Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-OTC)

NWBO: *Balance sheet boosted and Clinical programs on track to advance* -- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (01/22/13)	$3.32
Twelve-Month Target Price	**$10.00**

OUTLOOK

Northwest Biotherapeutics is making multiple progresses in its ongoing Phase III clinical trial of DCVax-L for brain cancer and Phase I/II trial of DCVax-Direct for solid tumors. DCVax-L has been expanded in Britain, and is poised to proceed in Germany soon. Further, the US clinical trial site has been expanded ahead of schedule with 41 sites open and recruiting as of May 17, 2012.

Recent financing boosted the Company's balance sheet.

Current valuation is attractive. We maintain our Outperform rating.

SUMMARY DATA

52-Week High	**$10.95**
52-Week Low	**$3.04**
One-Year Return (%)	**-10.05**
Beta	**1.75**
Average Daily Volume (sh)	**50,602**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$74**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	**2.0**
Insider Ownership (%)	**5.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.00 A	0.00 A	0.01 A	0.00 A	0.00 A
2012	0.00 A	0.33 A	0.12 A	0.00 E	0.45 E
2013					0.00 E
2014					0.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$1.75 A	-$2.07 A	-$1.13 A	-$0.69 A	-$5.08 A
2012	-$0.51 A	-$0.84 A	-$1.24 A	-$0.72 E	-$3.32 E
2013					-$2.93 E
2014					-$1.88 E

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

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WHAT'S NEW

Balance Sheet Boosted by New Financing

On Dec. 7, 2012, Northwest Biotherapeutics, Inc. (NWBO) announced the pricing of an underwritten public offering of 3,000,000 shares of common stock, and warrants to purchase up to an aggregate 1,500,000 shares of common stock, at an offering price of $4.00 per share and $0.01 per warrant. The Warrants have a per share exercise price of $5.00, are exercisable immediately, and expire 5 years from the date of issuance.

The Company also announced the full exercise of the over-allotment option granted to the underwriters to purchase an additional 450,000 shares of common stock and warrants to purchase 225,000 shares, at a public offering price of $4.00 per share and $0.01 per warrant, bringing total gross proceeds from the offering to $13.8 million.

All of the shares and warrants in the offering are being sold by the Company. In addition, in connection with the offering, more than $34.5 million of the Company's debt is being converted and being removed from the Company's balance sheet as a result of such conversions.

The Company intends to use the net proceeds received from the offering to fund its research and development activities and for working capital and general corporate purposes. The Company may also use a portion of the net proceeds to repay up to $3.8 million aggregate principal amount of convertible notes and notes, comprising most of the Company's remaining outstanding debt.

We are pleased with the new financing, which not only provides the Company much needed cash for its clinical trials, but also validates the Company's technology and clinical programs.

Visibility and Liquidity Increased Through NASDAQ Listing

Also on December 7, 2012, NWBO's common stock was approved for listing on the NASDAQ Capital Market and began trading on the same day under its ticker symbol NWBO.

We think the NASDAQ listing is important to the Company and its shareholders in the following matters:

- Trading on a major exchange will raise the Company's visibility and gain liquidity at the same time. NWBO shares have been traded OTC for a long time. Trading OTC is often viewed as highly risky and less liquid to most investors especially to institutional investors. As a result, many institutional investors are restricted from buying shares traded OTC.

- The successful upgrade to be listed in the NASDAQ Capital Market increased both visibility and liquidity of the Company. As a result, many institutional investors can buy its shares now.

- Another way to attract institutional investors is through the inclusion in an index. After being listed on NASDAQ Capital Market, NWBO could have the potential to be added into a small cap index, especially in a small cap biotech index. Inclusion in an index will further raise NWBO's visibility and at the same time, NWBO will be automatically included in some index funds which mirror the index which includes NWBO. This makes NWBO more suitable for a broader group of investors.

Therefore, the upgrading to NASDAQ Capital Market will bring additional liquidity and a lot of buying volume down the road.

