Zacks Small-Cap Research

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Cryoport Inc (CYRX-NASDAQ)

CYRX: Growth in Clinical Trial Customers Pushing Revenue To Record Heights

Average comparable PE/G (excluding high and low outliers) is 1.21 which is applied to our forecasted revenue growth rate of CYRX of 47% through fiscal 2021. The result, $9.30/share, is discounted back to the present at a CAPM-calculated discount rate of 14.6% to come to present value share price of approximately $6.

Current Price (03/21/17)	$3.52
Valuation	**$6.00**

OUTLOOK

As the biopharma segment has been the catalyst to the top-line growth, it should come as no surprise that this also marks the ninth straight quarter of consecutive revenue growth of that segment. The importance of the biopharma segment, which is where management has turned the majority of its focus, is also highlighted by its contribution to overall revenue. We think the ~43% growth in the number of regenerative medicine clinical trials that the company supports over just the last nine months along with the double-digit percentage of total regenerative medicine trials that they are involved in speaks to validation of the company's offerings. This is also a major component driving our modeled continued growth of the number of supported clinical trials – which in turn, drives our modeled revenue growth.

We are moving our price target to $6/share.

SUMMARY DATA

52-Week High	**$4.07**
52-Week Low	**$1.35**
One-Year Return (%)	**153.52**
Beta	**0.07**
Average Daily Volume (sh)	**19,844**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$63**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**13**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**80.3**
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	**Shipping**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (June)	Q3 (Sep)	Q4 (Dec)	Year (Mar)
2016	1556 A	1918 A	1977 A	2229 A	7,679 A
2017	2591 E	2745 E	2900 E	3253 E	11,490 E
2018					17,227 E
2019					26,092 E

Earnings per Share

	Q1 (June)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	-$0.26 A	-$0.28 A	-$0.14 A	-$0.25 A	-$0.93 A
2017	-$0.14 E	-$0.13 E	-$0.12 E	-$0.11 E	-$0.50 E
2018					-$0.37 E
2019					-$0.27 E

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

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Q3 Fiscal 2017: As Clinical Trial Count Ramps, So Does CYRX's Revenue…

CYRX reported financial results for their fiscal 2017 third quarter ending December 31st. (Note that the company is transitioning their fiscal year to that of the calendar year – our model beginning with this report reflects the new calendar-year reporting. CYRX has filed a 10-KT Transition Report and will begin reporting under the calendar year format beginning with the period ending March 31, which will now represent their first quarter).

Q3 revenue, at $2.2M, was up 53% yoy and about 5% higher than our estimate. It is also a new record and up almost 13% sequentially from fiscal Q2 '17. Results in the period ending December 31st shows that revenue has come in slightly better than our estimates for the third straight quarter with operating loss much better than our numbers for the second period in a row. While the specific reasons behind the revenue beat is tough to pinpoint, better than anticipated performance of the animal health and reproductive medicine segments has been a contributor.

Meanwhile, the company's rapid pace of onboarding new biopharma clients and clinical trial customers is undoubtedly a major catalyst to their consistent top-line growth – fiscal Q3 2017 marked the ninth straight quarter of consecutive total revenue growth.

