Zacks Small-Cap Research

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Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: Phase I portion of DCVax-Direct completed, Positive data reported from Phase I/II study of DCVax-Direct, German approval is a significant milestone--*Outperform*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (08/26/14)	$5.95
Twelve-Month Target Price	**$12.00**

OUTLOOK

NWBO 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. Phase III of DCVax-L has been enrolling patient in the US, UK, and Germany. Hospital Exemption in Germany further validates its immunotherapy platform.

Positive data from Phase I/II study of DCVax-Direct reported.

Current valuation is attractive. We maintain our Outperform rating.

SUMMARY DATA

52-Week High	**$9.18**
52-Week Low	**$3.18**
One-Year Return (%)	**70.19**
Beta	**2.96**
Average Daily Volume (sh)	**420,257**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$368**
Short Interest Ratio (days)	**4.67**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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)
2013	0.14 A	0.27 A	0.40 A	0.00 A	0.81 A
2014	0.00 A	0.00 A	0.05 E	0.08 E	0.13 E
2015					0.50 E
2016					1.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.54 A	-$0.40 A	-$0.44 A	-$0.42 A	-$1.78 A
2014	-$0.45 A	-$0.45 A	-$0.44 E	-$0.44 E	-$1.78 E
2015					-$1.21 E
2016					-$0.88 E

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

WHAT'S NEW

- **Reporting 2Q14 financials;**
- **New financing boosted balance sheet;**
- **Phase III of DCVax-L enrolling patients in the US, UK and Germany;**
- **Encouraging preliminary data reported for DCVax-Direct from Phase I/II trial;**
- **German Approvals represent a significant milestone;**
- **Top line results for Phase III of DCVax-L expected by end of 2015;**
- **We maintain Outperform rating and reiterate our PT of $12.00;**

NWBO Reports Second Quarter Financials

There was no revenue for the second quarter of 2014.

Research and development expense was $21.5 million for the three months ended June 30, 2014 compared to $8.4 million for the three months ended June 30, 2013. The increase was primarily attributable to costs associated with launching, manufacturing for, and conducting (including CRO costs) the Phase III DCVax-L trial in Europe and the Phase I/II DCVax-Direct, which were just beginning as of this period last year, as well as expansion of the Company's German subsidiary and its operations, and expansion of the ongoing Phase III trial in the US.

As of June 30, 2014, there were over 51 clinical trial sites in operation in the US in the Phase III trial with DCVax-L, as well as German sites, compared to 50 clinical trial sites in the US only at June 30, 2013.

General and administrative expense was $3.9 million for the three months ended June 30, 2014 compared to $3.3 million for the three months ended June 30, 2013. The increase in general and administrative expenses from the prior period was a result of increase in consulting expenses and increase in legal expenses, offset by decrease in stock based compensation expense.

Net loss was $25.9 million including $9.0 million in non-cash accounting charges for the three months ended June 30, 2014 compared to a net loss of $11.6 million for the three months ended June 30, 2013.

New Financing Boosts Balance Sheet

On August 19, 2014, Northwest Biotherapeutics (NWBO) closed a $17.5 million convertible note offering. The three-year notes have a 5% interest rate and are convertible at $7.30 per share of common stock. The investors also have an option, exercisable for 3 months, to purchase up to an additional 30% of these notes on the same terms.

The proceeds from this offering will help support an increase in the manufacturing capacity for the Company's DCVax products, as well as the Company's ongoing Phase III and Phase I/II clinical trials.

We are pleased to see that NWBO completed this convertible debt funding with an above market conversion price. This financing not only boosts the company's balance sheet, but also validates the company's immunotherapy platform technology as well as the company's clinical programs.

As of June 30, 2014, NWBO held $8.9 million in cash. Together with the $17.5 million new funds, the company's cash should be able to run into 2015.

Update on Phase III DCVax®-L Trial and Compassionate Use

On August 11, 2014, NWBO provided an update on the Company's Phase III clinical trial of DCVax®-L for Glioblastoma multiforme (GBM) brain cancer and certain changes to the Phase III trial.

According to NWBO, the Phase III trial is progressing on track. 55 patients who were not eligible to enroll in the trial due to unusually rapid tumor recurrence were included in a compassionate use "Information Arm" and are showing encouraging survival times.

The Phase III trial is enrolling patients at over 50 trial sites in the **US** and a number of sites in the **UK** and **Germany**. The current trial plan involves enrollment of 312 total patients in the trial, and counting 110 "events" of tumor recurrence or patient deaths from among these 312 patients to determine whether the primary endpoint of the trial is met.