Collaboration with Leading UK Cancer Institutions for DCVax®-Direct Trial

On Nov. 6 , 2012, Northwest Biotherapeutics (NWBO) announced that it has initiated a collaboration with **Sarah Cannon Research UK** and the **Leaders in Oncology Care** (LOC) on a **Phase I/II** trial with DCVax®-Direct for **metastatic colon cancer**.

Sarah Cannon Research UK is the UK arm of the Sarah Cannon Research Institute, which specializes in cancer drug development and has a network of more than 700 physicians in the US and UK. The Leaders in Oncology Care (LOC) was formerly known as the London Oncology Clinic, and is renowned in the UK as the leading private cancer center.

Colon cancer is the second leading cause of cancer deaths (after lung cancer), exceeding even deaths from breast cancer or prostate cancers. DCVax®-Direct offers an important potential new treatment option for colon cancer patients whose cancer has spread and is no longer operable. DCVax®-Direct is specifically designed to treat inoperable cancers in various tissues through direct injection into the tumors. It can be injected into any number of tumors, and virtually any location in the body (with imaging guidance for interior tissues).

As previously reported, the Company has received FDA approval for a **36-patient Phase I/II trial** in any solid tumor cancers. The primary endpoint of the trial will be a measure of tumor response (regression) in patients' existing, established tumors. As part of the collaboration with Sarah Cannon Research UK and LOC, the Company will pursue UK regulatory approval of Phase I/II trials.

Through over 10 years of research and development, NWBO has developed an unique DCVax-Direct technology with potential for any solid tumors. DCVax-Direct uses the DCVax platform to activate DCs in a manner suitable for direct injection into solid tumors. DCVax-Direct is designed to treat cancer patients whose **tumor tissue is not available** as their tumors are considered to be inoperable. The patient's dendritic cells are activated, but without addition of cancer antigens. The cells adhere to the plastic culture surface, which results in activation.

Several scientific studies have shown that DCs injected into solid tumors in animal models can result in tumor regression. **Pre-clinical** animal studies have demonstrated the ability of activated DCs, when injected directly into just a single tumor of mice bearing multiple tumors, to cause all tumors to regress. In these studies, subsequent challenge of these now tumor-free mice with the injection of additional tumor cells was met with total rejection of tumor growth demonstrating an immunization of the mouse against regrowth of the tumor. The DCs used in the formulation of DCVax-Direct are activated through a process similar to that used for DCVax-L and DCVax-Prostate, although they are not loaded with tumor antigens prior to injection. Rather, the antigen loading takes place in vivo after injection of the DCVax-Direct DCs into the tumor tissue, typically following radiation therapy, chemotherapy, or other treatments that kill tumor cells.

Current treatments for solid tumors typically involve cytotoxic therapy aimed at killing tumor cells. Such treatments include radiation therapy, chemotherapy, or other cell killing treatments such as cryotherapy. These treatments can still be used along with DCVax-Direct as they can potentially prepare the tumor tissue for the injection of DCVax-Direct. The ability to still use conventional cytotoxic agents along with DCVax-Direct will enable DCVax-Direct to be adopted in the market without requiring any change of existing clinical practice if so desired.

DCVax-Direct is the Company's third major product line. The Company's first product line, **DCVax-L**, is potentially applicable for all solid tumor cancers in which the tumors can be surgically removed. DCVax-L is currently in a 300-patient randomized Phase III clinical trial for Glioblastoma multiforme brain cancer. The Company's second product line, **DCVax-Prostate**, is for hormone independent prostate cancer, and has previously been cleared by the FDA for a 612-patient randomized Phase III clinical trial. The Company plans to enter into a partnership in order to proceed with this Phase III trial program.

Price Target Adjusted Due to Reverse Stock Split

We maintain our Outperform rating on Northwest Biotherapeutics (NWBO) due to recent reverse stock split and adjusted our price target to $10 per share from previous $0.75.

