Zacks Small-Cap Research

April 2, 2013
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: *Phase III of DCVax-L is accelerating enrollment, 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 (04/01/13)	$3.52
Twelve-Month Target Price	**$10.00**

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 is about to begin in Europe 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	**$3.03**
One-Year Return (%)	**-31.08**
Beta	**1.75**
Average Daily Volume (sh)	**189,812**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$93**
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

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 this 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.

Phase III of DCVax-L Is Moving Forward In Europe

One reason NWBO expects to complete enrollment of the Phase III trial faster is that the Company is cooperating with **PAREXEL International** to move forward with its Europe trials.

On Feb 15, 2013, after an extensive RFP process, the Company selected PAREXEL International to run its 312-patient Phase III trial in Europe. PAREXEL is a leading international CRO with expertise in managing international clinical trials. Over the past 30 years, they have developed significant expertise in oncology, including glioblastoma. Headquartered near Boston, Massachusetts, PAREXEL operates in 71 locations throughout 54 countries around the world, and have over 14,000 employees.

The Company's Phase III trial is well under way in the U.S., currently enrolling at 41 sites. In the U.S., the trial is being managed by a U.S. CRO that does not have operations in Europe that can handle this trial.

The Company's Phase III trial has undergone extensive preparations and regulatory approvals in Europe. The trial is poised to begin enrolling patients in the U.K. soon, and elsewhere in Europe in the next several months.

This engagement is based on extensive efforts NWBO had made in the past three years in terms of manufacturing development, regulatory processes and clinical preparations in Europe.

In the U.K., preparations completed by the Company for the Phase III trial include regulatory approval by the Medicines and Healthcare Products Regulatory Agency (MHRA), nationwide Ethics Committee approval, selection and qualification of the first four trial sites (major opinion leader centers), institutional reviews and approvals at the lead site, Kings College Hospital, and manufacturing technology transfer and validation in the U.K.

In Germany, preparations for the Phase III trial include the establishment of a wholly owned subsidiary (NWBO GmbH) with a highly experienced CEO, as well as selection of 24 candidate trial sites (including all major opinion leader centers in brain cancer), half a year of manufacturing technology transfer followed by a 2-year regulatory process for manufacturing certification by both the national and local regulators in Germany, further followed by development of a validated data package sufficient to support Phase III trial designation, then preparation and submission of the Phase III clinical trial application package to the national regulator (the PEI), and initial preparations for Ethics Committee approvals at trial sites.

As a further step to move forward in Europe for its Phase III trial, the Company has established cross-border manufacturing and distribution for DCVax® In Europe.

This represents a major area of competitive differentiation and strength for NWBO.

The Company and its partners have completed a 7-month process of obtaining the necessary regulatory and institutional approvals in both Germany and the U.K. to expand the scope of the manufacturing in Germany of the Company's DCVax-L product for brain cancer. The scope is being expanded in two major ways: in its geographical reach, and in the product categories covered.

Geographically, these approvals for expanded scope of German manufacturing will enable DCVax-L to be produced in Germany and supplied across borders to the U.K. for the clinical trials.

This approval for cross-border supply of DCVax-L is in addition to the manufacturing capacity in the U.K. already developed by the Company with its partner, Kings College London. Such cross-border supply and distribution will provide valuable flexibility to draw upon manufacturing capacity in either the U.K. or Germany as needed. It will also enable economies of scale for serving all of Europe.

In regard to the **product categories**, these approvals will enable DCVax-L to be produced in Germany not only for the Phase III clinical trial, but also for Hospital Exemption cases under Section 4b of the German Drug law (similar to compassionate use in the U.S.)

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

On March 5, 2013, NWBO announced that its **Phase I/II DCVax-Direct** clinical trial for all inoperable solid tumor cancers is planned to begin within approximately **the next sixty days**. This trial is not blinded and the results will be seen as the trial proceeds. With an efficacy endpoint of tumor regression (i.e., tumor shrinkage or elimination), this trial is expected to yield meaningful ongoing results by the second half of 2013.

This clinical trial is approved by the FDA for all types of solid tumor cancers and is configured to provide rapid results. In the Phase I portion, it will test both safety and a variety of dosing regimes, and will do so in multiple different cancers – avoiding the need to conduct separate Phase I studies in each such cancer, as is usually the case. Then, the trial will go directly into the Phase II portion, testing for efficacy, without the need for another FDA review.

The endpoint for measuring efficacy in the Phase II portion of the trial will be **tumor regression**. This endpoint 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).

