Zacks Small-Cap Research

August 26, 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 I/II of DCVax-Direct initiated, Phase III of DCVax-L initiated in UK, and is accelerating enrollment in the US--Outperform*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (08/23/13)	$3.59
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 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	**$3.03**
One-Year Return (%)	**-43.20**
Beta	**1.79**
Average Daily Volume (sh)	**218,473**
Shares Outstanding (mil)	**38**
Market Capitalization ($mil)	**$140**
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	0.27 A	0.20 E	0.20 E	0.81 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	-$0.40 A	-$0.47 E	-$0.57 E	-$1.97 E
2014					-$1.54 E

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

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WHAT'S NEW

- **NWBO reports second quarter of 2013 financials;**
- **Balance sheet boosted by new financing and conversion of account receivables;**
- **Phase I/II DCVax-direct initiated;**
- **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 added to the MSCI global microcap index;**

NWBO reports second quarter of 2013 financials

There was no revenue for the second quarter of 2013.

Research and development expense was a combined (cash and non-cash) total of $8.4 million for the three months ended June 30, 2013 compared to $7.0 million for the three months ended June 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.

As of June 30, 2013 NWBO had over 50 clinical trial sites in operation in the U.S in its Phase III trial with DCVax-L, compared to 25 clinical trial sites at June 30, 2012. At June 30, 2013, NWBO also had substantially expanded other clinical trial related operations compared with June 30, 2012 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, in addition to costs related to fully operational and approved manufacturing in Germany, cost of an established wholly owned German subsidiary, manufacturing activity in the U.K. and nearly 30 clinical trial sites in the U.K. and Germany in varying stages of preparation.

General and administrative expense included $1.9 million of cash expenses, and $1.4 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 $3.3 million for the three months ended June 30, 2013 compared to $2.0 million for the three months ended June 30, 2012. The increase in general and administrative expenses from the prior period is as a result of increased administrative costs for the Company's expanded product programs, and increased public relations and investor relations services and other consulting expenses of $1.5 million, offset by a $0.2 million decrease in stock based compensation expense.

Net loss was $8.2 million in cash outlays and $3.4 million in non-cash accounting charges (i.e. increase in accounts payable, stock-based compensation, issuance of warrants and debt discount charges etc.), for a combined (cash and non-cash) total net loss of $11.6 million ($0.40 per share) for the three months ended June 30, 2013 compared to a net loss of $10.2 million ($1.00 per share) for the three months ended June 30, 2012.

Net cash outflows from operations were $15.3 million for the six months ended June 30, 2013.

At June 30, 2013, cash and cash equivalents totaled $2.0 million, compared to $7.4 million at December 31, 2012.

New financing boosts balance sheet

On Aug. 9, 2013, NWBO announced that it has entered into an agreement with institutional investors, including an existing healthcare focused institutional investor and a dedicated healthcare mutual fund for a registered direct placement of **$15 million** of common stock at the price of $3.35 per share plus an

additional over-allotment warrant, exercisable within 12 months, to sell an additional $3.75 million of common stock at the same price which, if exercised, would result in gross proceeds to the Company of $18.75 million.

In addition, the Company will issue to each investor 25% warrant coverage to purchase shares of common stock with an exercise price of $4.00 per share. These warrants are exercisable beginning six months after closing, with an exercise period of five years.

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.

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.

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.**

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 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 Aug. 9, 2013, NWBO announced that it has received a decision from the German regulatory agency under which the Company's Phase III clinical trial will be able to proceed in Germany after the Company makes three modifications, none of which affect the body of the trial or the bases for seeking product approval.

Two of the three modifications directed by agency involve modest textual matters, as follows:

- One of the eligibility criteria for the trial is that patients must have adequate bone marrow function, since the immune cells with which DCVax is made are obtained through a leukapheresis blood draw. Currently the eligibility criteria set a general standard for bone marrow function, and identify a specific quantitative measure as an example ("e.g.,"). The agency has directed that the "e.g.," be removed and that the same quantitative measure be made into a requirement rather than an example of the requirement.

- Certain information about the risks and benefits of the DCVax treatment is currently contained in one of the key clinical documents (the Investigator's Brochure). The agency has directed that the same information also be added into the trial Protocol document.

The third modification involves dropping an extra arm of the trial which is gathering data on patients who do not meet the eligibility criteria for enrollment in the body of the trial which will form the basis for any product approval decision.

The extra arm of the trial is for patients who may have unusually aggressive cancer, such that they already have progression (tumor recurrence) by the end of 6 weeks of post-surgery radiation treatments as part of standard of care, when eligibility for the DCVax trial is determined. In these cases, today's imaging technology cannot distinguish between radiation damage or tumor re-growth. These patients are not eligible for the body of the trial, but are offered enrollment in a side group to receive DCVax treatment. This side group is not part of the clinical results or statistics which will form the basis for seeking product approval, but it provides additional data collection. Accordingly, dropping this side group in Germany as directed by the agency can readily be done without impacting the trial. The trial will continue to include the extra arm in countries other than Germany.

NWBO plans to make these modifications right away, and proceed as soon as possible.

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. 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 $140 million based on 38 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 $285 million in market cap based on the 38 million shares outstanding. Apparently, risk is high for NWBO at this stage, but return should also be high.

