Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: *Phase III of DCVax-L initiated in UK, and is accelerating enrollment in the US, Phase I/II of DCVax-Direct is on track to advance--Outperform*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (05/20/13)	$3.70
Twelve-Month Target Price	**$7.50**

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. Further, the US clinical trial site has been expanded ahead of schedule with 46 sites open and recruiting.

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	**$3.03**
One-Year Return (%)	**-13.39**
Beta	**1.78**
Average Daily Volume (sh)	**127,362**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$107**
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	0.32 A	0.77 A
2013	0.14 A	0.20 E	0.20 E	0.20 E	0.74 E
2014					1.00 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	-$1.86 A	-$4.87 A
2013	-$0.54 A	-$0.49 E	-$0.50 E	-$0.49 E	-$2.02 E
2014					-$1.54 E

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

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WHAT'S NEW

- **NWBO reports first quarter of 2013 financials; Raised $10 million in April 2013;**
- **Phase III DCVax-L for brain cancer is going well in the US;**
- **Phase III DCVax-L for brain cancer is initiated in Europe;**
- **NWBO is also making progress to advance DCVax-Direct;**

NWBO Reports First Quarter of 2013 Financials

There was no revenue for the first quarter of 2013.

Research and development expense was $11.6 million for the three months ended March 31, 2013 compared to $3.6 million for the three months ended March 31, 2012. 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, in the US and 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 included $1 million of cash expenses, and $1.5 million of non-cash charges (i.e. amortization of previously issued stock based compensation and restricted stock and warrants issued for services), for a combined total of $2.5 million for the three months ended March 31, 2013 compared to $2.2 million for the three months ended March 31, 2012. The slight increase in general and administrative expenses from the prior period is as a result of $0.9 million related to the issuance of restricted stock and warrants for public relations and investor relation services, offset by a $0.4 million decrease in stock based compensation expense.

Net loss was $ 14.4 million or $0.54 per share for the three months ended March 31, 2013 compared to a net loss of $10.2 million or $0.51 per share for the three months ended March 31, 2012.

At March 31, 2013, cash and cash equivalents totaled $0.4 million.

In April 2013, the Company entered into an agreement with one healthcare-dedicated institutional investor for a registered direct placement of $10.0 million of common stock at the closing market price of $3.90 per share. The number of shares of common stock issued was 2,564,103. The Company issued to the investor warrants exercisable for 1,025,641 shares of common stock. The Company also issued to the placement agent warrants exercisable for 128,205 shares of common stock. Net proceeds to the Company amounted to $9.2 million after deducting deal related costs. The warrants have an exercise price of $4.29 per share and are exercisable beginning six months after closing, with a term of five years.

Phase III DCVax-L For Brain Cancer Is Going Well

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 46 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.

NWBO has also been working on preparations for the clinical trial **in Germany**. On July 25, 2012, NWBO announced that manufacturing certification has been received from the German regulatory authorities for the clinical trial in Germany, which is the first step towards implementation of the Phase III trial in Germany. NBWO submitted the application to the German regulatory authority (the Paul Ehrlich Institute,

or PEI) for approval of the Phase III trial. As of March 31, 2013, 24 clinical centers are in varying stages of preparations as trial sites in Germany. Also, in October, 2012, ten major hospital centers across Germany, including the key opinion leaders in brain cancer, all applied to the German healthcare system for reimbursement of DCVax-L for brain cancer. In addition, medical centers in other European countries have requested to be added to the trial.

Phase III Trial Of DCVax-L: Completion Of Enrollment Expected To Be Faster

On March 7, 2013, Northwest Biotherapeutics (NWBO) announced that it expects to complete enrollment in its **312-patient Phase III clinical trial** for Glioblastoma multiforme (GBM) brain cancer by Q1 or early Q2 of next year, and expects to reach its first interim analysis for efficacy by approximately Q3 of next year. This is faster or more efficient than relevant comparison trials with immune therapies for the same brain cancer.

According to information publicly reported on www.clinicaltrials.gov and in company announcements and filings, currently, relevant comparisons include the following:

- **Celldex Therapeutics** (CLDX) is conducting a **Phase III** trial of **Rindopepimut** in Patients with newly diagnosed glioblastoma (**ACT IV**). This 440-patient Phase III trial began enrolling in November 2011 at multiple clinical trial sites worldwide, and appears likely to continue enrolling over at least a 4-year period through the end of 2015, with topline results expected at the end of 2016.
- **ImmunoCellular Therapeutics** (IMUC) is conducting a **Phase II** trial of **ICT-107** for the treatment of newly diagnosed GBM following resection and chemoradiation. The Phase II trial began enrolling in Jan 2011, and completed the enrollment in September 2012 (7 calendar quarters). A total of 278 patients at 25 participating sites had been enrolled in this trial. About 124 patients will be treated.
- **Agenus Inc.** (AGEN) is conducting a **Phase II** trial of **HSPPC-96** with 55 patients with newly diagnosed glioblastoma. This trial began recruiting in June, 2009 and stopped recruiting in Q2, 2012.

