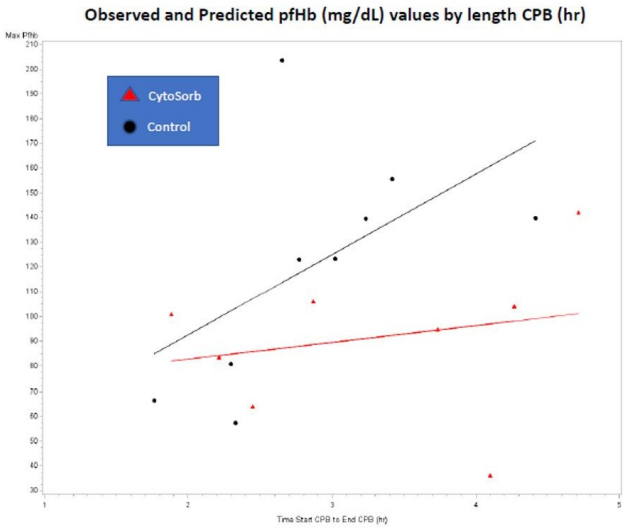
Valve replacement patients in the CytoSorb group fared better as it relates to PfHb levels. Among those patients in REFRESH I that underwent valve replacement surgery that lasted between 3 and 4.5 hours, CytoSorb demonstrated a statistically significant reduction in plasma free hemoglobin as compared to control.

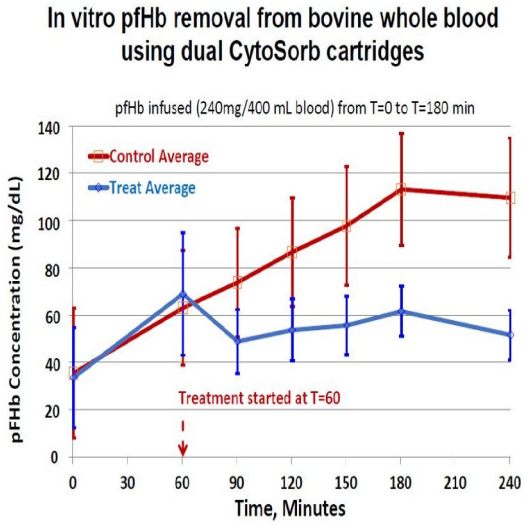
CPB Length	Mean Reduction of pfHb (mg/dL)	P-value
3.0	35 mg/dL	0.09
3.5	48 mg/dL	0.05
4.0	61 mg/dL	0.05
4.5	74 mg/dL	0.07

SOURCE CytoSorbents

[2] Iris C. Vermeulen Windsant, et al. Hemolysis during cardiac surgery is associated with increased intravascular nitric oxide consumption and perioperative kidney and intestinal tissue damage. Front Physiol. 2014; 5: 340. Published online 2014 Sep 8. doi: 10.3389/fphys.2014.00340

Interestingly, these findings are similar to an earlier pre-clinical study which found CytoSorb was more effective than standard bypass circuit in reducing free hemoglobin from bovine blood. In fact, the charts from REFRESH (left) and the in vitro bovine-blood study (right) have very similar patterns.





C3a / C5a:
In addition to plasma free hemoglobin, significant reductions in the activated complements C3a and C5a, high levels of which are associated with poor outcomes, were also observed.

In Summary:
Evidence to date has shown;

- high levels of PfHb generated during cardiac surgery with valve replacement surgery associated with particularly high levels
- an association between high levels (i.e. > 120 mg/dL) of PfHb and AKI
- CytoSorb's ability to significantly reduce PfHb vs. control in valve replacement procedures (3hr – 4.5hrs)

REFRESH II…
REFRESH II is expected to build on those findings. While the REFRESH II study design has yet to be finalized and could change based on findings from REFRESH I and interaction with FDA, management provided their current thoughts related to that topic in the Q1 call in May. Included is;

- N = 300-500
- enriching for procedures associated with high PfHb – such as valve replacement surgery
- primary endpoint: acute kidney injury or possibly a composite endpoint

Near-term Outlook

We continue to see no reason why product sales do not continue to set new regular records, particularly given some recent catalysts that came online. These include;

- **dedicated reimbursement in Germany** which became effective Jan 1, 2017. While the new code may have actually been an impediment to Q1 sales growth given that some hospitals in Germany may have delayed purchasing as they still awaited reimbursement amounts, that headwind appears to have begun to reverse with Q2 showing strong sequential product sales growth in Germany. If reimbursement expands to other parts of Europe, that would likely provide additional upside

- **accelerating adoption in Germany**, the largest (yet still barely tapped) medical device market in Europe. One hospital in Germany already generates over $1M in product sales for CTSO. With over 400 mid-to-large hospitals in the country and strong support from KOLs, we think there is considerable near-term upside from that market.

- **Fresenius**: roll-out began in Q2 2016. 2017 will benefit from full-year FMS contribution. In addition, co-marketing agreement, expected to kick-off 2H 17, will greatly expand FMS footprint

- **Terumo** (cardiac channel): launch began December 2016. 2017 should benefit from full-year contribution. We think Terumo could also be key in eventually accessing (very substantial) Japanese market

- **Biocon**: CTSO's large distributor in India recently reorganized CytoSorb into a separate division. Biocon has been a key partner and this restructuring is an indication they are putting even more resources behind CytoSorb

- **distribution/geographic expansion**: we expect additional territories and distribution agreements will continue to come online on a regular basis. Agreement with Aferetica for distribution in Italy was just extended through 2021 - CTSO believes this could generate $10M or more in sales through that time

