Zacks Small-Cap Research

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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 initiated in UK, will be initiated in Germany soon, and is accelerating enrollment in the US; Phase I/II of DCVax-Direct initiated --Outperform*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (11/20/13)	$5.00
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 over 50 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	**$3.03**
One-Year Return (%)	**-43.20**
Beta	**1.79**
Average Daily Volume (sh)	**218,473**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$210**
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)
2012	0.00 A	0.33 A	0.12 A	0.32 A	0.77 A
2013	0.14 A	0.27 A	0.40 A	0.20 E	1.01 E
2014					1.00 E
2015					1.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.51 A	-$0.84 A	-$1.24 A	-$1.86 A	-$4.87 A
2013	-$0.54 A	-$0.40 A	-$0.44 A	-$0.45 E	-$1.81 E
2014					-$1.23 E
2015					-$0.61 E

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

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WHAT'S NEW

- **Balance sheet boosted by $23.5 million new financing;**
- **Phase I/II DCVax-direct initiated, and enrollment will be accelerated;**
- **Phase III DCVax-L for brain cancer is going well in the US;**
- **Phase III DCVax-L for brain cancer is initiated in UK, will be initiated in Germany soon;**
- **Valuation is attractive;**

New financing Boosts Balance Sheet

On Nov. 20, 2013, Northwest Biotherapeutics, Inc. (NWBO) announced the pricing of an underwritten public offering of 4.9 million units at a public offering price of $4.80 per unit, resulting in gross proceeds of **$23.5 million**.

Each unit consists of one share of common stock, and a warrant to purchase 0.5 shares of common stock at an exercise price of $6.00 per share. The warrants are immediately exercisable and expire on the fifth anniversary of the date of issuance. The shares of common stock and warrants are immediately separable and will be issued separately.

The offering is expected to close on November 25, 2013, subject to the satisfaction of customary closing conditions. Northwest has granted the underwriters a 30-day option to purchase up to 734,374 additional shares of common stock and/or additional warrants to purchase up to 367,187 shares of common stock to cover over-allotments, if any.

This financing is important to NWBO. It not only provides much needed cash for advancing its clinical programs, but also validates the company's technology.

Also on July 31, 2013, Cognate BioServices agreed to convert an aggregate of $11.6 million in accounts payable into shares of common stock at a conversion price of $4.00 per share, which resulted in the issuance in August 2013 of an aggregate of 2.9 million shares of common stock. The conversion shares are subject to a lock-up period of 18 months from the date of their issuance. Under the lock-up, the shares cannot be sold or traded.

On a going forward basis, NW Bio and Cognate agreed to establish a regular ongoing arrangement for payment of at least half of each invoice in stock, and the remainder in cash, at $4.00 per share. The arrangement will continue until terminated by mutual agreement.

Net cash outflows from operations were $23.2 million for the nine months ended September 30, 2013.

As of September 30, 2013, NWBO had cash and cash equivalents of $2.9 million. Current cash balance combined with proceeds from the new financing will last through 2Q14.

Third Quarter 2013 Financials

There was no revenue for the third quarter ended September 30, 2013.

Research and development expense was a combined (cash and non-cash) total of $12.8 million for the three months ended September 30, 2013 compared to $9.9 million for the three months ended September 30, 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, 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 included $2.6 million of cash expenses, and $0.5 million of non-cash charges, for a combined total of $3.1 million for the three months ended September 30, 2013 compared to $3.9 million for the three months ended September 30, 2012. The decrease in general and administrative expenses from the prior period is as a result of decrease in administrative costs for the Company's expanded product programs, and by a decrease in public relations and investor relations services and other consulting expenses of $0.8 million, and a $0.5 million decrease in stock based compensation expense.

GAAP net loss was $7.9 million in cash outlays and $15.0 million in non-cash accounting charges (i.e. increase in stock-based compensation, inducement expense, issuance of warrants and debt discount charges etc.), for a combined (cash and non-cash) total net loss of $22.9 million ($0.65 per share) for the three months ended September 30, 2013 compared to a net loss of $16.5 million for the three months ended September 30, 2012.

Excluding the $7.5 million inducement expense, net loss was $15.5 million ($0.44 per share) for the third quarter of 2013.

As of September 30, 2013 NWBO had over 50 clinical trial sites in operation in the US and UK in its **Phase III trial** with DCVax-L, compared to 41 clinical trial sites in the US only at September 30, 2012. At September 30, 2013, the company also had substantially expanded other clinical trial related operations including extensive preparations and launch of the Phase III DCVax-L clinical trial in the UK, and launch of the Phase I/II DCVax-Direct trial in the US.