NWBO is modifying its trial plan so that it will enroll 348 total patients, and will count 248 "events" from among these 348 total patients to determine whether the primary endpoint of the trial is met. So, the number of "events" counted in the statistical analysis will increase from 110 to 248, but the total enrollment in the trial will only increase from 312 to 348.

Taking into account the time required for these approvals and implementation steps, and the 36-patient increase in the trial, as well as the gradual ramp-up of the trial in Europe, the Company currently anticipates that enrollment will be completed in approximately **3Q2015**, and the primary endpoint of the trial will be reached about 3-5 months after full enrollment or by around **year-end next year**.

During 2011 and 2012, in addition to conducting the trial, the Company also treated 55 GBM patients with DCVax-L on a compassionate basis in an "Information Arm" outside of the Phase III trial. These 55 patients received the same DCVax-L treatment regimen used in the trial. The 55 patients were not eligible for the Phase III trial because they were either definitely or potentially "rapid progressors", which means their tumor was already re-growing during the 6 weeks of daily radiation to the brain and daily chemotherapy which followed the surgical removal of their original tumor as part of the current standard of care.

Regular GBM patients survive for a median of about 14.6 months with current standard of care. "Rapid progressors" have a much shorter life expectancy, in the range of 7 to 10 months, and generally are not expected to respond much to any treatments.

The data received by the Company included the survival to date for all 55 patients in the "Information Arm" and data relating to the progression of their cancer for 43 of the 55 patients. According to initial analyses, the median Overall Survival for all 55 patients is 18 months; the median Overall Survival for the 43 patients is a little over 19 months. The Company is in the process of further analyses of the data on these patients.

In light of the extremely poor prognosis and short survival time of "rapid progressor" patients with standard of care today, the median Overall Survival observed in these patients who received treatment with DCVax-L in the "Information Arm" is unexpected and encouraging.

Phase I Trial of DCVAX®-Direct Recruitment Completed

On July 16, 2014, NWBO announced that the Phase I portion of the Company's Phase I/II DCVax-Direct clinical trial completed its 36-patient target recruitment, and the Company is now underway with preparations for the Phase II portion of this trial, as well as expansion of DCVax-Direct manufacturing.

As a reminder, in June, 2013, NWBO initiated its **60-patient Phase I/II** clinical trial of DCVax-Direct for all inoperable **solid tumor** cancers.

The trial is a combined Phase I and II trial. In the **Phase I stage**, the trial will test various dose levels of DCVax-Direct. The trial will then proceed directly into the **Phase II stage** to test the efficacy of the DCVax-Direct treatment. The primary endpoint for measurement of efficacy will be **tumor regression** (i.e., shrinkage or elimination). As is standard with Phase I/II trials, this trial will not be blinded – the

clinical results in patients will be seen as the trial progresses. The DCVax-Direct treatment regimen in the clinical trial includes a total of 6 injections: initially at Day 0, Day 7 and Day 14, followed by injections at Week 8, Week 16 and Week 32.

The Phase I portion of the trial has involved testing of 3 different dose levels, and a diverse range of cancers. The patients enrolled in Phase I will continue to receive treatments in accordance with the protocol.

With the closing of Phase I, the Company is now preparing to initiate the **Phase II** portion of the trial. This second part of the Phase I/II study will target **24 or more** patients in selected cancers. Additional trial sites are being brought on to facilitate and expedite enrollment.

Early Data from DCVax-Direct Phase I/II Trial Very Encouraging

On June 11, 2014, NWBO announced positive results from the ongoing Phase I/II clinical trial of DCVax-Direct for all types of inoperable solid tumors.

As of the reporting date, 20 patients have received at least 3 of the 6 total injections, and 13 of these 20 patients are showing tumor cell death, tumor shrinkage, substantial accumulation of immune cells in the tumors, and/or stabilization of their disease.

All 9 out of 9 patients who have received 4 of the 6 planned injections are showing tumor cell death, tumor shrinkage, substantial immune cell accumulation in their tumors and/or stabilization (i.e., stopping the progression) of their advanced cancer.

Also, in a new finding, biopsies taken in 3 of these 9 patients now show no live tumor cells in the tumor that was injected. These 3 cases include diverse, advanced and particularly aggressive cancers: 1 metastatic pancreatic cancer case, 1 metastatic colon cancer case and 1 metastatic sarcoma case. These patients' tumors showed some enlargement on imaging scans, but the biopsies showed that live tumor cells are no longer detectable and immune cells were found there. Each of these 3 patients was treated with the lowest dose level (2 million cells per treatment).

