Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-OTC)

NWBO: *DCVax-L Phase III clinical trial on track in both the US and Europe* -- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (09/14/12)	$0.29
Twelve-Month Target Price	**$0.75**

OUTLOOK

Northwest Biotherapeutics is making multiple progresses in its ongoing Phase III clinical trial of DCVax-L for brain cancer. This trial has been expanded in Britain, and is poised to proceed in Germany soon. Further, the US clinical trial site has been expanded ahead of schedule with 41 sites open and recruiting as of May 17, 2012.

The German government grant of $5.5 million not only boosts its balance sheet, but more importantly validates the Company's platform technology and clinical programs for cancer immunotherapy.

Current valuation is attractive. We maintain our Outperform rating.

SUMMARY DATA

52-Week High	**$0.57**
52-Week Low	**$0.19**
One-Year Return (%)	**-28.42**
Beta	**1.60**
Average Daily Volume (sh)	**634,586**
Shares Outstanding (mil)	**176**
Market Capitalization ($mil)	**$52**
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	0.00 E	0.00 E	0.33 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	-$0.11 A	-$0.13 A	-$0.07 A	-$0.04 A	-$0.32 A
2012	-$0.07 A	-$0.06 A	-$0.05 E	-$0.05 E	-$0.22 E
2013					-$0.15 E
2014					-$0.11 E

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

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WHAT'S NEW

NWBO has DCVax-L Phase III Trials in Both the US and Europe

Northwest Biotherapeutics (NWBO) recently updated its DCVax-L Phase III clinical trials for brain cancer in both the US and Europe.

Phase III trial of DCVax-L approved in the UK

On August 23, 2012, Northwest announced that it has received approval from the United Kingdom health authority for the Company's 300-patient Phase III clinical trial of DCVax®-L immune therapy for Glioblastoma multiforme brain cancer (GBM) to proceed in the U.K.

This Phase III clinical trial is already under way in the U.S., at 41 sites across the country. NWBO is now expanding this Phase III trial to make it an international trial, by including clinical trial sites in Europe. This international approach can potentially save years of time in clinical trials, compared with conducting trials in the U.S. and Europe separately.

NW Bio has already obtained Ethics Committee approval for this trial on a centralized basis from the National Research Ethics Committee in the U.K. Such Ethics Committee approval is equivalent to Institutional Review Board (IRB) approvals in the U.S. This centralized approval from the National Research Ethics Committee applies throughout the U.K., eliminating the need to obtain Ethics Committee (IRB) approvals at each clinical trial site (which typically takes months at each site in the U.S.).

Phase III trial of DCVax-L in the US is going well

On May 17, 2012, Northwest Biotherapeutics (NWBO) announced that it already has 41 clinical trial sites open and recruiting across the United States in its ongoing clinical trial of DCVax-L immune therapy for Glioblastoma multiforme (GBM).

This is ahead of the Company's previous projection of 40 sites by the end of Q2, 2012. The Company plans to continue adding clinical trial sites in the US and Europe, and expects to have at least 60 sites open and enrolling by the end of Q3, 2012. The Company plans to have total of 80 sites for the trial.

The Company also announced that the FDA has accepted an amendment of the clinical trial. The amendment does not make any change in the treatment regimen, which leaves all data collected to date intact for use in the trial's overall results. The amendment includes the following:

- The previous Phase II trial has been designation as a **Phase III** trial;
- Expanded and enhanced statistical endpoint analyses;
- With the addition of another cohort of patients which can potentially expand the application of DCVax-L, the trial size has been increased up to 300 patients from previous 240 patients;
- Addition of interim analyses for efficacy;

As a reminder, the previous Phase II trial of DCVax-L is an ongoing **randomized, placebo controlled**, **double blinded (2:1)** study with a cross-over arm allowing control patients to be treated with DCVax-L in the event that their cancer progresses. The primary end point is progression free survival (PFS) with overall survival (OS) as the secondary end point. The original 240-patient trial is designed to enable the Company to petition the FDA for **accelerated approval** if the study generates results similar to those achieved in the two prior Phase I clinical trials.

The Implications

This announcement is another indication that NWBO is making further progress in its key program DCVax-L for brain cancer.