Also, in November 2012, NWBO 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**. As part of the collaboration with Sarah Cannon Research UK and LOC, the Company will pursue UK regulatory approval of Phase I/II trials.

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 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.

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.

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.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on NWBO and reiterate our 12-month price target of $10.00. 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.

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 $3.50 per share which values the Company at about $91 million based on 26 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 $10.00 per share values NWBO at $260 million in market cap based on the 26 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.

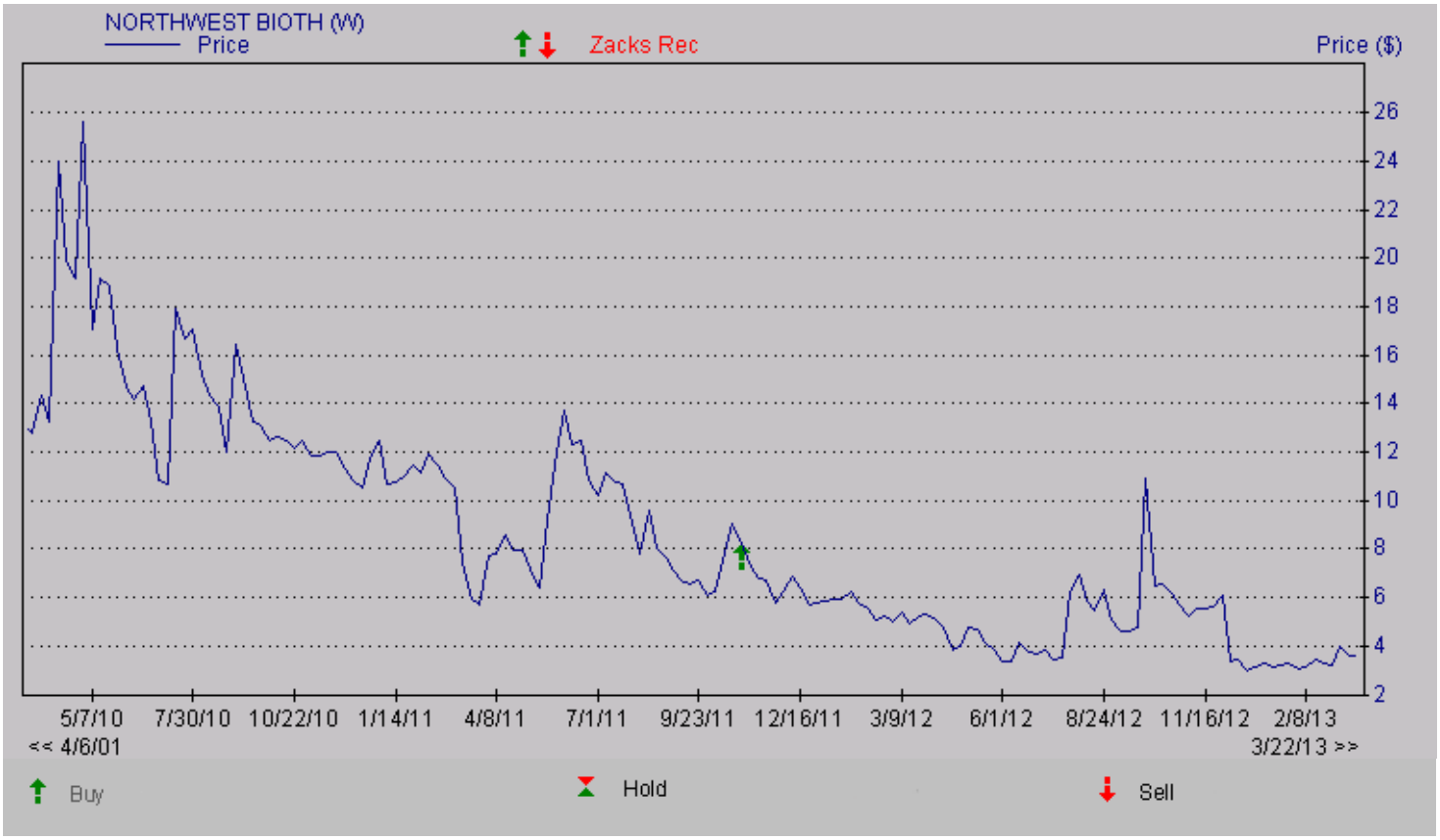
PROJECTED INCOME STATEMENT

	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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The current distribution of Zacks Ratings is as follows on the 1028 companies covered: Buy/Outperform- 14.2%, Hold/Neutral- 80.1%, Sell/Underperform – 5.2%. Data is as of midnight on the business day immediately prior to this publication.

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