On Sept. 25, 2012, Northwest Biotherapeutics (NWBO) effected a one (1) for sixteen (16) reverse split of its issued and outstanding common stock as a first step in a planned public offering of up to $25 million and listing of its common stock on the NASDAQ Capital Market.

Accordingly, as of the effective date, each 16 shares of issued and outstanding common stock will be converted into 1 share of common stock. In addition, the Company's common stock will trade under a new CUSIP number (66737P 600). The Company's ticker symbol will remain unchanged, although a "D" will be placed on the ticker symbol, NWBO, for 20 business days to alert the public to the Reverse Split.

The Company also increased the authorized number of shares of preferred stock to 40,000,000 shares. The Company has no current plans to issue any of the preferred stock. The foregoing corporate actions were taken via majority consent of the stockholders and all appropriate notifications were filed and transmitted.

As a result of the 1 for 16 reverse stock split, we have adjusted our financial model and adjusted our price target to $10 per share.

NWBO has made strong operational progress in its clinical programs in both the US and Europe recently on its Phase III lead program DCVax-L for brain cancer and Phase I/II program DCVax-Direct for solid tumors.

We think the reverse split and recent financing is an important step for NWBO to accelerate the advance of the Company's clinical programs. The expanded resources will enable the Company to maintain its momentum in its lead Phase III trial program with DCVax®-L for brain cancer, and accelerate its Phase I/II trial program with DCVax®-Direct for all solid tumor cancers, which have been hindered by shortage of cash.

NWBO has DCVax-L Phase III Trials in Both the US and Europe

Northwest Biotherapeutics (NWBO) recently updated its DCVax-L Phase III clinical trials for brain cancer in both the US and Europe.

Phase III trial of DCVax-L approved in the UK

On August 23, 2012, Northwest announced that it has received approval from the United Kingdom health authority for the Company's 300-patient Phase III clinical trial of DCVax®-L immune therapy for Glioblastoma multiforme brain cancer (GBM) to proceed in the U.K.

This Phase III clinical trial is already under way in the U.S., at 41 sites across the country. NWBO is now expanding this Phase III trial to make it an international trial, by including clinical trial sites in Europe. This international approach can potentially save years of time in clinical trials, compared with conducting trials in the U.S. and Europe separately.

NW Bio has already obtained Ethics Committee approval for this trial on a centralized basis from the National Research Ethics Committee in the U.K. Such Ethics Committee approval is equivalent to Institutional Review Board (IRB) approvals in the U.S. This centralized approval from the National Research Ethics Committee applies throughout the U.K., eliminating the need to obtain Ethics Committee (IRB) approvals at each clinical trial site (which typically takes months at each site in the U.S.).

Phase III trial of DCVax-L in the US is going well

On May 17, 2012, Northwest Biotherapeutics (NWBO) announced that it already has 41 clinical trial sites open and recruiting across the United States in its ongoing clinical trial of DCVax-L immune therapy for Glioblastoma multiforme (GBM).

This is ahead of the Company's previous projection of 40 sites by the end of Q2, 2012. The Company plans to continue adding clinical trial sites in the US and Europe, and expects to have at least 60 sites open and enrolling by the end of Q3, 2012. The Company plans to have total of 80 sites for the trial.

The Company also announced that the FDA has accepted an amendment of the clinical trial. The amendment does not make any change in the treatment regimen, which leaves all data collected to date intact for use in the trial's overall results. The amendment includes the following:

- The previous Phase II trial has been designation as a **Phase III** trial;
- Expanded and enhanced statistical endpoint analyses;
- With the addition of another cohort of patients which can potentially expand the application of DCVax-L, the trial size has been increased up to 300 patients from previous 240 patients;
- Addition of interim analyses for efficacy;

As a reminder, the previous Phase II trial of DCVax-L is an ongoing **randomized, placebo controlled**, **double blinded (2:1)** study with a cross-over arm allowing control patients to be treated with DCVax-L in the event that their cancer progresses. The primary end point is progression free survival (PFS) with overall survival (OS) as the secondary end point. The original 240-patient trial is designed to enable the Company to petition the FDA for **accelerated approval** if the study generates results similar to those achieved in the two prior Phase I clinical trials.