In these 3 patients, as well as the other patients in the trial, only one of their tumors has been injected with DCVax-Direct. The Company plans to inject multiple tumors in its further studies of DCVax-Direct.

The Company plans to report more details when the patients are further along in the treatment regimen. The first 3 injections are given in the first 2 weeks of the 32-week treatment regimen (at Day 0, Day 7 and Day 14).

We think the initial data are very encouraging. Though in early stage, the Phase I trial already demonstrated that over 65% patients are already showing positive response, and as of the 4th injection in week 8 of the treatments, 100% of the patients (9 of 9) have shown some positive effects. It's **especially excited** to see such responses while these patients are still only part way through their treatment and with only one tumor being injected with DCVax-Direct.

Through over 10 years of research and development, NWBO has developed a 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.

Two German Approvals Further Validate DCVax Platform Technology

In March, 2014, Northwest received **approval** from the German Health Authority of a "**Hospital Exemption**" early access program.

Under this Hospital Exemption, Northwest may provide DCVax-L to patients for the treatment of **any glioma** brain cancers (both Glioblastoma multiforme and lower grade gliomas), both newly diagnosed and recurrent, outside of the Company's clinical trial and charge full price. The patients may be from Germany or elsewhere. This approval has a term of five years, and can be re-applied for and re-issued at the end of that period.

Meanwhile, NWBO announced that the German reimbursement authority has determined that DCVax-L treatments for glioma brain cancers are **eligible to obtain reimbursement** from the Health Insurers of the German healthcare system. Applications for such reimbursement eligibility may only be submitted to the Health Insurers by German hospitals, not by a company. Six major hospital centers across Germany applied for such reimbursement eligibility for DCVax-L for glioma brain cancers. The amount and terms for such reimbursement will be negotiated by NWBO, the hospitals and the Health Insurer over the coming months, and will be applied to patients case by case. In the meantime, patients may self-pay for DCVax-L.

We view the two approvals in Germany a significant milestone for NWBO in the following aspects.

- First, the approvals will allow the company to record product revenue in 2014. The revenue may not be meaningful, but this marks the first time in the company's history that product sales will be booked for revenue.

- **More importantly**, the approvals further **validate** the company's DCVax immunotherapy platform technology.

- Furthermore, the German approvals also provide NWBO the opportunity to begin practicing for future commercial operations.

The evaluation of NWBO's application by the German regulatory authorities included comprehensive and detailed scrutiny of all aspects of the DCVax-L technology, all DCVax-L clinical data to date, all manufacturing processes, all product characteristics (including potency, composition, sterility and other aspects), all frozen storage of DCVax-L and frozen shelf life, and all distribution and handling of the DCVax-L products.

The approval for DCVax-L of hospital exemption is the **first such approval** granted by the German regulatory authorities in multiple key ways. Only two prior approvals have been given in the more than 2-1/2 years since the law was put in place, and those were for two German companies with tissue engineered products which had already been on the market commercially under prior laws and were grandfathered for regulatory purposes, and which did not have pharmacological effects.

In contrast, DCVax-L is the first product of its kind to receive Hospital Exemption approval from the German regulators, in the following key ways:

- the first immunotherapy;
- the first product which exerts pharmacological effects;
- the first product that has never previously been on the market commercially;
- the first product developed by a non-German company, not previously under the German regulators' oversight; and
- the first "somatic" cell therapy product (a somatic cell is any cell of the body other than a reproductive or embryonic cell).

Furthermore, **the scope** of the Hospital Exemption granted for DCVax-L is broader than the scope of the ongoing Phase III clinical trial. The Hospital Exemption for DCVax-L applies to all glioma brain cancers, including both the most severe grade (Grade IV, Glioblastoma multiforme or GBM) and lower grade

gliomas, while the clinical trial includes only GBM. The Hospital Exemption also includes both newly diagnosed and recurrent gliomas, while the clinical trial includes only newly diagnosed.

DCVax-L products that are to be covered by the Hospital Exemption in Germany must be manufactured in Germany, but can be administered to patients from anywhere. The Company will provide annual data reports to the German regulatory authority during the five-year term of the Hospital Exemption. The Company expects to activate this program over the coming months.

The German approval also provides NWBO the opportunity to begin practicing for future commercial operations.

As a follow-up to this announcement, the Company will periodically provide further information about its Hospital Exemption program and reimbursement as the information becomes available.

We Maintain Our Outperform Rating on NWBO Shares

We maintain our Outperform rating on NWBO and reiterate our 12-month price target of $12.00 per share.

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.

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.