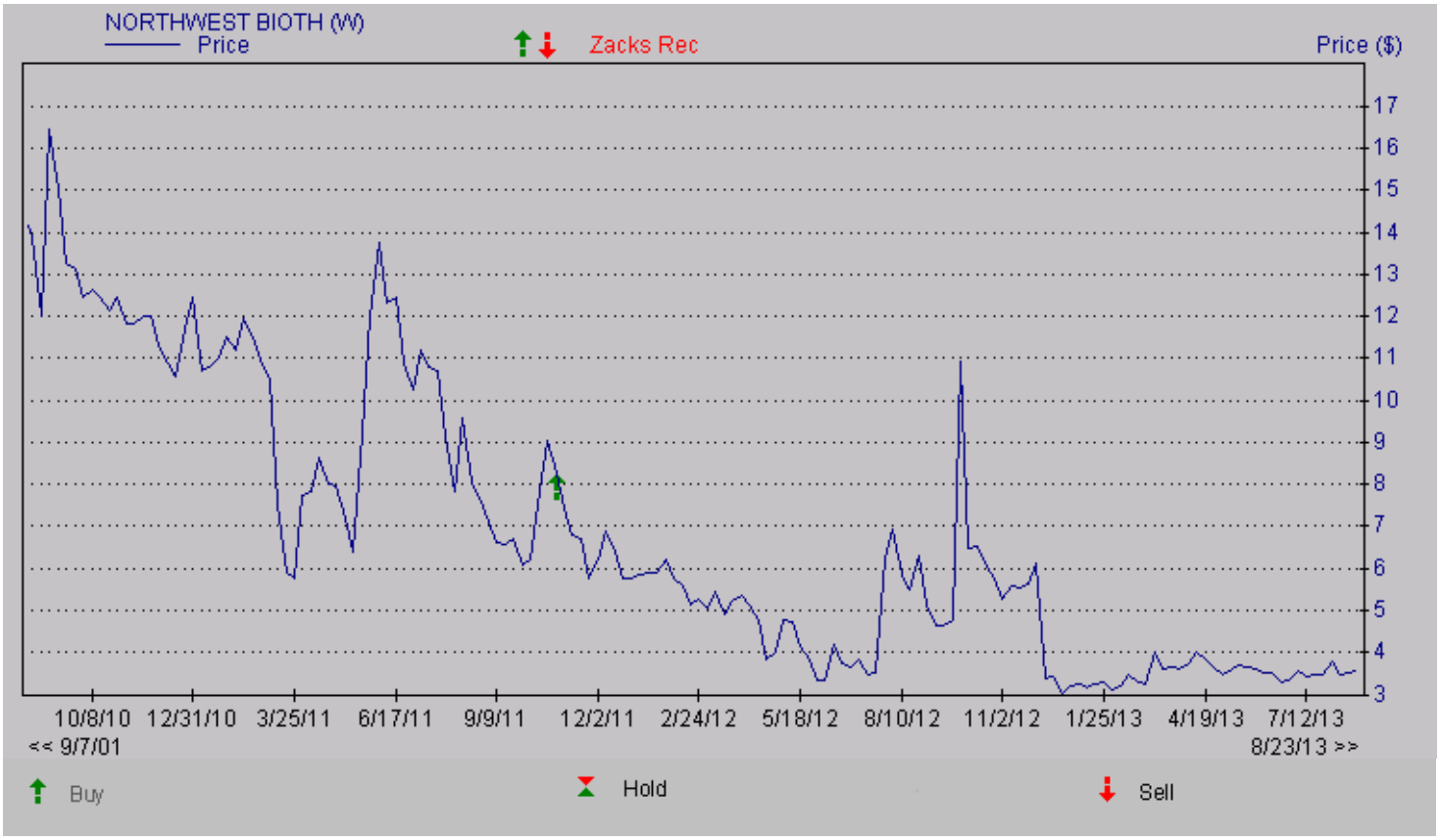
PROJECTED INCOME STATEMENT

	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	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	$0.27	$0.20	$0.20	$0.81	$1.00	$1.50
Total Revenues	**$0.01**	**$0.00**	**$0.33**	**$0.12**	**$0.32**	**$0.77**	**$0.14**	**$0.27**	**$0.20**	**$0.20**	**$0.81**	**$1.00**	**$1.50**
YOY Growth	-	-	-	-	-	-	-	-	*66.7%*	*-37.9%*	*4.8%*	*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**	**$0.20**	**$0.20**	**$0.81**	**$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	$11.70	$12.00	$43.69	$40.00	$15.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$13.34	$2.18	$2.03	$3.91	$7.55	$15.68	$2.47	$3.29	$3.50	$4.00	$13.26	$17.50	$18.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.01	$0.00	$0.00	$0.01	$0.01	$0.01	$0.00	$0.00	$0.01	$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)**	**($15.0)**	**($15.8)**	**($56.2)**	**($56.5)**	**($31.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($6.0)	($4.4)	($1.4)	($2.8)	($14.9)	($23.5)	($0.5)	($0.2)	($2.5)	($2.5)	($5.6)	($5.0)	($5.0)
Pre-Tax Income	**($32.8)**	**($10.1)**	**($10.2)**	**($16.5)**	**($30.5)**	**($67.3)**	**($14.4)**	**($11.6)**	**($17.5)**	**($18.3)**	**($61.8)**	**($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)**	**($17.5)**	**($18.3)**	**($61.8)**	**($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*	*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)**	**($0.40)**	**($0.58)**	**($0.57)**	**($2.10)**	**($1.54)**	**($0.73)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.61)*	*$5.23*	*$1.61*	*$2.79*	*$0.43*	*$10.05*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($34.4)**	**($4.9)**	**($8.5)**	**($13.7)**	**($30.1)**	**($57.3)**	**($14.4)**	**($11.6)**	**($17.5)**	**($18.3)**	**($61.8)**	**($61.5)**	**($36.5)**
Non GAAP EPS	**($5.08)**	**($0.51)**	**($0.84)**	**($1.24)**	**($1.86)**	**($4.87)**	**($0.54)**	**($0.40)**	**($0.58)**	**($0.57)**	**($2.10)**	**($1.54)**	**($0.73)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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