The Implications

This announcement is another indication that NWBO is making further progress in its key program DCVax-L for brain cancer.

The Company has continuously beats its expectations about adding new clinical trial sites. In addition, the official designation of the previous Phase II trial of DCVax-L as a Phase III trial makes DCVax-L one step closer to the market. This is also a further indication that management is making every effort to make this breakthrough medicine to brain cancer patients around the world though the evolution of this trial to a Phase III trial is no assurance of the outcome.

With the new announcement about the trial sites update and amendment to the Phase II trial, the Company's lead program has advanced and emerged as 300-patient, international **Phase III** trial, involving some of the best institutions in the US, UK and Germany.

The Company plans to petition for product approval in the U.S. and/or the European Union if the Phase III trial results are positive. In such a case, DCVax-L could potentially be the second active immunotherapy for cancer in the US and the first active immunotherapy for cancer in the EU.

Worldwide Production Capacity for DCVax®-L Expanded

In order to meet the demand of the DCVax-L Phase III clinical trial in both the US and Europe, NWBO has expanded its worldwide manufacturing capacity of DCVax-L.

On August 8, 2012, NWBO entered into amended agreements to double the production capacity in the U.S. for the manufacture of the Company's DCVax®-L immune therapy for Glioblastoma multiforme (GBM) patients.

The doubling of U.S. production capacity for DCVax®-L is being undertaken to respond to growing demand from clinical trial sites in the Company's 300-patient, Phase III clinical trial in GBM, which is under way at 41 sites across the U.S. The expansion is being undertaken on an expedited basis, with completion expected in about eight to ten weeks. This initial doubling of capacity will involve adding more production lines in the cGMP (clean room) facilities of **Cognate BioServices** (NW Bio's contract manufacturer) that are already dedicated to NWBO's programs. Thereafter, further expansion of capacity is planned on a modular basis, as needed, through additional facilities.

In Germany, the Company's partner, Fraunhofer IZI, has received all necessary regulatory approvals and certification for manufacturing of DCVax®-L, and is fully operational for such manufacturing. In the U.K., the Company's partner, Kings College London, already has all the necessary regulatory approvals as well, and is in the final stages of preparations for manufacturing. Each of these partners is highly experienced with living cell products, and each is operating under common SOPs (Standard Operating Procedures) and common oversight by Cognate BioServices to ensure worldwide consistency in manufacturing operations.

Both Fraunhofer and Kings College will produce DCVax®-L for the Company's ongoing Phase III clinical trial in GBM, as well as for compassionate treatment programs. The Phase III trial is expected to involve up to 30 sites across Germany, and 8 sites across the U.K., in addition to the 41 sites already in operation in the U.S.

Both Fraunhofer and Kings College will be able to deliver DCVax®-L products anywhere in Europe. This will enable them to handle temporary added-capacity needs for each other, if there are surges in demand from clinical trial sites, such as has been experienced in the U.S. Fraunhofer and Kings College will also be able to handle production for clinical sites in additional European countries besides Germany and the U.K. NWBO has also begun discussions with both partners regarding staged expansion of manufacturing capacity in each country.
These manufacturing bases, in three countries on two continents, form a strong and flexible manufacturing network for delivery of DCVax®-L throughout the U.S. and Europe. This production capacity has been obtained without major capital cost to NWBO.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on NWBO. Our adjusted 12-month price target is $10.00 due to the recent 1 for 16 reverse stock split.

Our call is based on the key progress the Company has made in the last few months.

Northwest is engaged in the business of developing cell-based immunotherapies for the treatment of various cancers. This is a relatively new area and has come to investors' attention due to recent two developments: the first in class immunotherapeutic drug Provenge from Dendreon was approved by the FDA in April 2010 and the 2011 Nobel Prize in Physiology or Medicine was awarded to the discovery of dendritic cells (DCs) as immune master cells.