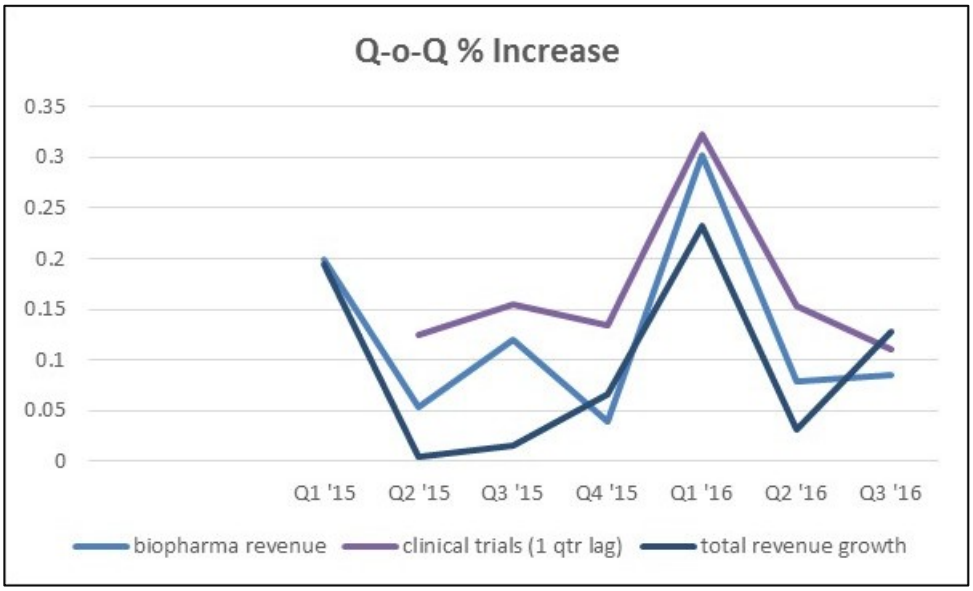
Revenue growth has also benefitted gross margins, which came in at 42.2% in fiscal Q3 – also a new record high and up from 40.3% in Q2 '17 and 26.3% in Q3 '16. We think GM has more room to widen – as does management – which continues to guide for gross margin to eventually increase to 60%.

The next major milestone will be to see improvement in operating leverage. Clearly investments in people, processes and technology have shown up in the revenue growth. SG&A expense was $8.2M over the last three quarters, or about 134% of revenue – which is the best in company history. We expect this will move around as well. But, coupled with expectations of consistent revenue growth and firming up in gross margins, we think there are a lot of positive signs that suggest CYRX is creeping ever closer to the inflection point where operating income begins to improve on a regular basis.

Cash
Cash used in operating activities (ex-changes in working capital) was $1.1M and $3.5M in the three and nine months ending 12/31/16. Cash balance at quarter end was $4.5M, which was recently bolstered by $3.2M (net) in warrant tenders/exercises.

As **the biopharma** segment has been the catalyst to the top-line growth, it should come as no surprise that this also marks the ninth straight quarter of consecutive revenue growth of that segment. The importance of the biopharma segment, which is where management has turned the majority of its focus, is also highlighted by its contribution to overall revenue. In the quarter ending September 30, 2014 (i.e. more than two years ago) the biopharma segment accounted for 50% of total revenue – that proportional contribution has grown almost every quarter since and now sits at 69%. Not coincidentally, the number of clinical trials that CYRX supports has also grown quarter-over-quarter – from about 40 in the quarter ending March 31, 2015 (the earliest date that we were able to find when trial customer counts were disclosed) to 129 as of the close of calendar 2016.

Interestingly, overlaying the trends in growth of the clinical trial customer count (with a one-month lag), to growth in biopharma and total revenue produces a very close correlation (chart below). In fact we ran a correlation function comparing the quarter-over-quarter growth in the number of clinical trials that CYRX is supporting (with one-month lag) to the growth in biopharma revenue beginning with the quarter ending June 30, 2015 and concluding with the quarter ending December 31, 2016. The result is a correlation of 96%. We have utilized this correlation to estimate revenue for the last few quarters – and while we have been slightly low, only missed by less than 4% in the prior two quarters combined. With CYRX adding 30 new clinical trials (~30% increase to the total base) in the quarter ending 12/31/16, this may suggest meaningful growth in biopharma revenue in the upcoming quarter.



Of the current 129 clinical trials that CYRX is currently supporting, 111 are in the regenerative medicine space – the outsized growth of that market over just the last few years has clearly created demand-pull for cryogenic shipping and related services. And clearly CYRX, with their expertise in cryogenic shipping and logistics including their real-time temperature monitoring and tracking capabilities, has been the beneficiary of the strict requirements aimed at ensuring the safety and viability of biological material during handling, transport and storage.

Importantly, CYRX not only continues to grow the number of clinical trials they are supporting, but also continues to consistently grow the number of late-stage trials it supports – they now support 18 phase III trials, which is up from about 10 just 12 months ago. Management noted on the earnings call that they expect to add additional phase III programs over the course of 2017. Later stage trials, which typical have significantly larger patient enrollments than earlier phases, offer similarly greater revenue potential to CYRX.