In comparison, NWBO has primarily been enrolling its Phase III trial since Q2 of 2011. The Company undertook a limited period of enrollment in 2008, and then kept the trial going with the patients already enrolled, but suspended new enrollment due to resource constraints during the worst of the economic downturn, through the end of 2010. The Company began the process of reactivating clinical trial sites for new enrollment in Q1 2011, and resumed screening in Q2 of 2011.

NWBO expects to complete enrollment in its Phase III trial by Q1 or early Q2 of 2014 – an overall enrollment period of 14 or 15 calendar quarters, including both the 2008 period and the period since Q2 2011. The rate of enrollment for the four companies is listed below for comparison.

	Total Trial Enrollment	Enrollment Period	Pace of Enrollment to Completion, Based On Enrollment Period
NWBO Ph. III	312 patients	14 quarters or 15 quarters	22.3 patients per quarter or 20.8 patients per quarter
IMUC Ph. II	124 patients	7 quarters	17.7 patients per quarter
Celldex Ph. III	440 patients	≥16 quarters [est.]	27.5 patients per quarter [164 clinical trial sites worldwide]
Agenus Ph. II	55 patients	12 quarters	4.6 patients per quarter

Notably, even if the completion of NWBO's Phase III trial enrollment were to take substantially longer than the Company's projection of Q1 or early Q2 2014, the Company's enrollment would still compare favorably with these relevant comparison trials.

This is the first time NWBO management provides detailed guidance for the Phase III clinical trial in terms of enrollment and interim analysis. The Company plans to provide periodic updates of this enrollment guidance through various communication channels. We are pleased that management began to communicate with investors in a positive way for transparency.

Results Expected in 2013 for DCVax®-Direct Phase I/II Trial For Solid Tumors

In parallel with these developments in the Phase III DCVax-L brain cancer program, NWBO has been making arrangements to launch its **DCVax-Direct** program.

In November, 2012, NWBO entered into a Letter of Intent for a collaboration with **Sarah Cannon Research Institute**, which specializes in oncology and has a network of more than 700 physicians in the US and UK who see more than 75,000 new cancer patients per year.

The trial is expected to be launched **in the second quarter 2013**. Target patients for inclusion in the trial include patients with melanoma, pancreatic cancer, liver cancer and liver metastases from colon or other cancers. As is standard with this type of trial, the DCVax-Direct trial will not be blinded, and the results will be visible as the trial proceeds over the course of 2013.

The primary objectives of this two-part trial are to evaluate safety, dose levels and efficacy. The **Part 1** stage of the trial involves dose escalation and confirmation. The **Part 2** stage of the trial will focus on efficacy. The primary measure of efficacy will be regression (i.e., shrinkage or elimination) of the inoperable tumors.

This endpoint of tumor regression is a particularly important one clinically: once tumors are established, if they cannot be surgically removed, it is very difficult to stop their growth and their spread. This endpoint is also important from a regulatory standpoint: it is the endpoint used most frequently for FDA-granted accelerated approval. Further, this endpoint is a rapid one: typically, if tumor regression is going to occur, it is anticipated to be seen within a few months after treatment – far sooner than other clinical trial endpoints such as progression free survival (PFS) or overall survival (OS).

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).

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.

In multiple **pre-clinical** studies of various cancers in animals, direct injection of DCVax-Direct into some of the tumors in each animal resulted in complete clearance of all tumors in 80% to 100% of all of the animals in the various studies – both the tumors that were injected and the tumors that were not injected, indicating a systemic immune response. Further, the tumors were cleared relatively rapidly: within weeks after the DCVax-Direct injections. Equally as important, sixty days after the tumors were cleared from the animals in these pre-clinical studies, the animals were re-injected with the same tumor cells that readily

established tumors at the outset of the studies. This time, tumors failed to establish, indicating immune memory.

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 in addition to **DCVax-L** and **DCVax-Prostate.**

Next Generation Technology Patented For Producing More Potent Dendritic Cells

On March 18, 2013, NWBO announced that it has been issued a key U.S. patent (#8389278) covering novel processes for manufacturing human dendritic cells. The cells produced through these processes are much more potent in their capacity to activate the immune system than those produced by the standard methods used throughout academia and industry today to produce dendritic cells.

