Zacks Small-Cap Research

May 11, 2012
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DATATRAK International (DATA-OTC)

DATA: Traction in New Contract Sales: OUTPERFORM

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/12/2010
Current Price (05/10/12)	$0.28
Target Price	**$2.00**

OUTLOOK

DATATRAK International, Inc. is a global technology and services company delivering electronic clinical (eClinical) solutions to support clinical research. Its software suite and service offerings are used to collect, review, report, store and submit to regulatory agencies clinical trial data electronically. While the competition uses an integrated heterogeneous solution (information silos), DATATRAK uses a unified system. The result is seamless communication, optimized data flow and lower costs. The products within the information silos were never designed to work together and "Real time" communications per customers is more like 24 hrs…not bad, but if a patient in site #102 is having an adverse reaction and a similar patient at site #3 has the potential to suffer a similar event…the “not bad” could cost a life.

SUMMARY DATA

52-Week High	**$0.65**
52-Week Low	**$0.26**
One-Year Return (%)	**-56.25**
Beta	**1.41**
Average Daily Volume (sh)	**9,415**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-12.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**High**
Type of Stock	**Growth**
Industry	**Comp-Periph**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	1.67 A	1.88 A	1.81 A	2.01 A	7.37 A
2011	1.88 A	2.13 A	2.05 A	1.85 A	7.92 A
2012	2.11 A	2.20 E	2.25 E	2.30 E	8.86 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$0.01 A
2011	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 A	-$0.06 A
2012	-$0.04 A	-$0.02 E	-$0.01 E	-$0.01 E	-$0.08 E

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WHATS NEW

DATATRAK Sees Traction in New Contract Sales

On May 9, 2012, DATATRAK International, Inc., reported financial results for its fiscal 2012 first quarter, ended March 31, 2012. The Company reported mixed results with first quarter revenues improving nearly 14 percent year over year to $2.119 million, compared to $1.888 million for the three months ended March 31, 2011. The jump in quarterly revenues was primarily due to new contract sales from the fourth quarter with new contract sales increasing by 170% compared to the first quarter of 2011.

Still, operating loss for the three months increased to $515,227 compared to an operating loss of $197,959 for the three months ended March 31, 2011 reflecting the Company's strategic investments in Sales, Marketing and Software Development, the accrual of management incentive plan awards, as well as costs incurred to protect the Company's intellectual property.

During the three months ended March 31, 2012, DATATRAK's net loss increased to $516,800 from a net loss of $200,453 for the first quarter fiscal 2011.

The increase in net loss was primarily a result of an increase in selling, general and administrative expense. Selling, general and administrative expense increased year over year by nearly 30 percent or $503,897 to $2.199 million.

Gross margin for the quarter remained steady at 81.3% compared to 81.4 for the quarter ended March 31, 2011.

Based on a weighted average number of basic and diluted shares of 14.714 million, basic and diluted net loss per share resulted in a net loss of $0.04 per share for the first quarter of fiscal 2012. This compared to a basic and diluted net loss per share of $0.01 based on a weighted average number of basic and diluted shares of 14.107 million during the three months ended March 31, 2011.

Still, DATATRAK's backlog as of March 31, 2012 jumped 20 percent year over year to $14.0 million compared to a backlog of $11.6 million at December 31, 2011.