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 of next year, and potentially reaching top line results by the end of next year.

DCVax®-Direct Phase I/II trial initiated for all solid Tumor cancers

On June 13, 2013, NWBO announced that its 60-patient **Phase I/II** clinical trial of DCVax-Direct for all inoperable solid tumor cancers has been initiated at The University of Texas MD Anderson Cancer Center in Houston, Texas.

On September 24, 2013, NWBO announced that the MD Anderson Cancer Center Orlando has become the second site participating in the Phase I/II clinical trial of DCVax-Direct. MD Anderson-Orlando is one of the predominant cancer centers in the Southeast United States. The wide range of cancers treated at the institution make it an excellent fit for this Phase I/II trial which is very broadly targeted, enrolling patients with all types of solid tumors for which surgery is not possible.

These two prominent centers bring a very strong combined patient flow, which will help accelerate the enrollment of the trial. In addition, other trial sites in the US and Europe are in various stages of preparation.

DCVax-Direct offers a potential new treatment option for the many clinical situations in which patients' tumors are considered inoperable either because of the location or type of cancer, or because of the spread of multiple tumors. A large number of patients with lung, colon, pancreatic, liver, ovarian, melanoma, head and neck, and other cancers such as sarcomas face this situation today, and it carries a bleak prognosis.

It is anticipated that multiple other leading centers in both the US and UK will be joining as trial sites as well. Since the Company's announcement of plans for this trial, NWBO has received inquiries from both patients and medical centers across the country seeking to participate.

The trial is expected to enroll groups or "cohorts" of patients with numerous different types of cancers, including pancreatic, colon, liver, melanoma, and various other 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. Accordingly, it is anticipated that early results of the trial may be emerging throughout the remainder of 2013.

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).

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.**

NWBO added to the MSCI global microcap index

On June 3, 2013, NWBO announced that the company was added to the MSCI Global MicroCap Index as of the close of the stock market on May 31, 2013.

MSCI Inc. is a leading provider of investment decision support tools to investors worldwide, including asset managers, banks, hedge funds and pension funds. Among MSCI's key products are its worldwide indices used in assessing portfolio risks and performance. Companies are moved both in and out of these key indices twice a year based on certain size and liquidity requirements.

The addition of NWBO to the MSCI global microcap index greatly raises the visibility of the company and enhances the trading liquidity.

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. In addition, NWBO initiated a Phase I/II clinical trial for its third candidate DCVax-Direct for solid tumors.

Currently, the Company shares are trading at about $5.00 per share which values the Company at about $210 million based on 42 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 $315 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

	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	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	$0.27	$0.40	$0.20	$1.01	$1.00	$1.50
Total Revenues	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.32**	**$0.77**	**$0.14**	**$0.27**	**$0.40**	**$0.20**	**$1.01**	**$1.00**	**$1.50**
YOY Growth	-	-	-	-	-	-	-	-	*233.3%*	*-37.9%*	*30.7%*	*629.9%*	*451.5%*
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**	**$0.27**	**$0.40**	**$0.20**	**$1.01**	**$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	$8.38	$12.79	$12.80	$45.59	$40.00	$15.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$13.34	$2.18	$2.03	$3.91	$7.55	$15.68	$2.47	$3.29	$3.06	$3.50	$12.32	$17.50	$18.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.01	$0.00	$0.00	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.02	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($26.8)**	**($5.8)**	**($8.7)**	**($13.7)**	**($15.6)**	**($43.8)**	**($13.9)**	**($11.4)**	**($15.5)**	**($16.1)**	**($56.9)**	**($56.5)**	**($31.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($6.0)	($4.4)	($1.4)	($2.8)	($14.9)	($23.5)	($0.5)	($0.2)	($7.5)	($2.5)	($10.6)	($5.0)	($5.0)
Pre-Tax Income	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($30.5)**	**($67.3)**	**($14.4)**	**($11.6)**	**($22.9)**	**($18.6)**	**($67.5)**	**($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)**	**($11.6)**	**($22.9)**	**($18.6)**	**($67.5)**	**($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*	*29.1*	*35.3*	*41.5*	*33.1*	*50.0*	*60.0*
Reported EPS	**($4.85)**	**($1.06)**	**($1.00)**	**($1.49)**	**($1.88)**	**($5.72)**	**($0.54)**	**($0.40)**	**($0.65)**	**($0.45)**	**($2.04)**	**($1.23)**	**($0.61)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.61)*	*$5.23*	*$1.61*	*$2.79*	*$0.43*	*$10.05*	*$0.00*	*$0.00*	*$7.45*	*$0.00*	*$7.45*	*$0.00*	*$0.00*
Non GAAP Net Income	**($34.4)**	**($4.9)**	**($8.5)**	**($13.7)**	**($30.1)**	**($57.3)**	**($14.4)**	**($11.6)**	**($15.5)**	**($18.6)**	**($60.1)**	**($61.5)**	**($36.5)**
Non GAAP EPS	**($5.08)**	**($0.51)**	**($0.84)**	**($1.24)**	**($1.86)**	**($4.87)**	**($0.54)**	**($0.40)**	**($0.44)**	**($0.45)**	**($1.81)**	**($1.23)**	**($0.61)**