This patent has also been issued in Europe, Japan, Australia, New Zealand, India, China, Korea, Singapore, Russia and other countries.

The standard methods used to produce dendritic cells today involve several key steps, which start with precursors of dendritic cells (called "monocytes") obtained through a blood draw, then develop the precursors into immature dendritic cells, and finally develop these cells into mature and activated dendritic cells. The standard methods cause some premature activation of the precursors before they become immature dendritic cells, and this premature activation orients the cells toward becoming an undesired cell type rather than dendritic cells. This has to be stopped and overcome by treating the cells with a biochemical factor known as IL-4. This redirection results in conflicting signals, and dendritic cells that are somewhat "confused."

In contrast, the patented NWBO processes closely track the natural processes that occur in a healthy person's immune system. These methods avoid the premature activation of the precursors (monocytes), and develop pure immature dendritic cells -- avoiding the conflicting and confusing signals, and the need to override those signals with IL-4.

NWBO's patented methods develop mature and activated dendritic cells that are far more potent than dendritic cells produced in the standard way. For example, NWBO's dendritic cells produce as much as 10X or more the amount of signaling compounds which are key to mobilizing other active agents of the immune system, such as T cells (which infiltrate and attack tumors) and B cells (which produce antibodies).

NWBO is already using these next generation methods for producing more potent dendritic cells in its production of DCVax-Direct. Going forward, NWBO's now patented methods of producing more potent dendritic cells will also enable development of the next generation of other two product lines: DCVax-L and DCVax-Prostate. Incorporating the patented methods for more potent dendritic cells will enable production of enhanced versions of these DCVax-L and DCVax-Prostate products.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on NWBO and our 12-month price target is $7.50 per share. 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.

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. The Company is planning Phase I/II clinical trials for its third candidate DCVax-Direct for solid tumors.

Currently, the Company shares are trading at about $3.70 per share which values the Company at about $107 million based on 29 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 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 $7.50 per share values NWBO at $218 million in market cap based on the 29 million shares outstanding. Apparently, risk is high for NWBO at this stage, but return should also be high.