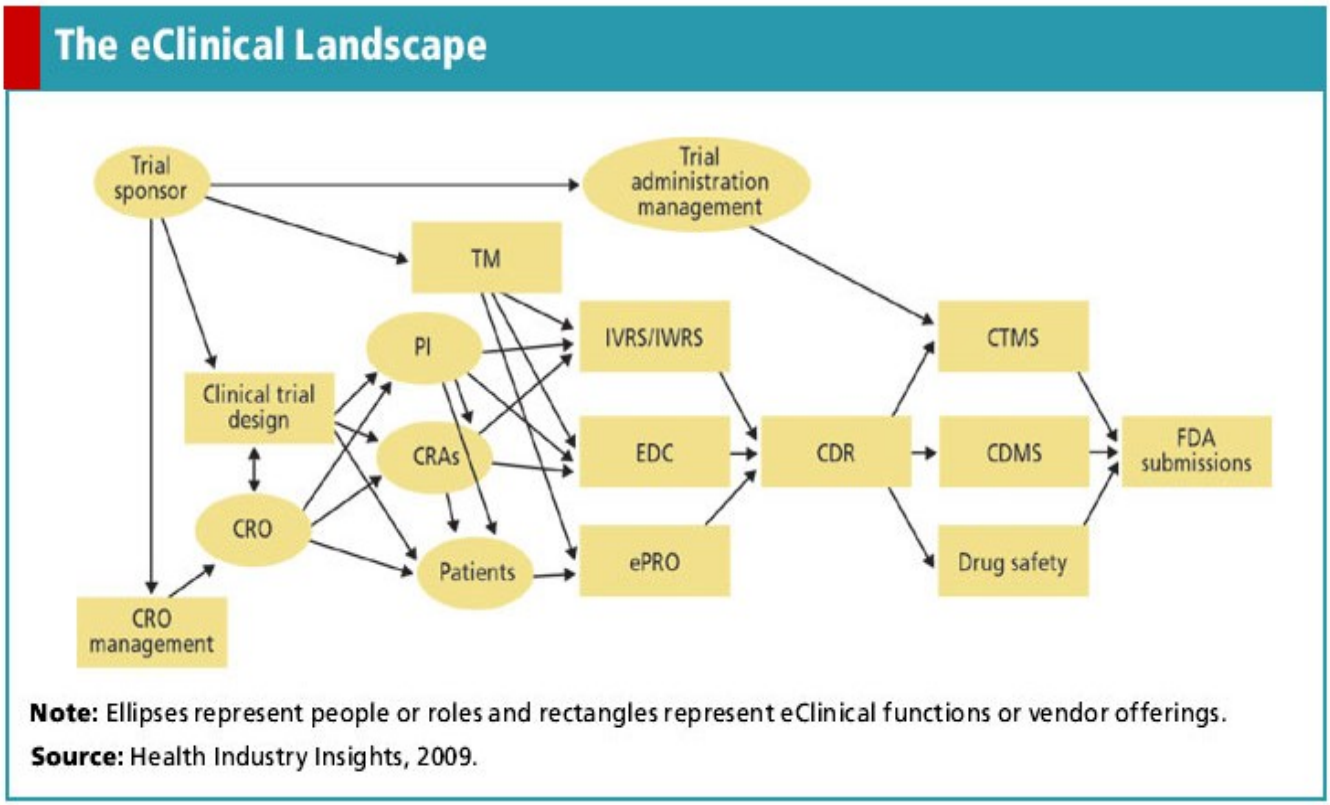
Furthermore, the first quarter resulted in a jump in new contract sales as well as a 38% year-over-year increase in the number of clients and a 233% year-over-year increase in clinical and consulting services clients.

The Company's first quarter cash balance remained strong with cash and investments at $1.431 million. This compares to cash and investments of $2.298 million as of December 31, 2011.

Finally, the Company believes its strategic growth investments over the last six months are starting to yield tangible results and believes it is achieving traction in exposing a larger audience.

INVESTMENT THESIS

Mayfield Heights, Ohio DATATRAK International, Inc., is a global technology and services company providing the only unified suite of eClinical software delivered in one database and utilizing one user interface providing electronic data capture (EDC), interactive voice response systems, medical coding, web-based randomization, clinical trial management, clinical data management, drug inventory management, digitized electrocardiograms, image collection, viewing and storing capabilities, and workgroup collaboration capabilities. DATATRAK ONE™ is the company's unified clinical approach that includes the cloud based eClinical platform as well as comprehensive consulting, professional services and support following a unified clinical process. DATATRAK and its partners apply this approach to assist customers in the collection and reporting of clinical research data from sites to sponsors and ultimately to regulatory authorities. DATATRAK's vision is to be the clinical enterprise solution to safely accelerate every drug, every biologic and every device *from concept to cure.*



Clinical Research Industry

DATATRAK's customers are sponsor companies and CROs that perform clinical trials in the pharmaceutical, biotechnology, and medical device industries. These industries are driven by regulatory requirements which mandate that new drugs and medical devices be adequately tested in clinical trials prior to marketing these drugs and devices.

