Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: 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 (05/27/14)	$6.53
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 initiated in the UK, and about to begin in Germany soon. 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	**$3.15**
One-Year Return (%)	**88.80**
Beta	**2.80**
Average Daily Volume (sh)	**1,882,776**
Shares Outstanding (mil)	**55**
Market Capitalization ($mil)	**$359**
Short Interest Ratio (days)	**2.91**
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)
2013	0.14 A	0.27 A	0.40 A	0.00 A	0.81 A
2014	0.00 A	0.00 E	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	-$0.29 E	-$0.28 E	-$0.29 E	-$1.31 E
2015					-$0.49 E
2016					-$0.48 E

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

WHAT'S NEW

- **Encouraging preliminary data reported for DCVax-Direct from Phase I/II trial;**
- **Reporting 1Q14 financials with cash on budget;**
- **German Approvals represent a significant milestone;**
- **Interim data analysis an important progress of Phase III trial;**
- **Top line results for Phase III of DCVax-L expected by end of 2014;**
- **We maintain Outperform rating and reiterate our PT of $12.00;**

Northwest Bio Announces Early Positive Data from DCVax-Direct Phase I/II Trail

After reporting an initial case study showing both **local** and **systemic** anti-tumor effects of the DCVax-Direct treatment, on May 27, 2014, Northwest Biotherapeutics further provided a summary of initial data in its ongoing **Phase I/II** clinical trial of **DCVax-Direct** for inoperable solid tumors.

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 includes **36 patients**. To date, 19 patients have completed at least half of the 6 treatments with DCVax-Direct, which are spread over 8 months. None have yet completed all 6 treatments. Although these patients have advanced metastatic disease, only one tumor is being injected in each patient because the current trial is a first-in-man study.

According to the Company, among the 19 patients, 11 patients (58%) have already shown some preliminary positive responses to the treatments. **Specifically**,

- 8 of the 11 patients have shown signs of tumor necrosis, immune cell infiltration, as well as stabilized disease;
- For all of these 8 patients, biopsies indicated substantial to extensive tumor necrosis, as well as substantial accumulations of immune cells infiltrating into and around the patients' tumors;
- For 6 of these 8 patients, imaging scans also indicated either tumor shrinkage or no disease progression;
- For the other 2 of these 8 patients, imaging scans indicated some enlargement of their tumors. However, the biopsies revealed that the tumor was filled with necrosis and infiltrating immune cells. In addition, these patients have reported significant improvement in their physical condition and clinical symptoms;
- The other 3 of the 11 patients have shown **stabilized disease**, but have not yet shown definitive necrosis or infiltration of immune cells into their tumors;

Among the remaining 8 of the 19 patients:

- 1 of these 8 patients requires more data before a preliminary assessment can be made;
- 7 of these patients have shown progression of their disease;

We think the initial data are very encouraging. Though in early stage, the Phase I trial already demonstrated that over 50% patients are already showing positive response. 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.

Since March, the trial has been accelerating enrollment. So far, **23 patients** are already enrolled, their DCVax-Direct personalized product was manufactured and released, and their treatment has begun (19 of these 23 patients have had at least half of the 6 total treatments in the trial protocol). **7 more patients** are beginning their DCVax-Direct treatments this week or during the next couple of weeks. **The remaining 6 patients**, who have already completed screening, will be having their personalized product manufactured in June, and will begin their treatment as soon as their product is released. We expect to see top line data in 3Q14.

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.

NWBO Reports 1Q14 Financials With Cash on Budget

There was no revenue for the three months ended March 31, 2014.

Research and development expense was $20.0 million for 1Q14, compared to $11.6 million for 1Q13. The increase was primarily attributable to the DCVax-Direct manufacturing and product development work and the preparation costs for the launch of two clinical trial programs, one in the US and one in the UK, as well as expansion of the ongoing Phase III trial in the US, and increased manufacturing of DCVax®-L for the Phase III trial.

General and administrative expense was $3.7 million for 1Q14 compared to $2.5 million for 1Q13. The increase was as a result of increase in consulting expenses of $1.4 million and increase in legal expenses of $0.4 million.

GAAP net loss for 1Q14 was $46 million including $10.6 million in cash outlays and $35.4 million in non-cash accounting charges compared to a net loss of $14.4 million for the three months ended March 31, 2013.

At March 31, 2014, the Company held cash of $12.2 million, compared to $18.5 million at December 31, 2013. Current cash balance will last through 2Q14.

On April 10, 2014, NWBO entered into an agreement with a single institutional investor for a registered direct placement of up to **$32 million**. The Stock Purchase Agreement provides for the sale of an initial $15 million of common stock at $6.60 per share (approximately 8% discount to the closing market price), which was closed on April 15. The Stock Purchase Agreement also provides a non-transferable Oversubscription Option for the investor to purchase up to $17 million of common stock at $7.50 per share (approximately 5% premium to the closing market price) during the twelve months following the initial closing.