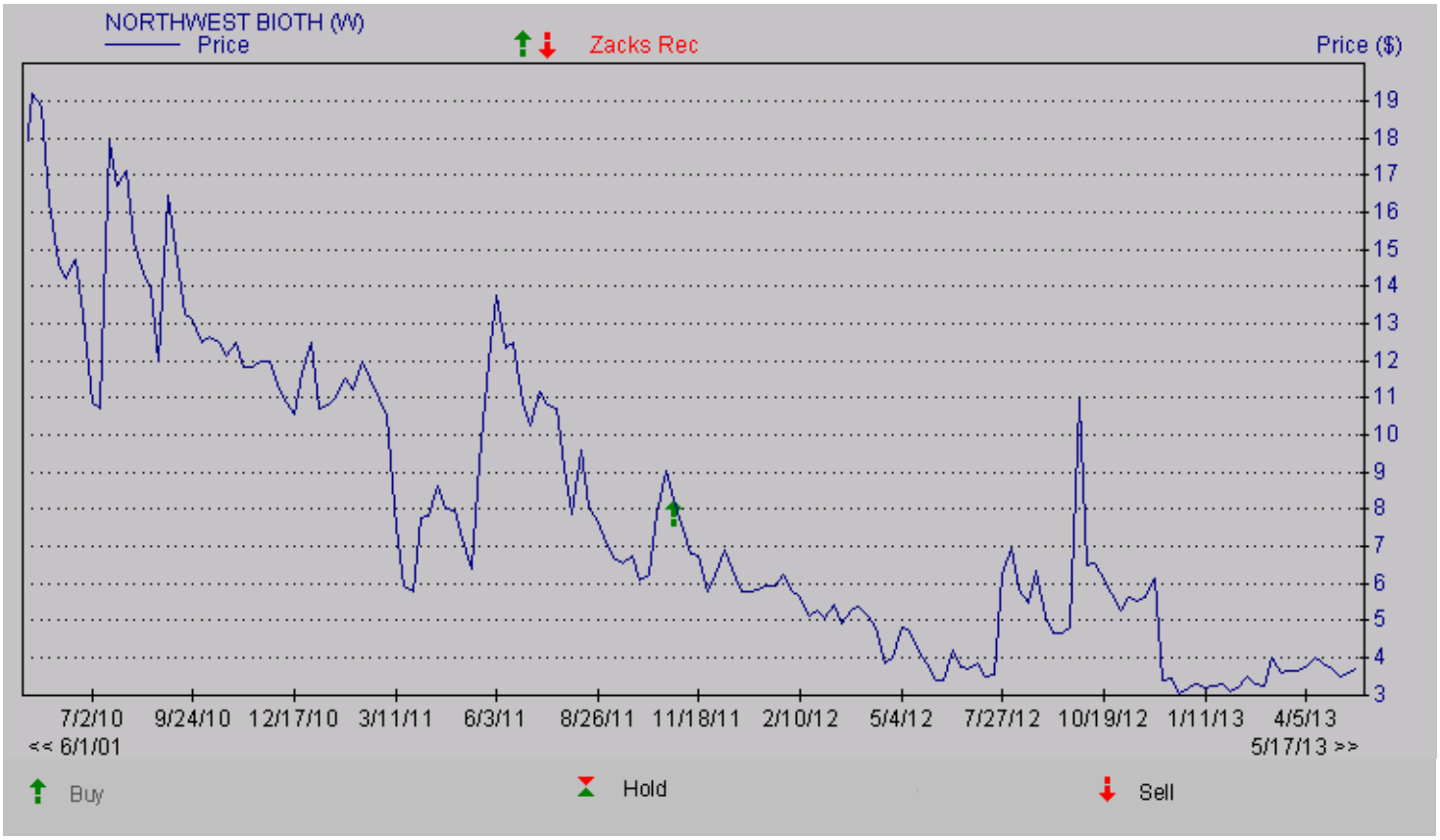
PROJECTED INCOME STATEMENT

	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2E	Q3E	Q4E	FYE	FYE	FYE
Research material sales	$0.01	$0.00	$0.00	$0.00	$0.00	$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	$0.33	$0.12	$0.32	$0.77	$0.14	$0.20	$0.20	$0.20	$0.74	$1.00	$1.50
Total Revenues	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.32**	**$0.77**	**$0.14**	**$0.20**	**$0.20**	**$0.20**	**$0.74**	**$1.00**	**$1.50**
YOY Growth	-	-	-	-	-	-	-	*-39.4%*	*66.7%*	*-37.9%*	*-4.5%*	*629.9%*	*650.0%*
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	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.32**	**$0.77**	**$0.14**	**$0.20**	**$0.20**	**$0.20**	**$0.74**	**$1.00**	**$1.50**
Gross Margin	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$13.45	$3.58	$7.04	$9.94	$8.34	$28.91	$11.61	$11.60	$11.70	$12.00	$46.91	$40.00	$15.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$13.34	$2.18	$2.03	$3.91	$7.55	$15.68	$2.47	$3.00	$3.50	$4.00	$12.97	$17.50	$18.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.01	$0.00	$0.00	$0.01	$0.01	$0.01	$0.00	$0.01	$0.01	$0.01	$0.03	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($26.8)**	**($5.8)**	**($8.7)**	**($13.7)**	**($15.6)**	**($43.8)**	**($13.9)**	**($14.4)**	**($15.0)**	**($15.8)**	**($59.2)**	**($56.5)**	**($31.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($6.0)	($4.4)	($1.4)	($2.8)	($14.9)	($23.5)	($0.5)	($2.5)	($2.5)	($2.5)	($8.0)	($5.0)	($5.0)
Pre-Tax Income	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($30.5)**	**($67.3)**	**($14.4)**	**($16.9)**	**($17.5)**	**($18.3)**	**($67.1)**	**($61.5)**	**($36.5)**
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	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($30.5)**	**($67.3)**	**($14.4)**	**($16.9)**	**($17.5)**	**($18.3)**	**($67.1)**	**($61.5)**	**($36.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*6.8*	*9.6*	*10.1*	*11.1*	*16.2*	*11.8*	*26.7*	*29.3*	*30.0*	*32.0*	*29.5*	*40.0*	*50.0*
Reported EPS	**($4.85)**	**($1.06)**	**($1.00)**	**($1.49)**	**($1.88)**	**($5.72)**	**($0.54)**	**($0.58)**	**($0.58)**	**($0.57)**	**($2.28)**	**($1.54)**	**($0.73)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.61)*	*$5.23*	*$1.61*	*$2.79*	*$0.43*	*$10.05*	*$0.00*	*$2.50*	*$2.50*	*$2.50*	*$7.50*	*$0.00*	*$0.00*
Non GAAP Net Income	**($34.4)**	**($4.9)**	**($8.5)**	**($13.7)**	**($30.1)**	**($57.3)**	**($14.4)**	**($14.4)**	**($15.0)**	**($15.8)**	**($59.6)**	**($61.5)**	**($36.5)**
Non GAAP EPS	**($5.08)**	**($0.51)**	**($0.84)**	**($1.24)**	**($1.86)**	**($4.87)**	**($0.54)**	**($0.49)**	**($0.50)**	**($0.49)**	**($2.02)**	**($1.54)**	**($0.73)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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