Competitive pressures are forcing the pharmaceutical and biotechnology industries to become more efficient when developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are continuing to develop new products, while at the same time attempting to shorten product development timelines. These efforts have placed more drugs into the clinical development process and have increased the pressure for companies to develop products faster in order to maintain growth and continue to achieve acceptable returns on research and development expenditures. Sponsors of clinical trials have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

"Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs."

*Tufts Center for the Study of Drug Development

Escalating Drug Costs
U.S. drug companies spent $39.4 billion on research and development in 2005. DiMasi, Hansen and Grabowski (2003) estimate the cost of bringing a drug from phase I to market. Their data come from the Tufts Center for the Study of Drug Development (CSDD). The final estimate is that it costs–including the expense of failed drugs–$802 million to take a drug from phase I trials to approval. Over 50% of this figure is the cost of capital needed to finance the R&D over such a long period. By 2009 health economists peg the current cost of drug development at US$1.3 billion, others at US$1.7 billion. It costs more than a billion dollars to overcome the 1-in-5000 odds of a new chemical compound making it to market. (About two-thirds of true research and development costs).

Criticism of studies that produce numbers in the billion-dollar range are numerous, but virtually all can agree that bringing a drug to market is expensive. Beyond the cost issue lies the sheer confusion of getting the right systems connecting with one another as evidenced by the eClinical Landscape slide above.

The old way
Under the traditional method of clinical research, clinical trial data from each patient is recorded and maintained on paper in a binder, known as a case report form. A separate case report form is maintained for each patient. Clinical research associates then visit research sites to review the clinical trial data for accuracy and integrity. During these visits, known as monitoring visits, the research associate must review each page of each case report form. These visits may last several days, and corrections to the case report forms are frequently required before the data can be delivered to the clinical trial sponsor. Several weeks, or even months, of data may be reviewed during each monitoring visit. At the completion of a monitoring visit, the completed case report form pages are physically transferred to a central location where the data is then entered into a database for statistical compilation. Using this method of data collection and quality control, the duration of the clinical trial process, from patient visit to delivery of clean data to the clinical trial sponsor, can range from six to nine months. Such delays are significant because errors or trends may not be detected until long after the interaction between the patient and clinical investigator.

Backdrop of Growth
Expectations of eClinical market are that it is set to nearly double from 2008 to 2012 and DATATRAK, with its superior product, is poised to capture that growth.

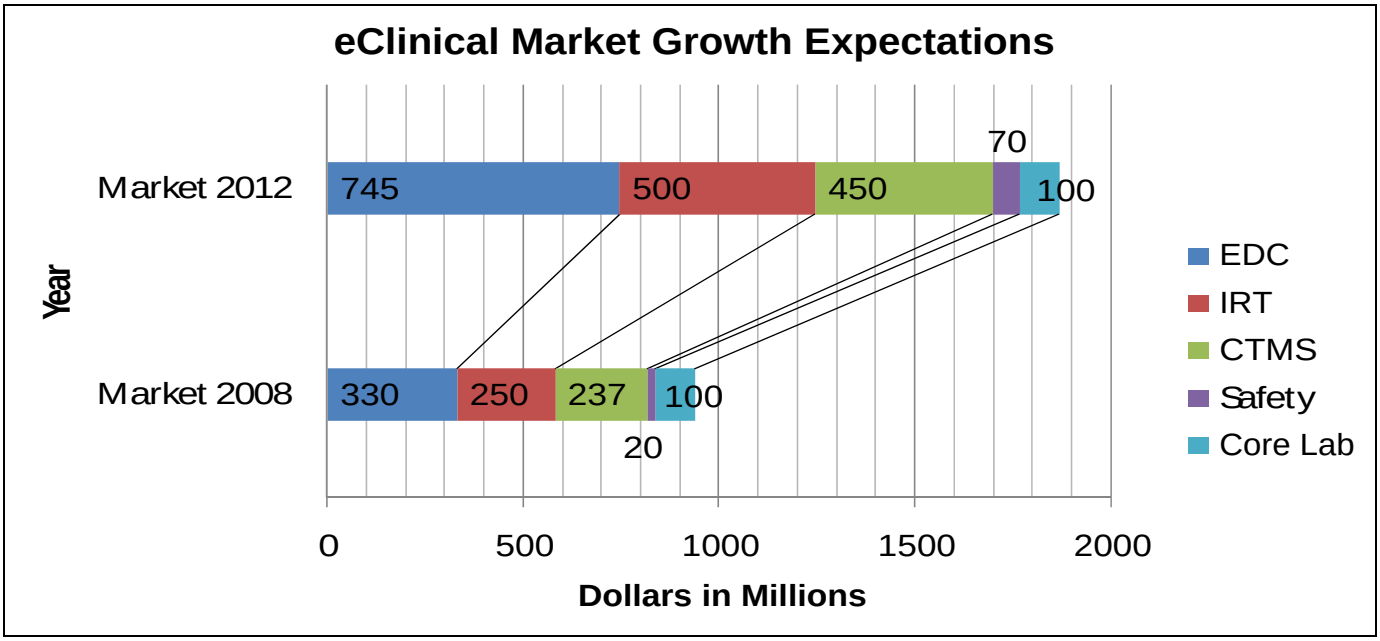
- The 2007 EDC market opportunity was roughly $330 million and is expected to increase to roughly $745 million in 2012. The growth rate is 15% per year through 2012.