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. In addition, NWBO initiated a Phase I/II clinical trial for its third candidate DCVax-Direct for solid tumors and initial data have been very encouraging.

Currently, the Company shares are trading at about $5.90 per share which values the Company at about $350 million based on 60 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 $1 billion depending on how advanced the pipeline is and which indications the company is targeting. NWBO is a 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.

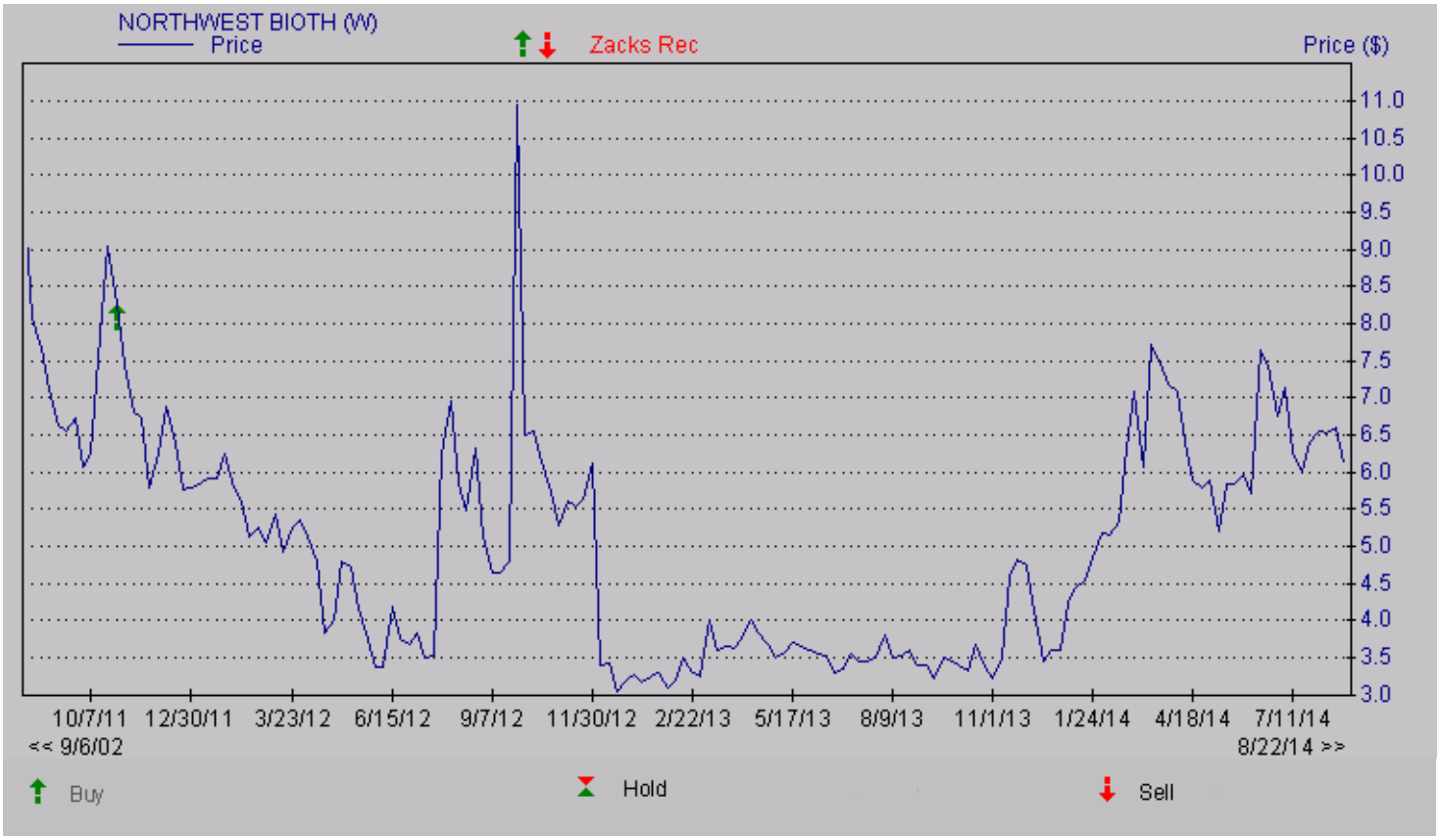
Our price target of $12.00 per share values NWBO at $720 million in market cap. Apparently, risk is high for NWBO at this stage. The major concern is cash burn. As the company moves forward with the Phase III of DCVax-L and Phase I/II DCVax-Direct, R&D expense is soaring. We will keep a close eye on the company's balance sheet. That said, return should also be high.