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.

Important Progress Made in Interim Data Analysis By DSMD for Phase III of DCVax-L

On March 7, 2014, NWBO announced that the Data Safety Monitoring Board (DSMB) has made an unblinded review of the safety data for the Company's ongoing international Phase III GBM Trial of DCVax-L, and has recommended that the trial continue as planned. The DSMB's review of the efficacy data is still pending.

We view this recommendation an important step in the ongoing progress of the Phase III DCVax-L trial. The DSMB usually has three kind of recommendations based on interim data.

- Stop trial early due to excellent safety data and efficacy data, this is a rare case;
- Continue the trial based on good safety data and efficacy data; this is the most common case. In such a case, the safety data are good, and the efficacy data are fine, but have not reached statistically significance;
- Discontinue the trial due to poor safety and efficacy data;

NWBO did not disclose the interim data. Our guess is that the safety data are excellent, and the efficacy data have not reached statistical significance. This is understandable. At this point, the number of patients is still not enough to power the statistics.

We plan to update investors once the second interim analysis is available.

Top Line Results of Phase III DCVax-L for Brain Cancer Expected by the End of 2014

This **Phase III trial of DCVax-L** is for newly diagnosed Glioblastoma multiforme (GBM), the most common and most lethal form of brain cancer.

The trial is well **under way in the US**, with over 50 active sites at present, and is expected to enroll an aggregate total of 312 patients in the US and Europe.

On May 16, 2013, NWBO announced that **Phase III** clinical trial with DCVax®-L for brain cancer has been initiated at King's College Hospital **in the UK**. This is one of the first late-stage clinical trials in Europe with active immune therapies. Three other sites in the UK are also preparing to open.

On September 17, 2013, NWBO announced that the **German regulatory authority** has approved the Company's implementation of the three minor amendments required by the authority's initial decision announced in August, and has authorized the Company's **Phase III GBM** clinical trial to open **in Germany.**

This rapid regulatory response enables NWBO to proceed with its Phase III trial in Germany, where the Company plans to include more than 20 top German hospital centers. These German centers will be

joining more than 55 clinical trial sites currently operating in the US, as well as sites in the UK, as part of NWBO's international 312-patient, double blind, randomized, placebo-controlled Phase III clinical trial of DCVax®-L for Glioblastoma multiforme (GBM).

NWBO will now proceed with the final administrative steps with the individual German hospital centers, in order for enrollment to begin.

NWBO expects to complete enrollment by the late summer, and potentially reaching top line results by the end of this year.

As of March 31, 2014 there were over 51 clinical trial sites in operation in the US and UK in the Phase III trial with DCVax-L.

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 $6.50 per share which values the Company at about $359 million based on 55 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 billioin 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.