Source: Company filings and Zacks Investment Research estimates

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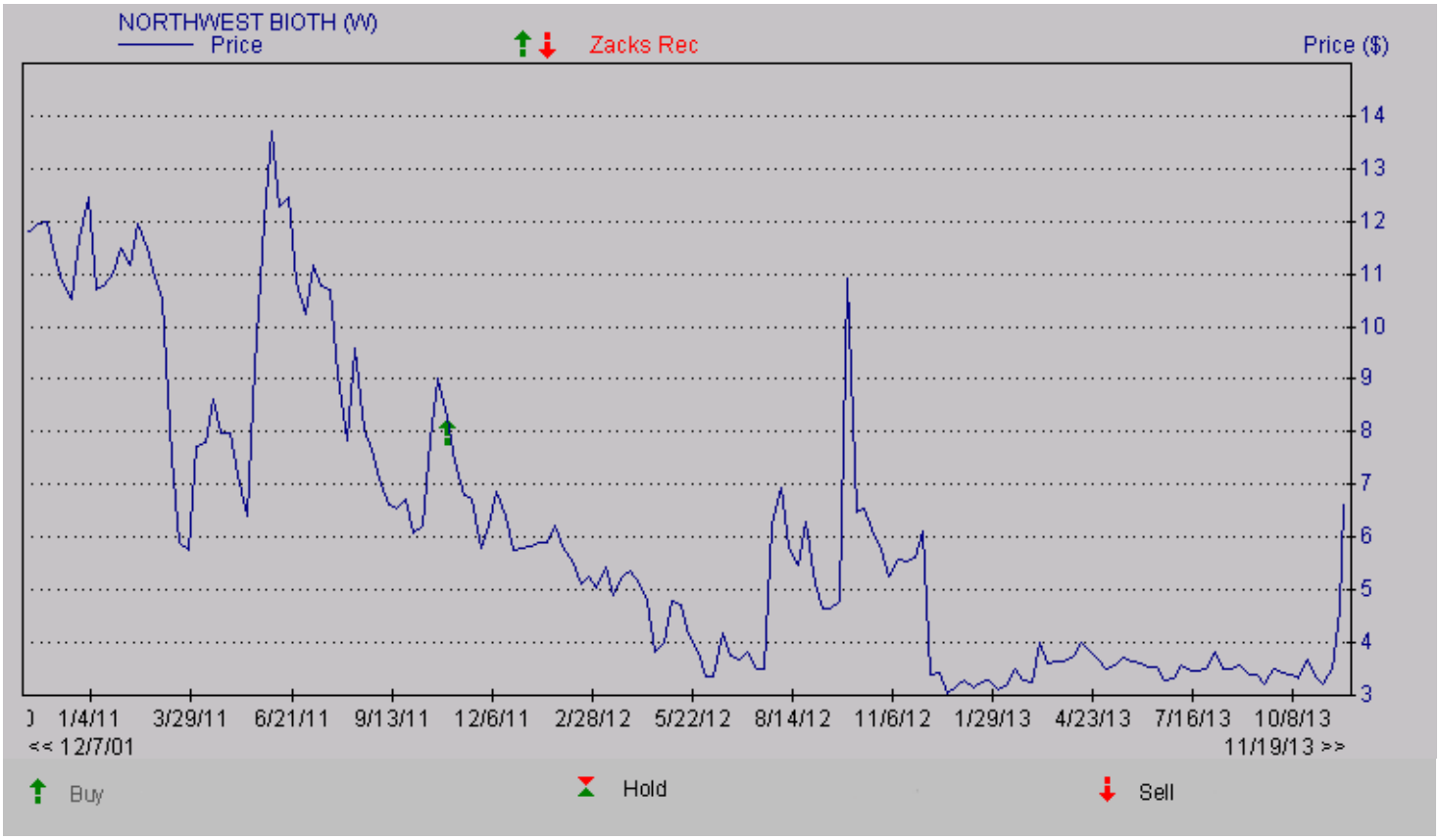
HISTORICAL ZACKS RECOMMENDATIONS



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