The Company has continuously beats its expectations about adding new clinical trial sites. In addition, the official designation of the previous Phase II trial of DCVax-L as a Phase III trial makes DCVax-L one step closer to the market. This is also a further indication that management is making every effort to make this breakthrough medicine to brain cancer patients around the world though the evolution of this trial to a Phase III trial is no assurance of the outcome.

With the new announcement about the trial sites update and amendment to the Phase II trial, the Company's lead program has advanced and emerged as 300-patient, international **Phase III** trial, involving some of the best institutions in the US, UK and Germany.

The Company plans to petition for product approval in the U.S. and/or the European Union if the Phase III trial results are positive. In such a case, DCVax-L could potentially be the second active immunotherapy for cancer in the US and the first active immunotherapy for cancer in the EU.

Worldwide Production Capacity For DCVax®-L Expanded

In order to meet the demand of the DCVax-L Phase III clinical trial in both the US and Europe, NWBO has expanded its worldwide manufacturing capacity of DCVax-L.

On August 8, 2012, NWBO entered into amended agreements to double the production capacity in the U.S. for the manufacture of the Company's DCVax®-L immune therapy for Glioblastoma multiforme (GBM) patients.

The doubling of U.S. production capacity for DCVax®-L is being undertaken to respond to growing demand from clinical trial sites in the Company's 300-patient, Phase III clinical trial in GBM, which is under way at 41 sites across the U.S. The expansion is being undertaken on an expedited basis, with completion expected in about eight to ten weeks. This initial doubling of capacity will involve adding more production lines in the cGMP (clean room) facilities of **Cognate BioServices** (NW Bio's contract manufacturer) that are already dedicated to NWBO's programs. Thereafter, further expansion of capacity is planned on a modular basis, as needed, through additional facilities.

In Germany, the Company's partner, Fraunhofer IZI, has received all necessary regulatory approvals and certification for manufacturing of DCVax®-L, and is fully operational for such manufacturing. In the U.K., the Company's partner, Kings College London, already has all the necessary regulatory approvals as well, and is in the final stages of preparations for manufacturing. Each of these partners is highly experienced with living cell products, and each is operating under common SOPs (Standard Operating Procedures) and common oversight by Cognate BioServices to ensure worldwide consistency in manufacturing operations.

Both Fraunhofer and Kings College will produce DCVax®-L for the Company's ongoing Phase III clinical trial in GBM, as well as for compassionate treatment programs. The Phase III trial is expected to involve up to 30 sites across Germany, and 8 sites across the U.K., in addition to the 41 sites already in operation in the U.S.

Both Fraunhofer and Kings College will be able to deliver DCVax®-L products anywhere in Europe. This will enable them to handle temporary added-capacity needs for each other, if there are surges in demand from clinical trial sites, such as has been experienced in the U.S. Fraunhofer and Kings College will also be able to handle production for clinical sites in additional European countries besides Germany and the U.K. NWBO has also begun discussions with both partners regarding staged expansion of manufacturing capacity in each country.

These manufacturing bases, in three countries on two continents, form a strong and flexible manufacturing network for delivery of DCVax®-L throughout the U.S. and Europe. This production capacity has been obtained without major capital cost to NWBO.

$5.5 Million Government Grant Awarded for DCVax-L Manufacturing and Clinical Trial

On May 1, 2012, Northwest Biotherapeutics, Inc. (NWBO) received approval of a major grant of € 4.15 million (~$5.5 million) from **the Sächsische Aufbau Bank (SAB)** in Germany. The grant will reimburse fifty percent (50%) of the costs for manufacturing in Germany and for NWBO's clinical trial with DCVax®-L for brain cancer at up to 30 clinical sites in Germany.

As a reminder, NWBO has an ongoing 240-patient double blind, randomized, placebo-controlled **Phase II** clinical trial of DCVax-L for newly diagnosed glioblastoma multiforme (GBM). The clinical sites in Germany and their data will become part of the ongoing Phase II trial, and will also provide domestic data for European Union (EU) approval processes.

The approval of the grant is the result of a close collaboration between NWBO and its German partner **the Fraunhofer IZI Institute**. This is one of the largest such R&D grants ever made by the SAB.

