Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: Zacks Company Report

NWBO: Updated Positive data from Phase I of DCVax-Direct reported; Three new Phase II combination trial to be initiated; Phase III of DCVax-L remains on track

Current Price (01/04/17)	$0.35
Valuation	**$2.00**

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 has completed enrolling patients and data "events" have been accumulating towards the endpoints of the Trial.

Encouraging data from Phase I/II study of DCVax-Direct reported and three Phase II combination trials to be initiated soon.

Current valuation is attractive.

SUMMARY DATA

52-Week High	**$3.06**
52-Week Low	**$0.32**
One-Year Return (%)	**-87.72**
Beta	**1.70**
Average Daily Volume (sh)	**3,866,914**
Shares Outstanding (mil)	**125**
Market Capitalization ($mil)	**$55**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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)
2014	0.00 A	0.00 A	0.58 A	0.87 A	1.45 A
2015	0.19 A	0.39 A	0.29 A	0.86 A	1.74 A
2016	0.24 A	0.16 A	0.16 A	0.16 E	0.71 E
2017					0.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.45 A	-$0.45 A	-$0.44 A	-$0.38 A	-$1.71 A
2015	-$0.33 A	-$0.51 A	-$0.17 A	-$0.59 A	-$1.63 A
2016	-$0.18 A	-$0.14 A	-$0.22 A	-$0.19 E	-$0.75 E
2017					-$0.59 E

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

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WHAT'S NEW

Balance Sheet Boosted by New Financing

In late October 2016, Northwest entered into a definitive agreement with an institutional investor for a registered direct offering with gross proceeds of approximately **$5 million**.

Pursuant to the agreement, the Company has agreed to sell to the investor up to 14 million shares of the Company's Common Stock at a purchase price of $0.38 per share.

As of September 30, 2016, Northwest held $1.5 million in cash, which included $0.7 million in restricted cash.

The new financing immediately boosted the company's balance sheet. The proceeds from the new financing will be used in connection with upcoming **Phase II** clinical trials.

Management has implemented lower levels of fundraising while the company's research and development costs have been substantially lower. Management indicated that they plan to increase its fundraising activities as the upcoming Phase II trials become ready for enrollment and execution.

NWBO to Initiate Phase II Trial Combining DCVax®-L and Keytruda® for Colorectal Cancer

In November 2017, NWBO and the University Medical Center (UMC) of the Johannes Gutenberg University Mainz in Germany announced a **Phase II** clinical trial program combining DCVax®-L and Pembrolizumab (Keytruda®) for colorectal cancer with liver metastases.

The trial will be conducted as an **investigator-initiated** trial led by the University of Mainz, thereby substantially reducing the costs involved. NWBO will provide the DCVax-L products and MSD Sharp & Dohme GmbH will provide the Pembrolizumab. (MSD Sharp & Dohme is the operating name used by U.S.-based Merck & Co., Inc. outside the U.S. and Canada.) All of the parties contributed to and approved the novel trial design.

This trial will combine a broad spectrum personalized vaccine (DCVax®-L) with a highly targeted checkpoint inhibitor drug (Pembrolizumab). In contrast, most combination trials to date have combined two specifically targeted agents, with no broad spectrum agent included.

After the parties complete certain preparatory activities, including obtaining regulatory approvals, the Phase II trial will treat patients for up to 6 months with DCVax®-L and Pembrolizumab, followed by long-term follow-up regarding patient survival.

Update on Phase III Trial Of DCVax®-L for Newly Diagnosed GMB

In early December 2016, NWBO provided an update about the Company's **Phase III** trial of DCVax®-L for Glioblastoma multiforme (GBM) brain cancer. The Company announced that 331 of the planned 348 patients have been enrolled in the Trial, and that data "events" have been accumulating towards the endpoints of the Trial.

The Company remains blinded in regard to the Trial data and, as before, will only be receiving such updates on a blinded basis.

Since the summer of last year, the trial has been subject to a partial clinical hold, only on recruitment. As a result of the partial hold, the Trial has not enrolled the last 17 of the total 348 patients. To date, the regulators have not agreed to remove the partial hold, but have allowed all of the patients in the Trial to continue being treated in accordance with the Protocol. The Company is pursuing ongoing dialog with

regulators. However, at this point the Company believes that the potential benefits that could be obtained from enrolling the final 17 patients would not be worth the time it would take, as the process of re-starting and re-training the sites (including through Institutional Review Board renewals) for further enrollment would take months, followed by further months for the recruitment itself.