- The IRT Market [Randomization and Inventory Management] was valued at $250 million in 2008 with a growth rate of around 15% a year.

- The Safety Market [Coding and PMS] opportunity was approximately $20 million as of 2008 and is expected to grow roughly to $70 million by 2012.

- The CTMS Market Size [CTMS] generated revenues of $237.6 million in 2007 and is expected to grow at a rate of 14.5 percent per year until 2014.

- The Core Lab Market [ECGs and Images] is valued at $100 million in 2008



The real key for drug development is to get your winning drugs to market faster and to quit your losing drugs sooner. The firm's solutions,

- Increase Process Efficiency in Clinical and Safety
- Create Data Availability in real time
- Provide cost Reduction in maintenance, validation, administration and training
- Creates a Unified User Experience(the eClinical platform), anywhere in the world
- LOWER TRIAL COSTS

Building on the concept of lowering trial costs, DATATRAK eliminates the 8 - 12% of clinical trial costs associated with moving data around:

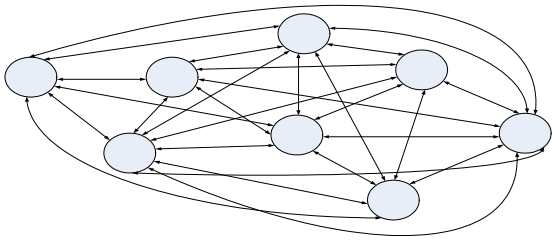
  - No need to move coding data
  - No need to synchronize randomization data
  - No need to batch process edit checks in separate system
  - No need to upload coding and edit work back into system

On the typical $2 million dollar phase III trial that is significant and the technology essentially could pay for itself. On a $400 million drug, should you close the trial six months early, the pull forward could reach $200 million in new product revenue.

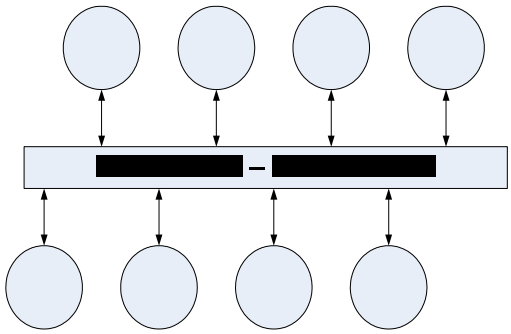
Unified Solutions versus Integrated.

While acquiring products which creates the information silos and integrated IT approach may provide a short term fix, the result is that integration tends to lead to errors and rising costs from the manual management of data, systems and user accounts. It also leads to multiple vendor contracts which in turn brings up the price. System upgrades tend to be difficult and rare.