Our takeaways from the grant award:

- This grant will help NWBO build its base in Germany, and accelerate NWBO's brain cancer clinical trial in Europe as well as the US.
- This grant not only boosts the Company's balance sheet, but more importantly, it validates the Company's DCVax platform technology and clinical programs for cancer immunotherapy.
- It's also a reward for management's commitment to bringing innovative cancer immunotherapy to the medical community including patients and physicians.
- With the support of the grant and local government, NWBO will have the opportunity to expand its development and long-term marketing activities for DCVax-L in Europe.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on NWBO. Our 12-month price target is $0.75.

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.

The Provenge case is positive for the whole class of cell-based therapeutics because it has defined the regulatory path for such drug candidates. 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.

Currently, the Company shares are trading at about $0.29 per share which values the Company at about $52 million based on 176 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 mid to 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 $0.75 per share values NWBO at $132 million in market cap based on the 176 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.

RISKS

Liquidity is our Chief Concern

The Company has experienced recurring losses from operations. As of June 30, 2012, the Company had only $430,000 in cash.

Even with the $5 million German government grant and current financing plan, cash burn is still a concern. As the Company advances its lead program DCVax-L into Phase III clinical trial, R&D costs will increase, not to mention the costs of other clinical programs. According to our model, the Company will incur operational loss of $30 million in fiscal 2012 alone. Although current financing plan provides some cushion, we believe the Company needs to tap the capital market very soon and do so in a regular basis down the road before a long term financing is secured.

We remind investors that equity financing will dilute existing shareholder base and reduce its share price.

NWBO is still a development stage biotech company. Although lead candidates DCVax-L and DCVax-Prostate have or will, enter into pivotal trials, failure cannot be ruled out completely.