Cryoport added 30 new clinical trials over the last few months, some of which we think could make a meaningful near-term contribution. These include Gradalis' Vigil immunotherapy candidate undergoing several oncology studies. CYRX will support their phase II/III trial for ovarian cancer, phase IIb study for Ewing's sarcoma and their pilot combination studies.

Another potential near-term needle-mover relates to Moffitt Cancer Center. In December CYRX penned an agreement with Moffitt Cancer Center, which is one of the largest cancer hospital in the U.S., whereby the company will act as the hospitals' exclusive cryogenics logistics provider for their immunology cancer research and therapy programs. Management noted that the reasons that Moffitt chose CYRX included their monitoring, tracking and logistics capabilities to ensure the safety of their biological material – which essentially translates into, Moffitt chose CYRX for 'piece-of-mind' that their cargo will be well-cared for - which we view as just one more vote of confidence for CYRX as a leader in cryogenic shipping and logistics.

Relative to CYRX's **reproductive medicine segment**, which currently accounts for approximately 20% of total revenue, revenue was up 52% yoy and 27% sequentially in Q3 '17 to $465k – which is an all-time high. The relatively big jump in reproductive medicine revenue also largely relates to the total revenue beat to our number in the quarter. While reproductive medicine had been recently negatively impacted by a change in regulations in certain Asian countries, CYRX has been resilient in looking for ways to accelerate growth of the segment which included targeted awareness-building campaigns. Cryoport also just launched its new CryoStork Next Flight Out service which will provide express transportation to the reproductive medicine market and could represent another revenue growth opportunity for that segment.

Animal health, which accounts for approximately 10% of total revenue, had been somewhat of a laggard in terms of growth. While revenue fell 13% through the first six months of fiscal 2017, it did an about-face in Q3 – posting 22% growth over Q3 '16 and up 16% sequentially. Cryoport will look to build on this recent growth and in January was chosen by Jackson Laboratory support its Cryopreservation Group and Necropsy Laboratory for its sites in Bar Harbor, Maine and Sacramento, California.

Growth In Clinical Trials, Commercialized Products Will Continue To Drive Top-Line…
CYRX should not only benefit from onboarding of additional clinical trial clients and progression of currently supported programs to later stages but even more significantly from supporting these candidates if and when approved and commercialized. Management noted on the Q3 call that of the 18 phase III programs that they are currently supporting, they are in late-stage discussions with at least three of these companies related to commercialization and launch requirements – two of which expect to file Biologic License Applications (BLA) "in the coming months".

One of these is Kite Pharma which initiated a rolling BLA submission for KTE-C19, a chimeric antigen receptor, to FDA for accelerated approval for aggressive Non-Hodgkin Lymphoma. In February 2017 they announced positive clinical trial data. If all goes well Kite believes they could have FDA approval and launch later this year. CYRX noted that they are supporting all of Kite's current seven clinical trials including for their T cell receptor candidate being developed for the treatment of solid tumors. We think Kite could be the first major commercial launch that CYRX supports – meaningful revenue from which we think could begin in calendar 2018. Management has noted that they believe supporting a commercialized product could contribute between $2M and $20M annually to the company – assuming that is the case and Kite launches KTE-C19 by early 2018, we expect CYRX's 2018 top-line to see a meaningful contribution from this program.

In addition to these expected BLA candidates, the other potential near-term commercial-product related revenues could come from CYRX's previously announced relationship with a big pharma customer – which was revealed to be Bristol-Myers (BMY). CYRX is still somewhat tight-lipped on exactly what their role will be, although management said that they will be involved in the "cryogenic component" and will generate revenue from management fees as well as on a per-shipment basis. The specific drug that the agreement relates to has also not been disclosed, although we do know it is a multi-billion dollar monoclonal antibody - which could suggest it relates to BMY's coveted oncology portfolio (either owned or licensed by BMY). Revenue related to this relationship is expected to commence following completion of quality and regulatory requirements – which may be wrapped up sometime this summer. We think this could be a good litmus test and potentially lead to additional follow-on services either directly related to the existing agreement or with other of BMY's products.