PROJECTED INCOME STATEMENT

	2013A (Dec)					2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3E	Q4E	FYE	FYE	FYE	FYE	FYE
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.05	$0.08	$0.13	$0.50	$1.50	$3.00	$5.00
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	$0.00
Research grants and other	$0.14	$0.27	$0.40	$0.00	$0.81	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.14**	**$0.27**	**$0.40**	**$0.00**	**$0.81**	**$0.00**	**$0.00**	**$0.05**	**$0.08**	**$0.13**	**$0.50**	**$1.50**	**$3.00**	**$5.00**
YOY Growth	-	-	*233.3%*	*-100.0%*	*4.8%*	*-100.0%*	*-100.0%*	*-87.5%*	-	*-83.9%*	*284.6%*	*200.0%*	*100.0%*	*66.7%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.01	0.02	0.08	0.23	0.45	0.75
Gross Income	**$0.14**	**$0.27**	**$0.40**	**$0.00**	**$0.81**	**$0.00**	**$0.00**	**$0.04**	**$0.07**	**$0.11**	**$0.43**	**$1.28**	**$2.55**	**$4.25**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	-	*100.0%*	-	-	*85.0%*	*85.0%*	*85.0%*	*85.0%*	*85.0%*	*85.0%*	*85.0%*
R&D	$11.61	$8.38	$12.79	$11.12	$43.91	$19.99	$21.55	$22.00	$22.50	$86.04	$65.00	$50.00	$20.00	$22.50
% R&D	-	-	-	-	-	-	-	*44000.0%*	*28125.0%*	*66180.8%*	*13000.0%*	*3333.3%*	*666.7%*	*450.0%*
SG&A	$2.47	$3.29	$3.06	$3.55	$12.36	$3.69	$3.88	$4.00	$4.20	$15.77	$17.50	$19.50	$21.00	$22.50
% SG&A	-	-	-	-	-	-	-	*8000.0%*	*5250.0%*	*12129.2%*	*3500.0%*	*1300.0%*	*700.0%*	*450.0%*
Other expenses	$0.00	$0.00	$0.00	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($13.9)**	**($11.4)**	**($15.5)**	**($14.7)**	**($55.5)**	**($23.7)**	**($25.4)**	**($26.0)**	**($26.6)**	**($101.7)**	**($82.1)**	**($68.2)**	**($38.5)**	**($40.8)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.5)	($0.2)	($7.5)	($2.2)	($10.3)	($22.4)	($0.4)	($0.5)	($0.5)	($23.8)	($2.5)	($2.5)	($2.5)	($2.5)
Pre-Tax Income	**($14.4)**	**($11.6)**	**($22.9)**	**($16.9)**	**($65.8)**	**($46.0)**	**($25.9)**	**($26.5)**	**($27.1)**	**($125.5)**	**($84.6)**	**($70.7)**	**($41.0)**	**($43.3)**
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	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($14.4)**	**($11.6)**	**($22.9)**	**($16.9)**	**($65.8)**	**($46.0)**	**($25.9)**	**($26.5)**	**($27.1)**	**($125.5)**	**($84.6)**	**($70.7)**	**($41.0)**	**($43.3)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*26.7*	*29.1*	*35.3*	*40.4*	*32.9*	*52.4*	*57.4*	*60.0*	*62.0*	*58.0*	*70.0*	*80.0*	*90.0*	*100.0*
Reported EPS	**($0.54)**	**($0.40)**	**($0.65)**	**($0.42)**	**($2.00)**	**($0.88)**	**($0.45)**	**($0.44)**	**($0.44)**	**($2.17)**	**($1.21)**	**($0.88)**	**($0.46)**	**($0.43)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$0.00*	*$7.45*	*$0.00*	*$7.45*	*$22.36*	*$0.00*	*$0.00*	*$0.00*	*$22.36*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($14.4)**	**($11.6)**	**($15.5)**	**($16.9)**	**($58.3)**	**($23.7)**	**($25.9)**	**($26.5)**	**($27.1)**	**($103.1)**	**($84.6)**	**($70.7)**	**($41.0)**	**($43.3)**
Non GAAP EPS	**($0.54)**	**($0.40)**	**($0.44)**	**($0.42)**	**($1.78)**	**($0.45)**	**($0.45)**	**($0.44)**	**($0.44)**	**($1.78)**	**($1.21)**	**($0.88)**	**($0.46)**	**($0.43)**

Source: Company filings and Zacks Investment Research estimates

HISTORICAL ZACKS RECOMMENDATIONS



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