- **clinical data / validation**: has been and continues to be the driving force behind adoption. In addition to REFRESH I, a fairly regular flow of clinical data from case studies and investigator-initiated trials should be forthcoming. CytoSorb has now been used in more than 27k human treatments

- **increasing use in a number of critical care applications** where CytoSorb has been associated with positive patient outcomes including sepsis

- **ECMO kit launch**: provides seamless and rapid connection of CytoSorb to extracorporeal membrane oxygenation. CTSO noted on the Q2 2017 call (August) that CytoSorb has now been used more than 1k times with ECMO

- **increased capacity**: a new manufacturing facility, which is expected to increase capacity to support up to $80M in sales, is expected to come online in Q1 2018

Valuation

We expect to see continued strength in product sales growth through 2H, as well as more strides on the operational front. We see several catalysts that begin to make either an initial or a greater impact by the end of this year including dedicated reimbursement in Germany and accelerating adoption in that country, greater contribution from Fresenius (i.e. full year impact, additional experience, co-marketing agreement) as well as from Terumo (which just came online in December 2016), maturation of existing distribution relationships and expansion of the overall sales footprint, and the release of additional clinical data supporting the utility of CytoSorb in a several indications.

We have made some upward revisions to modeled revenue following the sizeable beat in Q2 which we think carries through to the remainder of the year with expectations of continued sequential growth. The result was our estimated current-year revenue moving from $13.5M to $14.2M, although the net effect to operating loss was offset as we now forecast a higher expense base. The updates to the out-years in our model was more muted.

We show CTSO nearly reaching GAAP full-year operating profitability in our out-year (2020) in our model and also believe management's guidance of reaching a level of break-even operating profitability (excluding clinical trial-related and non-cash expenses) in 2018 is also achievable. We note that we do not currently model any contribution from potential cancer-related applications - as such, eventual validation for such an indication would likely provide upside to our estimates (and possibly our price target as well).

Based on our 10-year DCF model, which uses a 13% discount rate to account for certain risks and uncertainties that CytoSorbents faces, and a 2% terminal growth rate, the shares are valued at approximately $12.

FINANCIAL MODEL

CytoSorbents Inc.

	2016 A	Q1A	Q2A	Q3E	Q4E	2017 E	2018 E	2019 E	2020 E
CytoSorb Sales	$8,206.1	$2,596.1	$3,041.0	$3,136.4	$3,366.5	$12,140.0	$19,690.0	$29,516.0	$41,700.0
y-o-y growth	*102.9%*	*62.5%*	*64.1%*	*46.3%*	*28.8%*	*47.9%*	*62.2%*	*49.9%*	*41.3%*
Total Royalties/Grants/Other	$1,321.8	$517.4	$525.2	$528.0	$510.0	$2,080.0	$1,388.0	$1,160.0	$1,005.0
y-o-y growth	*76.8%*	*143.2%*	*42.1%*	*96.6%*	*8.3%*	*57.4%*	*-33.3%*	-	-
Revenue	$9,527.9	$3,113.5	$3,566.2	$3,664.4	$3,876.5	$14,220.6	$21,078.0	$30,676.0	$42,705.0
YOY Growth	*98.8%*	*72.0%*	*60.5%*	*51.9%*	*25.7%*	*49.3%*	*48.2%*	*45.5%*	*39.2%*
Cost of Goods Sold	$3,953.8	$1,254.5	$1,482.0	$1,499.3	$1,536.3	$5,772.1	$7,086.8	$9,398.1	$12,321.8
Gross Income	$5,574.1	$1,859.0	$2,084.2	$2,165.1	$2,340.2	$8,448.5	$13,991.2	$21,277.9	$30,383.3
Gross Margin	*58.5%*	*59.7%*	*58.4%*	*59.1%*	*60.4%*	*59.4%*	*66.4%*	*69.4%*	*71.1%*
SG&A	$12,282.7	$2,947.0	$3,927.5	$3,427.0	$3,884.0	$14,185.5	$16,579.0	$20,690.7	$24,728.1
SG&A % of Prod Sales	*149.7%*	*113.5%*	*129.2%*	*109.3%*	*115.4%*	*116.8%*	*84.2%*	*70.1%*	*59.3%*
R&D	$4,783.5	$469.5	$487.6	$584.0	$748.0	$2,289.2	$7,287.0	$6,956.0	$7,295.0
R&D % Tot Sales	*50.2%*	*15.1%*	*13.7%*	*15.9%*	*19.3%*	*16.1%*	*34.6%*	*22.7%*	*17.1%*
Operating Income	($11,492.1)	($1,557.5)	($2,330.9)	($1,845.9)	($2,291.8)	($8,026.1)	($9,874.8)	($6,368.8)	($1,639.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$765.3	($179.5)	($1,214.5)	$249.6	$249.6	($894.8)	$772.8	$361.1	$44.1
Pre-Tax Income	($12,257.3)	($1,378.0)	($1,116.4)	($2,095.5)	($2,541.4)	($7,131.3)	($10,647.6)	($6,729.9)	($1,684.0)
Taxes (benefit)	($318.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*2.6%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($11,938.8)	($1,378.0)	($1,116.4)	($2,095.5)	($2,541.4)	($7,131.3)	($10,647.6)	($6,729.9)	($1,684.0)
Net Margin	*-125.3%*	*-44.3%*	*-31.3%*	*-57.2%*	*-65.6%*	*-50.1%*	*-50.5%*	*-21.9%*	*-3.9%*
EPS	($0.47)	($0.05)	($0.04)	($0.07)	($0.09)	($0.26)	($0.34)	($0.20)	($0.05)
YOY Growth		-	-	-	-				
Diluted Shares O/S	25,433	25,504	27,954	28,200	28,600	27,564	31,500	33,500	34,500

Brian Marckx, CFA

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