On the Q3 '17 call management mentioned that they also now have agreements with Sanofi and J&J – while again not disclosing exactly what their involvement will be, CYRX indicated that it relates to operational components in support of one (or maybe more) of their drug therapies. While we continue to not model any revenue related to these big-pharma agreements due to the lack of clarity of the role that CYRX is playing and what to expect in terms of potential revenue contribution and related timing, our model is subject to updating if and when there is more clarity around these.

As we noted in a recent update, while the delay in kicking off the program with BMY is somewhat of a disappointment, we think that the reasons behind it may actually be a benefit to CYRX in the long-run. Management provided some interesting insight on the Q2 call relative to the strict regulatory requirements and procedures that FDA mandates for shipping biological material in order to ensure reproducibility and integrity of the cargo is maintained. Even slight changes to the shipping method or container can require demonstrating in a study that these changes resulted in no adverse consequences to the cargo.

We think that while these **strict regulatory requirements, which are perhaps somewhat of an irritant in this situation with BMY, may prove to be beneficial as they may act as a barrier to competition.** CYRX's clinical trial clients have already validated the company's storage and shipping process, procedures, methods, logistics and packaging/containers. As such and given the additional regulatory hoops necessary to switch to a different shipping and related services provider, they have an additional reason to utilize CYRX upon commercialization of their products. And while this may be viewed as somewhat of a hurdle to CYRX scoring other late-stage clinical trial customers (or those with an already commercialized product) which are currently utilizing a competing shipping/logistics/storage provider, CYRX's expertise, reputation and history should work in their favor. And clearly the BMY agreement suggests that companies are willing to switch to CYRX despite the regulatory burden of doing so – which we view as additional validation of the superiority of Cryoport's offerings and abilities, particularly as it relates to product safety and integrity.

Additional Validation of CYRX's Capabilities…
CYRX has recently been much more deliberate in their efforts to exploit their technological, logistics and expertise advantages in building their customer base. Long conversion timelines related to customers kicking the tires (i.e. validation) on CYRX's services has meant that eventual adoption can be a drawn out process. But a study conducted in collaboration with KCAS Bioanalytical and Biomarker Services (KCAS) and Heat Biologics comparing

different shipping systems, including dry ice and Cryoport Express, and the impact on the integrity of biological cargo could provide another compelling marketing message and help to speed customer onboarding.

The study found that more than one-third of biomarkers shipped by dry ice were negatively impacted. These temperature excursions often result in compromised integrity of biological material and in cell viability. Management noted on the Q2 call that results from this study have already helped to generate interest from additional potential pharma and biotech customers. This type of validation should facilitate greater and more widespread acceptance of Cryoport as the preeminent provider of cryogenic shipping. Management noted on the Q3 ’17 call that they will continue to build on these types of validation studies.

Revenue Opportunity Grows with Later Stage Trials, Commercialization

CYRX's clinical trial pipeline has rapidly grown, from supporting 52 studies as of November 2015 to 59 (including 10 in phase III) at February to 78, including 13 in phase III at June 2016 to 129 including 18 in phase III, today. We think garnering this number of clinical trials in a relatively short period is a powerful endorsement for CYRX's capabilities. Management noted on the Q3 ’17 call that they think they will add additional phase III programs during calendar 2017. Opportunity in this segment is where we continue to see the bulk of CYRX revenue growth emanating from, particularly in the near-to-mid terms.

And while supporting clinical trials can be a meaningful revenue contributor, logistics and shipping support for a commercialized product could be much more significant. For reference management estimates that the potential revenue range for support of a phase I program is $15k - $75k, phase II is $50k - $150k, phase III is $200k - $1M and for a commercialized product is $2M - $20M.

A large study assessing clinical development success rates found that approximately 50% of phase III candidates and 85% BLA/NDA submissions are ultimately approved for sale in the U.S. by FDA. Assuming these ratios prove to be consistent with the outcomes of CYRX’s current clinical trial customer’s development experiences and given our supposition (above) that regulatory burdens provide barriers to switching to another shipping/logistics/storage provider upon commercialization, we might expect that CYRX could be supporting as many as eight commercialized products from their current phase III customers and one of the two (upcoming) BLA candidates within the next 12 – 36 months. As noted, the first of these (Kite’s KTE-C19) could potentially launch later this year. As CYRX’s clinical customer pipeline grows, including into later stages, so does their shots on goal and opportunities for additional revenue growth. And, as we illustrated above, CYRX’s revenue growth has closely track growth in their clinical trial customer base.