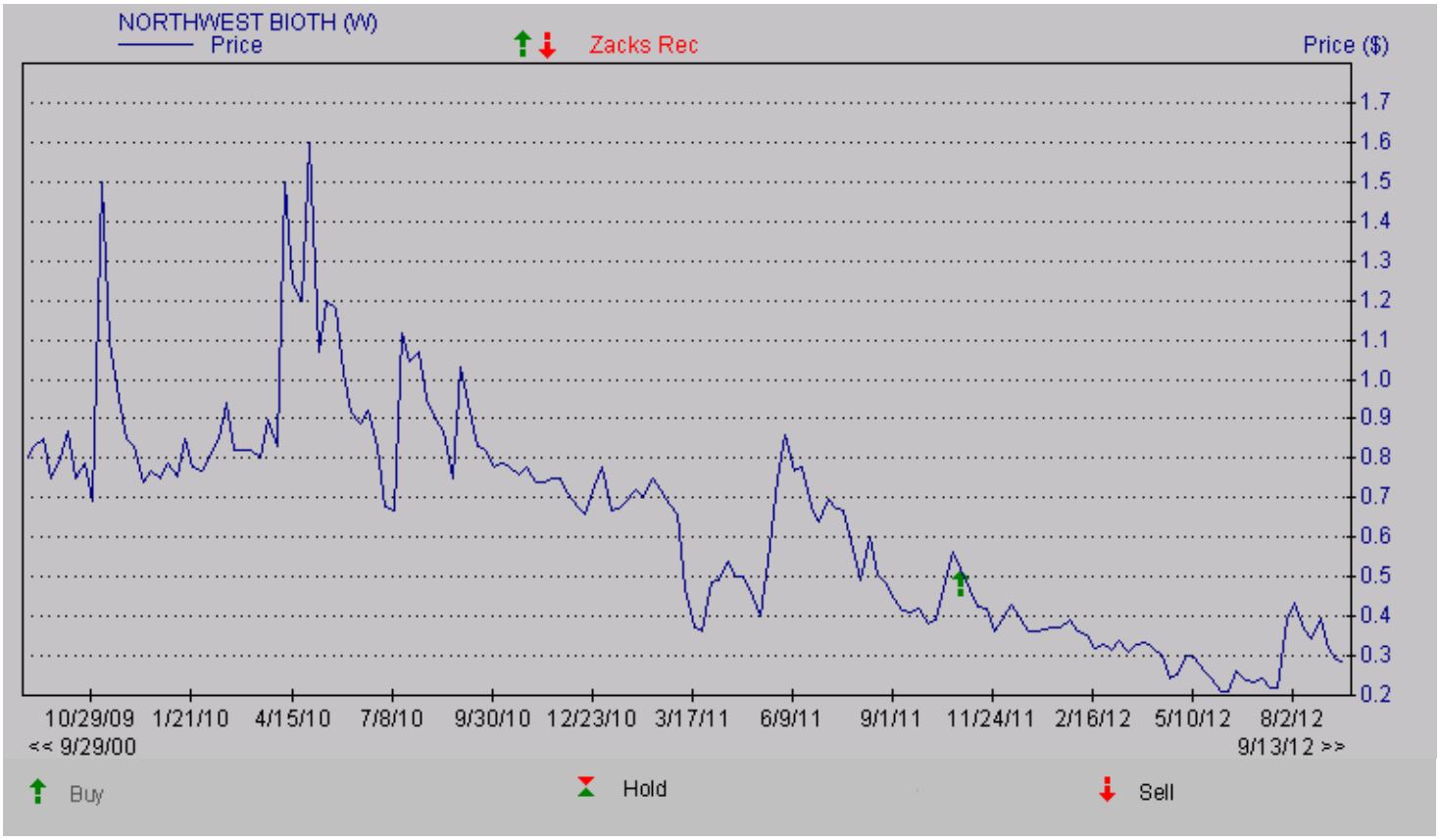
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3E	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	$0.00	$0.00	$0.33	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$0.01**	**$0.00**	**$0.01**	**$0.00**	**$0.33**	**$0.00**	**$0.00**	**$0.33**	**$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**	**$0.00**	**$0.00**	**$0.33**	**$0.00**	**$0.00**	**$0.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$4.44	$3.47	$3.56	$1.98	$13.45	$3.58	$7.04	$4.50	$5.50	$20.62	$14.50	$12.00	$10.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$2.32	$5.56	$2.80	$2.66	$13.34	$2.18	$2.03	$2.50	$2.50	$9.21	$11.50	$12.50	$14.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.00	$0.00	$0.00	$0.00	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($6.8)**	**($9.0)**	**($6.4)**	**($4.6)**	**($26.8)**	**($5.8)**	**($8.7)**	**($7.0)**	**($8.0)**	**($29.5)**	**($26.0)**	**($24.5)**	**($24.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($1.7)	($3.3)	$6.8	($7.9)	($6.0)	($4.4)	($1.4)	($2.5)	($2.5)	($10.8)	($7.5)	($5.0)	($5.0)
Pre-Tax Income	**($8.4)**	**($12.3)**	**$0.5**	**($12.6)**	**($32.8)**	**($10.1)**	**($10.2)**	**($9.5)**	**($10.5)**	**($40.3)**	**($33.5)**	**($29.5)**	**($29.0)**
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)**	**($9.5)**	**($10.5)**	**($40.3)**	**($33.5)**	**($29.5)**	**($29.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*77.1*	*83.9*	*123.1*	*149.3*	*108.4*	*153.6*	*162.4*	*185.0*	*220.0*	*180.2*	*230.0*	*260.0*	*310.0*
Reported EPS	**($0.11)**	**($0.15)**	**$0.00**	**($0.08)**	**($0.30)**	**($0.07)**	**($0.06)**	**($0.05)**	**($0.05)**	**($0.22)**	**($0.15)**	**($0.11)**	**($0.09)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$1.46*	*($9.21)*	*$6.15*	*($1.61)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($8.4)**	**($10.9)**	**($8.7)**	**($6.4)**	**($34.4)**	**($10.1)**	**($10.2)**	**($9.5)**	**($10.5)**	**($40.3)**	**($33.5)**	**($29.5)**	**($29.0)**
Non GAAP EPS	**($0.11)**	**($0.13)**	**($0.07)**	**($0.04)**	**($0.32)**	**($0.07)**	**($0.06)**	**($0.05)**	**($0.05)**	**($0.22)**	**($0.15)**	**($0.11)**	**($0.09)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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