Integrated Solutions



Unified Solutions



Unified solutions on the other hand provide improved usability through one database and one interface. The number of vendors to manage is also reduced and the cost is therefore less. Further the unified system is simply designed with less moving parts and is less susceptible to crashes.

Integrated	*Unified*
Silos of Automation	One System
Silos Never Intended / Designed to Talk	Seamless Module Communication
Silos Built Independently	Common Vendor, Common Technology
Silos need Bridges to Communicate	One Underlying Framework
Bridges Limit Data Traffic	Optimized Data Flow
Susceptible to Crashes and Bugs	Fewer Moving Parts = Fewer Problems
Promise of Real -Time Data Visibility Often Not Delivered	Data Always Visible
Increased Maintenance Costs	Lower Maintenance Costs
Process Reengineering Hard	Process Reengineering Easy
Higher trial budget costs	Lower trial budget costs

Attracting Attention

On June 23, 2010 Phase Forward Incorporated (PFWD), a leading provider of data management solutions for clinical trials and drug safety, announced that it had agreed to merge with Oracle Corporation ("Oracle") and Pine Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of Oracle. Phase Forward is a leading provider of integrated data management solutions for clinical trials and drug safety. Phase Forward's products and services have been utilized in over 10,000 clinical trials involving more than 1,000,000 clinical trial study participants at over 300 organizations and regulatory agencies worldwide including. This $685 million deal creates a significant competitor but it also legitimizes the growth potential of the space and shows the strategic importance of the industry.

Progress Continues

DATATRAK's unified system is clearly superior to integrated solutions. That said maybe the firm is not yet seeing explosive top–line growth right now because firm's look at the financial power of a firm trading on the pink sheets. It is important to realize just how far DATA has come since 2008. Just three short years ago backlog was trending down, the firm was incurring losses, had a $3 million dollar balloon debt payment due, and cash flow was negative $1.8 million. Flash forward to the recently completed 2010 and the company shows backlog trending up, no balance sheet debt, a profit, and positive cash flow. As these metrics continue to improve the growth will follow. If you build it they will come. We would add shares at these levels.

Item	2008	2009	2010
Backlog:	Trending Down	Trending Up	Trending Up
Income/Loss:	$(17) M	$(1.9) M	Profit
Balance Sheet Debt:	$3M Note	No Debt	No Debt
Cash Flow:	$(1.8) M	$(1.4) M	Turned Cash Flow Positive in Q2
Auditor Opinion:	Noted $3M Balloon Debt Payment Due	Going Concern	Clean

The firm has four characteristics that should enable it to outperform the industry and the competition.

- Superior Technology
- A Debt Free Balance Sheet
- Growing Backlog
- Increasing Market Share in a Growing Complex Industry.

As complexity and regulatory challenges increase in clinical trials, paper based methods as well as integrated systems will prove more expensive and less reliable. Investors that buy the stock today they

are essentially buying a firm that emerged from the recession of 2008/2009 with no debt, has grown its backlog in six of the last seven quarters, and continues to gain traction in clinical research.

The firm is pricing at a reasonable 0.47x EV/Revenue compared to the software industry average of 3-4x depending on the size of the firm.

Enterprise value is often thought of as the true price of a business since buying a business includes receiving its cash and taking on its debt. Using enterprise value instead of market cap in a valuation metric has the effect of penalizing debt and rewarding cash. If DATA's top-line continues to expand as we think it will and the firm trades closer to industry metrics we feel $2.00 per share is a reasonable valuation for the stock.

RISKS

- Changes in the regulatory environment could lead to a decrease in the industry's research and development expenditures.
- In the EDC market, the firm must compete with the traditional paper method of collecting clinical trial data. The major competitors in the EDC market also include in house development teams, EDC software vendors and single component solutions.