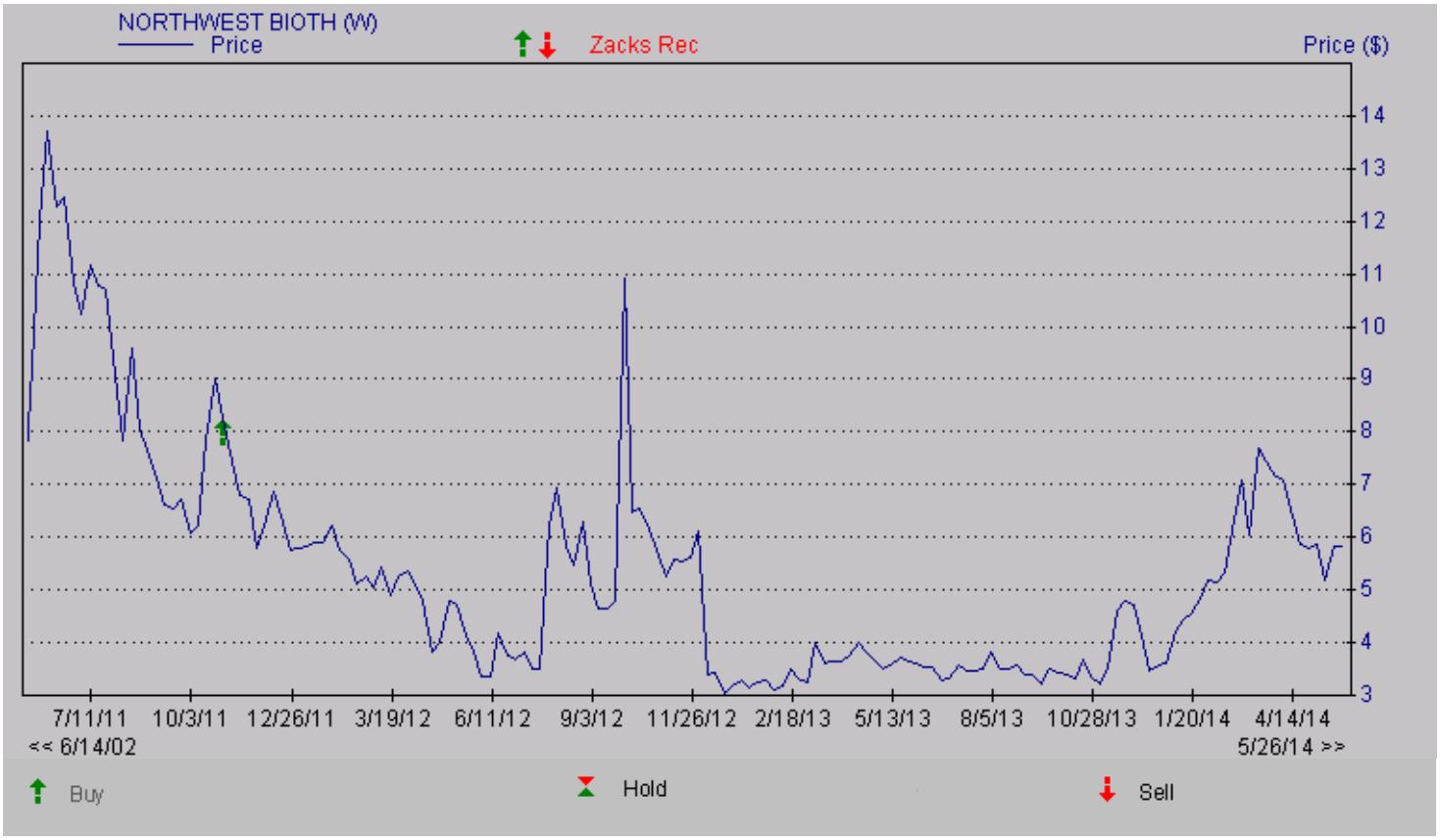
Our price target of $12.00 per share values NWBO at $660 million in market cap. Apparently, risk is high for NWBO at this stage. The major concern is cash burn. As the company moves forward with the Phase III of DCVax-L and Phase I/II DCVax-Direct, R&D expense is soaring. We will keep a close eye on 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	Q2E	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	$11.80	$12.50	$13.50	$57.79	$15.00	$17.50	$20.00	$22.50
% R&D	-	-	-	-	-	-	-	*25000.0%*	*16875.0%*	*44450.8%*	*3000.0%*	*1166.7%*	*666.7%*	*450.0%*
SG&A	$2.47	$3.29	$3.06	$3.55	$12.36	$3.69	$3.80	$4.00	$4.20	$15.69	$17.50	$19.50	$21.00	$22.50
% SG&A	-	-	-	-	-	-	-	*8000.0%*	*5250.0%*	*12071.5%*	*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	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($13.9)**	**($11.4)**	**($15.5)**	**($14.7)**	**($55.5)**	**($23.7)**	**($15.6)**	**($16.5)**	**($17.6)**	**($73.4)**	**($32.1)**	**($35.7)**	**($38.5)**	**($40.8)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.5)	($0.2)	($7.5)	($2.2)	($10.3)	($22.4)	($0.5)	($0.5)	($0.5)	($23.9)	($2.5)	($2.5)	($2.5)	($2.5)
Pre-Tax Income	**($14.4)**	**($11.6)**	**($22.9)**	**($16.9)**	**($65.8)**	**($46.0)**	**($16.1)**	**($17.0)**	**($18.1)**	**($97.2)**	**($34.6)**	**($38.2)**	**($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)**	**($16.1)**	**($17.0)**	**($18.1)**	**($97.2)**	**($34.6)**	**($38.2)**	**($41.0)**	**($43.3)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*26.7*	*29.1*	*35.3*	*40.4*	*32.9*	*52.4*	*54.8*	*60.0*	*62.0*	*57.3*	*70.0*	*80.0*	*90.0*	*100.0*
Reported EPS	**($0.54)**	**($0.40)**	**($0.65)**	**($0.42)**	**($2.00)**	**($0.88)**	**($0.29)**	**($0.28)**	**($0.29)**	**($1.70)**	**($0.49)**	**($0.48)**	**($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)**	**($16.1)**	**($17.0)**	**($18.1)**	**($74.9)**	**($34.6)**	**($38.2)**	**($41.0)**	**($43.3)**
Non GAAP EPS	**($0.54)**	**($0.40)**	**($0.44)**	**($0.42)**	**($1.78)**	**($0.45)**	**($0.29)**	**($0.28)**	**($0.29)**	**($1.31)**	**($0.49)**	**($0.48)**	**($0.46)**	**($0.43)**

Source: Company filings and Zacks Investment Research estimates

HISTORICAL ZACKS RECOMMENDATIONS



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