Accordingly, the Company is no longer seeking to enroll the last 17 of the 348 patients. Rather, the Company is focused on accumulation of the "events" necessary for the Trial endpoints. When sufficient "events" have accumulated, the external parties managing the Trial will then begin the process of moving toward "data lock" and then analysis of the data, which are typically each multi-month processes, particularly for large international trials.

Update on DCVax®-Direct Phase I Trial

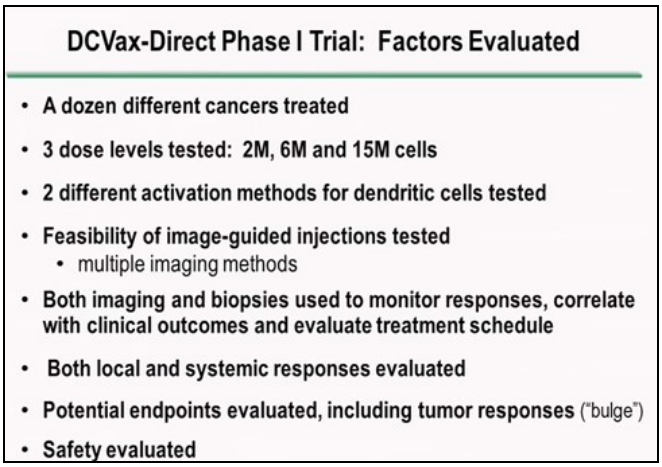
Overview of the Phase I Trial

All patients enrolled in the Phase I trial had late stage cancers, with an average of three inoperable tumors. The patients had failed multiple prior therapies and had a poor prognosis.

As of the reporting date at the ASCO, the trial enrolled 40 patients, and 39 were evaluable. Although the patients had multiple inoperable tumors, only 1 tumor was injected with DCVax-Direct. The treatments included only 3 injections in the first 2 weeks (Day 0, 7 and 14), and up to 3 additional injections spaced months apart thereafter (Weeks 8, 16 and 32), over a total period of 8 months.

Patients typically received their first injection about 1-1/2 months after recruitment. Four patients are still in the process of completing the study visits, and data collection is ongoing on all of the patients.

The trial tested three different dose levels of DCVax-Direct, two different methods of activating the dendritic cells that comprise DCVax-Direct, and a dozen different cancers. Findings to date include encouraging survival data and substantial induction of immune checkpoint expression (PDL-1).



Updated Data Presented at New York and London

In September 2016, NWBO presented additional information relating to the DCVax®-Direct **Phase I** Trial at the Second CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in New York City and at the 5th Annual SMi Cancer Vaccines Conference in London, England.

Some highlights included:

- The top 20% of these patients have so far exceeded 2 years of survival and are still alive. The longest survivor to date has reached nearly 3 years.
- The top 30% of these patients (including pancreatic, melanoma, lung, ovarian, sarcoma and other cancers) as a combined group have an average survival to date of 26.7 months, compared with an average of expected survival times of 12.3 months. Individually, these patients have also substantially exceeded their respective expected survival times.
- The continuing positive survival results correlate with underlying mechanisms of action and cellular and immune profiles, including phenotype analyses, relative production of a wide range of diverse cytokines by the dendritic cells. Additional positive observations include T-cell infiltration, and PD-L1 expression.
- 64% of the patients evaluable for PD-L1 checkpoint expression (14 of 22) showed either de novo or significantly increased expression of PD-L1 following DCVax-Direct treatment, indicating potential for combination of DCVax-Direct and checkpoint inhibitors.
- The diverse cancers covered in this trial are responsible for approximately 800,000 new cases annually in the US and also at least 800,000 new cases in Europe. When these cancers reach the inoperable metastatic stage, there are no effective treatments available today.