PROJECTED INCOME STATEMENT

INCOME STATEMENT ($ Thousands)	Mar-11 Q1 11	Jun-11 Q2 11	Sep-11 Q3 11	Dec-11 Q4 11	Mar-12 Q1 12	Jun-12 Q2 12 E	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012 E
REVENUE												
Net Revenue	**1,888.32**	**2,132.85**	**2,050.69**	**1,854.48**	**2,119.20**	**2,200.00**	**10,562.00**	**8,826.00**	**6,935.27**	**7,390.66**	**7,926.34**	**8,860.00**
Sequential Growth		*13%*	*-4%*	*-10%*	*14%*	*4%*						
OPERATING EXPENSES												
Cost of Revenues	350.98	334.22	337.10	343.87	396.65	398.00	4,583.00	2,833.00	1,786.78	1,170.85	1366.2	1600.0
% of Revenue	*18.6%*	*15.7%*	*16.4%*	*18.5%*	*18.7%*	*18.1%*						
Gross Profit -	**1537.3**	**1798.6**	**1713.6**	**1510.6**	**1722.6**	**1802.0**	**5,979.00**	**5,993.00**	**5,148.49**	**6219.8**	**6560.2**	**7260.0**
Proforma Gross Margin	*81.4%*	*84.3%*	*83.6%*	*81.5%*	*81.3%*	*81.9%*	*56.6%*	*67.9%*	*74.2%*	*84.2%*	*82.8%*	*81.9%*
R&D + Engg	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.0	0.0	0.0	0.0	0.0
% of Revenue	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
SG&A	1695.11	1913.51	2140.25	1896.56	2199.00	2100.00	13,097.00	10,179.00	6,106.03	6,098.95	7,645.42	8,250.00
% of Revenue	*89.8%*	*89.7%*	*104.4%*	*102.3%*	*103.8%*	*95.5%*	*124.0%*	*115.3%*	*88.0%*	*82.5%*	*96.5%*	*93.1%*
GW Amort, Restructuring, other	*40.20*	*38.94*	*39.13*	*40.10*	*38.83*	*40.00*	*3,850.0*	15,287.0	*940.4*	7.40	*158.37*	*160.00*
% of Revenue												
Total Operating Expenses	1735.30	1952.45	2179.38	1936.66	2237.83	2140.00	16,947.00	25,466.00	7,046.44	6,106.34	7,803.79	8,410.00
% of Revenue	*91.9%*	*91.5%*	*106.3%*	*104.4%*	*105.6%*	*97.3%*	*160.5%*	*288.5%*	*101.6%*	*83%*	*98%*	*95%*
Operating Income -	**-198.0**	**-153.8**	**-465.8**	**-426.0**	**-515.3**	**-338.0**	**(10,968.00)**	**(19,473.00)**	**(1,897.95)**	**113**	**-1244**	**-1150**
Operating Margin	*-10.5%*	*-7.2%*	*-22.7%*	*-23.0%*	*-24.3%*	*-15.4%*	*-104%*	*-221%*	*-27%*	*2%*	*-16%*	*-13%*
NON-OPERATING ITEMS												
Non operating Income/Expense	-2	-4	252	-8	-2	-3	68.0	3,061.00	-9.9	-12	237	-15
% of Revenue	*-0.13%*	*-0.21%*	*12.28%*	*-0.44%*	*-0.07%*	*-0.13%*	*0.64%*	*34.68%*	*-0.14%*	*-0.17%*	*2.99%*	*-0.17%*
Tax Provision	0.0	0.0	0.0	0.0	0.0	0.0	-46.00	385.00	0.0	0	0	0
Effective Tax Rate												
Net Income -	**-200.45**	**-158.26**	**-213.99**	**-434.19**	**-516.80**	**-340.75**	**(10,854.00)**	**(16,797.00)**	**(1,907.85)**	**101.1**	**-1006.9**	**-1165.0**
Net Income Margin	*-10.6%*	*-7.4%*	*-10.4%*	*-23.4%*	*-24.4%*	*-15.5%*	*-102.8%*	*-190.3%*	*-27.5%*	*1%*	*-13%*	*-13%*
EARNINGS PER SHARE												
EPS - Basic	-$0.01	-$0.01	-$0.01	-$0.03	-$0.04	-$0.02	-$0.82	-$1.23	-$0.14	$0.01	-$0.06	-$0.08
EPS - Diluted	-$0.01	-$0.01	-$0.01	-$0.03	-$0.04	-$0.02	-$0.82	-$1.23	-$0.14	$0.01	-$0.06	-$0.08

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