Valuation: Raising Price Target to $6/share

Cryoport estimates that there are 804 ongoing clinical trials in the regenerative medicine space – which means they are supporting approximately 14% (111/804). We think the ~43% growth in the number of regenerative medicine clinical trials that the company supports over just the last nine months along with the double-digit percentage of total regenerative medicine trials that they are involved in speaks to validation of the company's offerings. This is also a major component driving our modeled continued growth of the number of supported clinical trials – which in turn, drives our modeled revenue growth.

We have updated our valuation methodology to what we believe best represents publicly traded industry comparables of companies in the delivery and logistics/transportation sectors. Our list does not include peers solely focused on cold/cryogenic shipping of biological materials or any logistics organizations primarily operating in the biotechnology/pharmaceutical space – the reason is that, other than CYRX, there are no publicly traded companies with viable operations solely focused on those areas. We do believe, however, that there is enough crossover among our list and CYRX in terms of industry fundamentals, challenges and opportunities that it is a fair representation of comparable valuation.

Average comparable PE/G (excluding high and low outliers) is 1.21 which is applied to our forecasted revenue growth rate of CYRX of 47% through fiscal 2021. The result, $9.30/share, is discounted back to the present at a CAPM-calculated discount rate of 14.6% to come to present value share price of approximately $6.

	P/E		P/S							
Delivery	1yr trailng	1yr frwrd	1yr Tr	1yr Fr	5yr G	P/E 4yr Fr	P/S 4yr Fr	PE/G	P/B	EV/EBITDA
FDX	28.53	14.16	0.92	0.81	10.6%	17.26	0.56	1.63	3.59	7.72
UPS	19.07	16.54	1.53	1.38	8.6%	12.65	1.01	1.48	34.03	13
DPSGY	16.01	14.15	0.65	0.62	18.6%	6.81	0.28	0.37	4.6	10.59
ABC	14.41	14.16	0.13	0.12	9.3%	9.23	0.08	0.99	9.42	10.42
Logist/Transp										
CHRW	20.87	19.35	0.83	0.73	7.3%	14.69	0.58	2.02	8.67	12.91
RLGT	-54.34	32.21	0.29	0.28	24.6%	16.65	0.10	0.68	1.85	9.64
RRTS	10.84	9.61	0.14	0.13	NA	NA	NA	NA	0.42	6.49
JANL	13.66	NA	0.07	NA	NA	NA	NA	NA	0.69	5.95
EXPD	23.17	22.06	1.63	1.54	3.6%	19.39	1.36	~~5.34~~	5.33	11.93
HUBG	21.9	18.87	0.47	0.41	24.0%	7.49	0.16	~~0.31~~	2.79	10.03
LSTR	27.24	22.29	1.15	1	11.9%	15.55	0.66	1.31	7.17	13.63
Average								**1.21**		

Inputs			**CYRX**				
Treasury	Disc Rate	Ind. PE/G	Beta	5yr G	Yr5 EPS	Yr5 Value	PV
2.60%	14.6%	1.40	1.62	47%	$0.14	$9.3	**$6.15**

