Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: Phase III of DCVax-L remains on track, Positive data from Phase I of DCVax-Direct reported at ASCO--*Buy*

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (08/28/15)	$8.11
Twelve-Month Target Price	**$16.00**

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 been enrolling patient in the US, UK, Canada and Germany. Hospital Exemption in Germany is under way and UK is following suit.

Encouraging data from Phase I/II study of DCVax-Direct reported at ASCO 2015.

Current valuation is attractive. We maintain our Buy rating.

SUMMARY DATA

52-Week High	**$12.24**
52-Week Low	**$3.94**
One-Year Return (%)	**38.87**
Beta	**2.14**
Average Daily Volume (sh)	**868,274**
Shares Outstanding (mil)	**78**
Market Capitalization ($mil)	**$634**
Short Interest Ratio (days)	**14.78**
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	0.20 E	0.20 E	0.99 E
2016					1.00 E
2017					15.00 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	-$0.33 E	-$0.27 E	-$1.44 E
2016					-$0.90 E
2017					-$0.61 E

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

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WHAT'S NEW

Update on Second Quarter 2015 Financials

On August 10, Northwest filed its 10-Q for the second quarter ended June 30, 2015.

Revenue was $0.39 million in 2Q15, compared to no revenue in 2Q14. Revenue was primarily derived from research grant.

Research and development expense was $29.4 million for the three months ended June 30, 2015 versus $21.5 million for the three months ended June 30, 2014.

Research and development expense was $29.4 million for the three months ended June 30, 2015 versus $21.5 million for the three months ended June 30, 2014. The increase was primarily attributable to costs associated with manufacturing for, conducting (including CRO and site costs) and expanding the Phase III DCVax-L trial in Europe and the preparations for multiple Phase II trials of DCVax-Direct, as well as establishment and expansion of the company's German and UK subsidiaries and operations.

General and administrative expense was $9.8 million for the three months ended June 30, 2015 versus $3.9 million for the three months ended June 30, 2014. The increase can be mainly attributed to non-cash stock based payment to Cognate's designee.

Net loss for the three months ended June 30, 2015 and 2014 was $66.8 million ($0.88 per share) and $25.9 million ($0.45 per share), respectively.

Non-GAAP net loss for 2Q15 was $38.9 million ($0.51 per share), compared to non-GAAP not loss in 2Q14 of $25.9 million ($0.45 per share).

As of June 30, 2015, Northwest held $20.2 million in cash. During the six months ended June 30, 2015, net cash outflows for operations and for one-time expenses was $44.7 million.

In April 2015, NWBO closed $40 million investment from Woodford investment funds in the UK.

Woodford first invested $25 million in NWBO in November, 2014. On April 2, 2015, Woodford entered into an agreement with the company for a further $40 million investment in two tranches ($11.5 million and $28.5 million). Both of these tranches have been completed in accordance with the agreement. Woodford has also made substantial open market purchases of NWBO shares.

The $40 million investment was done with the purchase of the Company's common stock at $7.40 per share, for a total of 5,405,405 shares. There are no warrants, pre-emptive rights, or other rights or preferences. There was no investment banker involved in the transaction.

Update on Phase III of DCVax-L Trial

Recently, some blog articles and social media comments have misunderstanding and wrong reading of the company ongoing **Phase III** trial of DCVax-L for newly diagnosed glioblastoma multiforme (GBM). As such, the company issued a few news releases to clarify and confirm that the Phase III trial is ongoing per the protocol.

According to our understanding, the company's Phase III trial of DCVax®-L for newly diagnosed GBM is ongoing and the patients enrolled in the trial are continuing to be treated per the protocol.

The only change in status of the trial is that new screening of patient candidates for the trial has been temporarily suspended while the Company submits certain information from the trial for regulatory review.

Such screening involves the initial evaluation of patient candidates to determine whether they meet eligibility criteria for the trial (e.g., whether they are within the eligible age range, do not have certain viral diseases, etc.). The Company is in the process of preparing the trial information for regulatory review and anticipates submission within the next couple of weeks.