Data Presented at the ASCO 2016

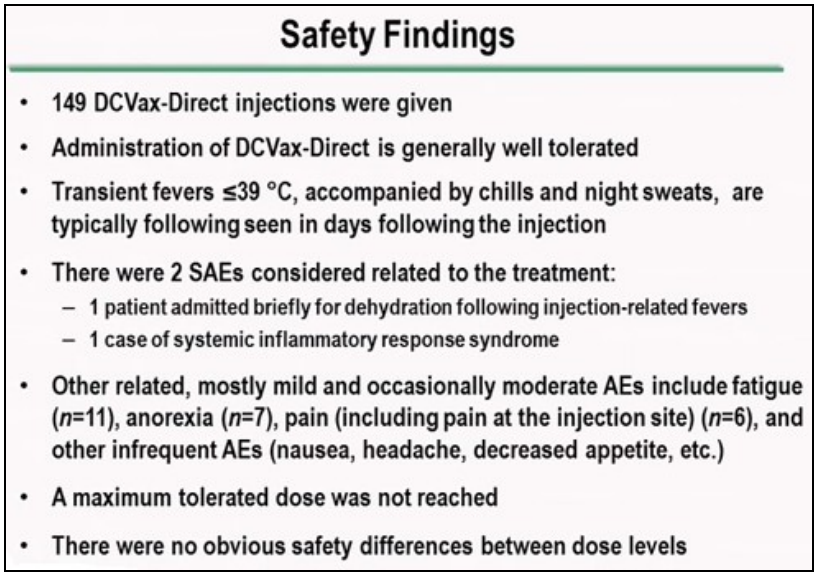
Key findings as of the presentation day include the following:

- 27 of 39 patients (69%) are still alive at up to 18 months after first injection.
- With the preferred method of dendritic cell activation, 18 of 21 patients (86%) are still alive.
- The effectiveness of treatment have been observed in diverse cancers, including lung, breast, colorectal, pancreatic, sarcoma, melanoma, neuro-endocrine and other cancers.
- Patient survival correlates with the number of DCVax-Direct injections.
- Patient survival also correlates with stabilization of disease at Week 8 (4th injection visit). Among patients treated with the preferred method of dendritic cell activation, 16 of 19 achieved stable disease (i.e., less than 25% increase in tumor size from baseline) at Week 8.

Findings relating to immunological responses include the following:

- Induction of PDL-1 immune checkpoint expression was seen in 64% of evaluable patients (14 of 22) following DCVax-Direct treatment. This suggests that the tumors are putting up defenses against the immune responses induced by DCVax-Direct, and marks these patients as potential candidates for treatment with checkpoint inhibitor therapies.
- An increase in T-cell infiltration into tumors, by functionally active T-cells, was seen following DCVax-Direct treatment.
- Both local effects (in the injected tumor) and systemic effects were observed.

DCVax-Direct was safe and well tolerated in the Phase I trial.



Our Takeaways from the Phase I Data Presentation

We think data from the ASCO and Immunotherapy Conference presentations are very encouraging. We are especially impressed with these positive results across diverse types of cancers in late stage patients with multiple inoperable tumors who have exhausted other treatment options, and with quite a conservative DCVax-Direct treatment regimen.

We further believe the positive data from the Phase I trial will accelerate the initiation of the planned Phase II trial of DCVax-Direct, which, in addition to the Phase III trial of DCVax-L for brain cancer, will serve as another key value driver the company.

The findings from the Phase I trial also open the door for potential combination therapy of DCVax-Direct with checkpoint inhibitors.

Phase II Trial of DCVax-Direct Planned

Based on the findings from the Phase I trial, the company plans to enhance its **Phase II trials** in several ways, including:

- Using only the preferred activation method of the DCVax dendritic cells.
- Injecting multiple inoperable tumors at each treatment visit, not just one.
- Providing more frequent treatments and a larger total number of treatments.

The company plans to pursue Phase II trials in non-small cell lung cancer and sarcoma, as well as a Phase II trial for multiple diverse types of cancers similar to the Phase I study. The company also plans to expand the trial sites to include countries beyond the U.S.



Valuation

Northwest is engaged in the business of developing cell-based immunotherapies for the treatment of various cancers.

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 just reported encouraging positive data from its Phase I trial of its third candidate DCVax-Direct for solid tumors.

Currently, the Company shares are trading at about $0.35 per share which values the Company at about $43 million based on 125 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 $1 billion 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.

We are especially optimistic about the company's DCVax-Direct for solid tumors. The company has reported positive Phase I data at various medical conferences and plans to initiate a Phase II trial soon.

We maintain our fair value of $2.00 per share, which values the company at $250 million in market cap. Apparently, risk is high for NWBO at this stage. Both clinical and regulatory hurdles are still high. And cash burn is another concern. As the company moves forward with the Phase III of DCVax-L and Phase II DCVax-Direct, R&D expense will soar. We will keep a close eye on the company's balance sheet.