The high profile approval of the first in class Provenge ignited investors' hope that Provenge would quickly become a blockbuster for Dendreon, but sales of Provenge has been disappointing so far since the product was launched in the middle of 2010. One of the major reasons is Provenge's high price tag ($93,000/month per person) and reimbursement mechanics. Through over 10 years of lab research and development, NWBO's DCVax technology has overcome this major bottleneck in immunotherapeutic development. NWBO's batch manufacturing process and cryopreservation technology allow for sharp price reduction of DCVax products. In addition to the cost reduction, DCVax is also superior in terms of ease of administration, and higher concentration of DCs.

The Provenge case is positive for the whole class of cell-based therapeutics because it has defined the regulatory path for such drug candidates. Both DCVax-L and DCVax-Prostate are in late stage of development and both, if approved, have blockbuster potential. The Company needs to find a partner for DCVax-Prostate.

Currently, the Company shares are trading at about $6.55 per share which values the Company at about $70 million based on 11 million shares outstanding. This is certainly a discount compared to its peers. Most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. NWBO is a mid to late stage development biotech company, and its lead candidate DCVax-L is under a Phase III clinical trial. Another lead candidate DCVax-Prostate is also cleared for a Phase III trial. Market potential is huge for either product.

Our price target of $10.00 per share values NWBO at $110 million in market cap based on the 11 million shares outstanding. Apparently, risk is high for NWBO at this stage, but return should also be high. Investors with high risk tolerance and relatively long investment horizon may consider NWBO as a component of their portfolios.

Liquidity is our Chief Concern

The Company has experienced recurring losses from operations. As of September 30, 2012, the Company had only $111,000 in cash.

Even with the $13.8 million proceeds from recent financing, cash burn is still a concern. As the Company advances its lead program DCVax-L into Phase III clinical trial, R&D costs will increase, not to mention the costs of other clinical programs. According to our model, the Company will incur operational loss of $38.7 million in fiscal 2012 alone. Although current cash provides some cushion, we believe the Company needs to tap the capital market very soon and do so in a regular basis down the road before a long term financing is secured.

We remind investors that equity financing will dilute existing shareholder base and reduce its share price.

NWBO is still a development stage biotech company. Although lead candidates DCVax-L and DCVax-Prostate have or will, enter into pivotal trials, failure cannot be ruled out completely.