The **Phase III** trial has reached late stage in patient enrollment. Currently there are more than 60 clinical sites open and operating for the trial across the U.S. and in the U.K., Germany and Canada.

The original trial plan involves enrollment of 312 total patients in the trial, and counting 110 "events" of tumor recurrence or patient deaths from among these 312 patients to determine whether the primary endpoint of the trial is met.

NWBO has modified its trial plan so that it will enroll **348 total patients**, and will count 248 "events" from among these 348 total patients to determine whether the primary endpoint of the trial is met. So, the number of "events" counted in the statistical analysis will increase from 110 to 248, but the total enrollment in the trial will only increase from 312 to 348.

So far, over 300 patients have been **recruited and treated** in the trial. And, none of these 300 patients are in the information arm or the pseudo-progression arm, each of which is parallel with the trial but outside the trial.

As far as what information the Company is submitting to regulators, the company responded that such submissions would not normally be discussed in the middle of a regulatory process or dialog, and that the Company plans to report when the process has been completed. This is in accordance with the industry standard in our view.

Even with the screening delay, we still anticipate that the Phase III trial will reach its first interim analysis for efficacy during late 2015 and anticipates that the Phase III trial will reach its primary endpoint PFS (progression free survival) **in 2016**, potentially in the spring or summer. According to this schedule, we expect an NDA will be submitted in late 2016 and DCVax-L will be approved in **2H2017**.

Interim Survival Data of DCVax-L are Encouraging

In March 2015, NWBO presented encouraging survival data on 51 Glioblastoma multiforme (GBM) brain cancer patients treated with DCVax®-L at the 2nd Immunotherapy of Cancer (ITOC) Conference in Munich, Germany.

The 51 GBM patients were treated in an **Information Arm outside the Company's Phase III clinical trial** because they were not eligible for the trial, due to evidence of early tumor re-growth following 6 weeks of daily radiotherapy and chemotherapy. Overall Survival data is available for all 51 patients; however, MRI images are only available for 46 of the 51 patients. These 46 patients were classified by an independent medical imaging company into 3 groups, as follows. The other 5 patients remained unclassified, due to lack of available images.

The survival to date, for each of these groups of Information Arm patients treated with DCVax-L, is as follows:

- The median OS of the group of 51 Information Arm patients as a whole is 18.3 months. About 30% of the patients (15 of the 51) lived beyond 2 years, and most of these patients (12 of the 15) remain alive.
- The median OS among the 20 rapid-progressors patients is 15.3 months (with patients surviving as long as 37.1 months), compared to expected median OS of 8.3 – 10.8 months with existing treatments, based on published literature on comparable patient populations — a 50% improvement over the expected survival time. Further, one-third of these patients (7 of the 20) lived beyond 18 months – a doubling of the expected survival time with existing treatments.

- The median OS among the 25 indeterminate patients is 21.5 months (with patients surviving as long as 40.7 months), compared to median OS in the general population of newly diagnosed GBM patients of 14.6 months – a 50% improvement over the expected survival time. Further, 9 of these 25 patients remain alive today at more than 24 months, 6 of these 9 patients have exceeded 30 months, and 4 of these 9 patients have reached 35-40+ months.
- 1 pseudo-progressor patient is still alive, with OS of 30.1 months to date.
- The median OS for the 5 unclassified patients is 9.2 months (with patients surviving as long as 30.1 months).

DCVax-L also continues to show an excellent safety profile, with no serious adverse events observed in these Information Arm patients.

We are impressed with these data with all patients treated with DCVax-L are surviving substantially longer than would be expected based on clinical experience reported in the literature.

This survival data, which has been collected by the independent CRO managing the company's Phase III trial, provides an encouraging insight into the potential results of the DCVax-L treatments for newly diagnosed patients in the Phase III trial.

Update on DCVax®-Direct Phase I Trial

The Company presented promising survival data from its ongoing **Phase I** trial of DCVax-Direct for solid tumors at ASCO 2015 in June.