PROJECTED INCOME STATEMENT

	2015A (Dec)					2016E (Dec)					2017E (Dec)	2018E (Dec)	2019E (Dec)	2020E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$50.00	$175.00
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	$0.00
Research grants and other	$0.19	$0.39	$0.29	$0.86	$1.74	$0.24	$0.16	$0.16	$0.16	$0.71	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.19**	**$0.39**	**$0.29**	**$0.86**	**$1.74**	**$0.24**	**$0.16**	**$0.16**	**$0.16**	**$0.71**	**$0.00**	**$5.00**	**$50.00**	**$175.00**
YOY Growth	-	-	*-50.0%*	*-1.0%*	*19.6%*	*21.6%*	*-59.8%*	*-45.4%*	*-81.5%*	*-59.1%*	-	*#DIV/0!*	*900.0%*	*250.0%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.75	7.50	26.25
Gross Income	**$0.19**	**$0.39**	**$0.29**	**$0.86**	**$1.74**	**$0.24**	**$0.16**	**$0.16**	**$0.16**	**$0.71**	**$0.00**	**$4.25**	**$42.50**	**$148.75**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*#DIV/0!*	*85.0%*	*85.0%*	*85.0%*
R&D	$19.70	$29.43	$9.17	$44.81	$103.12	$13.44	$8.71	$21.09	$20.00	$63.25	$50.00	$50.00	$50.00	$50.00
% R&D	*10156.2%*	*7527.9%*	*3151.2%*	*5192.7%*	*5929.8%*	*5694.9%*	*5549.7%*	*13266.7%*	*12500.0%*	*8883.0%*	*#DIV/0!*	*1000.0%*	*100.0%*	*28.6%*
SG&A	$3.32	$9.81	$4.33	$7.44	$24.90	$4.28	$6.47	$4.58	$5.00	$20.32	$30.00	$35.00	$40.00	$45.00
% SG&A	*1710.8%*	*2509.2%*	*1489.3%*	*862.0%*	*1432.0%*	*1811.4%*	*4119.1%*	*2881.1%*	*3125.0%*	*2854.4%*	*#DIV/0!*	*700.0%*	*80.0%*	*25.7%*
Other expenses	$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	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($22.8)**	**($38.9)**	**($13.2)**	**($51.4)**	**($126.3)**	**($17.5)**	**($15.0)**	**($25.5)**	**($24.8)**	**($82.9)**	**($80.0)**	**($80.8)**	**($47.5)**	**$53.8**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($23.6)	($28.0)	$35.8	$27.3	$11.5	$11.4	($1.8)	($6.7)	$0.0	$2.9	($2.5)	($2.5)	($2.5)	($2.5)
Pre-Tax Income	**($46.4)**	**($66.8)**	**$22.6**	**($24.1)**	**($114.7)**	**($6.1)**	**($16.8)**	**($32.2)**	**($24.8)**	**($80.0)**	**($82.5)**	**($83.3)**	**($50.0)**	**$51.3**
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	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($46.4)**	**($66.8)**	**$22.6**	**($24.1)**	**($114.7)**	**($6.1)**	**($16.8)**	**($32.2)**	**($24.8)**	**($80.0)**	**($82.5)**	**($83.3)**	**($50.0)**	**$51.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*69.4*	*75.6*	*78.1*	*87.8*	*77.7*	*97.7*	*103.8*	*114.8*	*128.0*	*111.1*	*140.0*	*170.0*	*200.0*	*220.0*
Reported EPS	**($0.67)**	**($0.88)**	**$0.29**	**($0.27)**	**($1.48)**	**($0.06)**	**($0.16)**	**($0.28)**	**($0.19)**	**($0.72)**	**($0.59)**	**($0.49)**	**($0.25)**	**$0.23**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$23.60*	*$27.99*	*($35.83)*	*($27.31)*	*($11.54)*	*($11.37)*	*$1.79*	*$6.72*	*$0.00*	*($2.86)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($22.8)**	**($38.9)**	**($13.2)**	**($51.4)**	**($126.3)**	**($17.5)**	**($15.0)**	**($25.5)**	**($24.8)**	**($82.9)**	**($82.5)**	**($83.3)**	**($50.0)**	**$51.3**
Non GAAP EPS	**($0.33)**	**($0.51)**	**($0.17)**	**($0.59)**	**($1.63)**	**($0.18)**	**($0.14)**	**($0.22)**	**($0.19)**	**($0.75)**	**($0.59)**	**($0.49)**	**($0.25)**	**$0.23**

Source: Company filings and Zacks estimates

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HISTORICAL STOCK PRICE



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