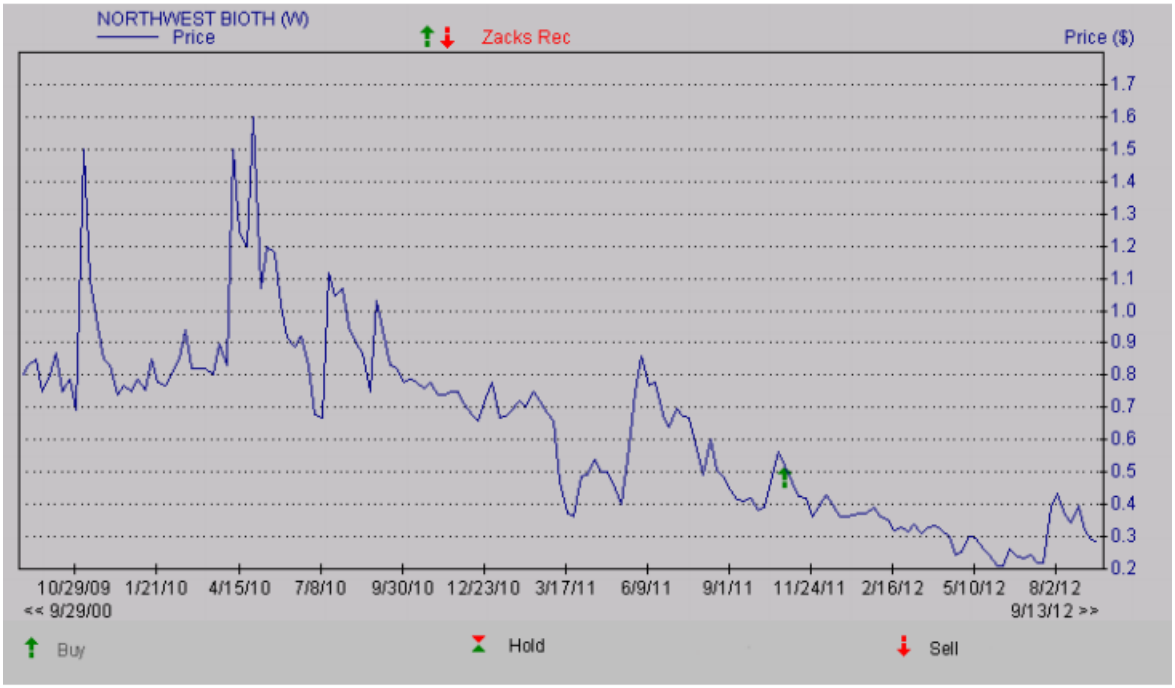
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE
Research material sales	$0.00	$0.00	$0.01	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Contract R&D from related parties	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Research grants and other	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.33	$0.12	$0.00	$0.45	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$0.01**	**$0.00**	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.00**	**$0.45**	**$0.00**	**$0.00**	**$0.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.00**	**$0.00**	**$0.01**	**$0.00**	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.00**	**$0.45**	**$0.00**	**$0.00**	**$0.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$4.44	$3.47	$3.56	$1.98	$13.45	$3.58	$7.04	$9.94	$7.50	$28.06	$25.00	$20.00	$15.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$2.32	$5.56	$2.80	$2.66	$13.34	$2.18	$2.03	$3.91	$3.00	$11.12	$11.50	$12.50	$14.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.00	$0.00	$0.00	$0.00	$0.01	$0.00	$0.00	$0.01	$0.00	$0.01	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($6.8)**	**($9.0)**	**($6.4)**	**($4.6)**	**($26.8)**	**($5.8)**	**($8.7)**	**($13.7)**	**($10.5)**	**($38.7)**	**($36.5)**	**($32.5)**	**($29.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($1.7)	($3.3)	$6.8	($7.9)	($6.0)	($4.4)	($1.4)	($2.8)	$0.0	($8.6)	($7.5)	($5.0)	($5.0)
Pre-Tax Income	**($8.4)**	**($12.3)**	**$0.5**	**($12.6)**	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($10.5)**	**($47.3)**	**($44.0)**	**($37.5)**	**($34.0)**
Income taxes(benefit)	$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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($8.4)**	**($12.3)**	**$0.5**	**($12.6)**	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($10.5)**	**($47.3)**	**($44.0)**	**($37.5)**	**($34.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*4.8*	*5.2*	*7.7*	*9.3*	*6.8*	*9.6*	*10.1*	*11.1*	*14.5*	*11.3*	*15.0*	*20.0*	*25.0*
Reported EPS	**($1.75)**	**($2.35)**	**$0.06**	**($1.35)**	**($4.85)**	**($1.06)**	**($1.00)**	**($1.49)**	**($0.72)**	**($4.17)**	**($2.93)**	**($1.88)**	**($1.36)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$1.46*	*($9.21)*	*$6.15*	*($1.61)*	*$5.23*	*$1.61*	*$2.79*	*$0.00*	*$9.63*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($8.4)**	**($10.9)**	**($8.7)**	**($6.4)**	**($34.4)**	**($4.9)**	**($8.5)**	**($13.7)**	**($10.5)**	**($37.7)**	**($44.0)**	**($37.5)**	**($34.0)**
Non GAAP EPS	**($1.75)**	**($2.07)**	**($1.13)**	**($0.69)**	**($5.08)**	**($0.51)**	**($0.84)**	**($1.24)**	**($0.72)**	**($3.32)**	**($2.93)**	**($1.88)**	**($1.36)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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