FINANCIAL MODEL

CryoPort Inc.
Format Reflects Calendar-Year Reporting

	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	$5,525.2	$1,555.5	$1,917.6	$1,976.8	$2,228.9	$7,678.8	$2,591.1	$2,745.0	$2,900.4	$3,253.1	$11,489.7	$17,227.0	$26,091.9
YOY Growth	*54.7%*	*29.8%*	*34.0%*	*37.6%*	*52.8%*	*39.0%*	*66.6%*	*43.2%*	*46.7%*	*46.0%*	*49.6%*	*49.9%*	*51.5%*
Cost of Revenues	$3,846.6	$973.7	$1,135.6	$1,180.0	$1,288.0	$4,577.4	$1,515.8	$1,592.1	$1,638.7	$1,815.3	$6,561.9	$9,216.5	$13,359.1
Gross Income	$1,678.6	$581.8	$782.0	$796.8	$940.8	$3,101.4	$1,075.3	$1,152.9	$1,261.7	$1,437.9	$4,927.8	$8,010.6	$12,732.9
Gross Margin	*30.4%*	*37.4%*	*40.8%*	*40.3%*	*42.2%*	*40.4%*	*41.5%*	*42.0%*	*43.5%*	*44.2%*	*42.9%*	*46.5%*	*48.8%*
SG&A	$8,997.6	$3,061.4	$2,625.4	$2,743.0	$2,839.6	$11,269.4	$3,425.5	$3,307.8	$3,437.0	$3,578.5	$13,748.7	$15,883.3	$18,916.6
%SG&A	*162.8%*	*196.8%*	*136.9%*	*138.8%*	*154.0%*	*146.8%*	*132.2%*	*120.5%*	*118.5%*	*110.0%*	*119.7%*	*92.2%*	*72.5%*
R&D	$490.8	$144.5	$135.8	$214.7	$103.1	$598.1	$154.0	$161.0	$144.0	$150.0	$609.0	$684.0	$715.0
%R&D	*8.9%*	*9.3%*	*7.1%*	*10.9%*	*4.6%*	*7.8%*	*5.9%*	*5.9%*	*5.0%*	*4.6%*	*5.3%*	*4.0%*	*2.7%*
Operating Income	($7,809.8)	($2,624.1)	($1,979.3)	($2,160.8)	($2,001.9)	($8,766.1)	($2,504.2)	($2,315.9)	($2,319.3)	($2,290.6)	($9,429.9)	($8,556.8)	($6,898.8)
Operating Margin		*-168.7%*	*-103.2%*	*-109.3%*	*-89.8%*		*-96.6%*	*-84.4%*	*-80.0%*	*-70.4%*	*-82.1%*	*-49.7%*	*-26.4%*
Other income, net	($6.5)	($4.9)	($1,931.7)	($1.4)	$1.5	($1,936.6)	($1.5)	$0.0	$0.0	$0.0	($1.5)	($12.0)	($15.0)
Interest income, net	($1,227.4)	($81.2)	($21.2)	($19.3)	($17.7)	($139.4)	($16.8)	$0.0	$0.0	$0.0	($16.8)	$0.0	$2.0
Loss on asset sale	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Change in derivative value	$0.0	$0.0	$0.0	$0.0	($2,265.4)	($2,265.4)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9,043.7)	($2,710.2)	($3,932.2)	($2,181.6)	($4,283.5)	($13,107.5)	($2,522.4)	($2,315.9)	($2,319.3)	($2,290.6)	($9,448.2)	($8,568.8)	($6,911.8)
Taxes	$3.6	$0.0	$2.5	$2.9	$0.0	$5.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*				*0.0%*	*0.0%*	*0.0%*
Charge	($6,376.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($9,845.0)	($2,785.6)	($3,934.7)	($2,184.5)	($4,283.5)	($13,188.4)	($2,522.4)	($2,315.9)	($2,319.3)	($2,290.6)	($9,448.2)	($8,568.8)	($6,911.8)
YOY Growth		*-29.5%*	*-40.4%*	*-18.0%*	*42.8%*		*-9.4%*				*-28.4%*	*-9.3%*	*-19.3%*
Net Margin		*-179.1%*	*-205.2%*	*-110.5%*	*-192.2%*		*-97.3%*				*-82.2%*	*-49.7%*	*-26.5%*
EPS	($1.65)	($0.26)	($0.28)	($0.14)	($0.25)	($0.93)	($0.14)	($0.13)	($0.12)	($0.11)	($0.50)	($0.37)	($0.27)
YOY Growth		*-66.6%*	*-78.8%*	*-64.7%*	*-38.8%*		*-45.5%*				*-45.8%*	*-10.6%*	*-33.9%*
Diluted Shares O/S	5,951	10,601	14,200	15,120	16,847	14,192	17,610	18,400	19,000	20,000	18,753	23,400	25,200

Brian Marckx, CFA

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