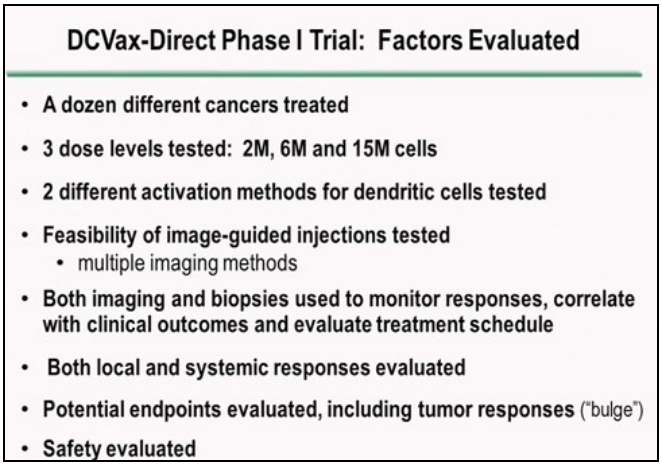
Overview of the Phase I Trial

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 from the Presentation

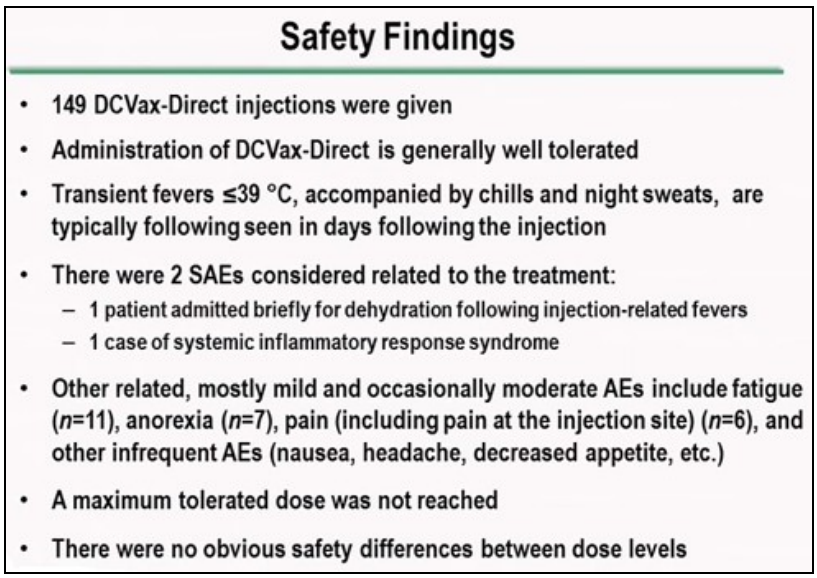
Key findings as of the presentation day include the following:

- 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 to date 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.



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.



Our Takeaways

We think data from the ASCO presentation 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.

We Maintain Our Buy Rating on NWBO Shares

We maintain our Buy rating on NWBO shares and raise our 12-month price target to $16.00 per share from original $12.00 per share.

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 $8.50 per share which values the Company at about $660 million based on 78 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 estimate DCVax –L will be approved in 2H17. Sales of DCVax-L will reach $300 million in 2020 and EPS will be $1.43. We think a 30x P/E multiple is appropriate for NWBO, and then we come up with our fair value of $12 for the DCVax-L using 30% discount for 5 years. Then adding the $4 per share value from the company's early stage DCVax-Direct, we come up with the fair value of the company of $16 per share.

Our price target of $16.00 per share values NWBO at $1.2 billion 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

	2013A (Dec)	2014A (Dec)	2015E (Dec)					2016E (Dec)	2017E (Dec)	2018E (Dec)	2019E (Dec)	2020E (Dec)
$ in million except per share data	FYA	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE	FYE
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$15.00	$75.00	$150.00	$300.00
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
Research grants and other	$0.81	$1.45	$0.19	$0.39	$0.20	$0.20	$0.99	$1.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.81**	**$1.45**	**$0.19**	**$0.39**	**$0.20**	**$0.20**	**$0.99**	**$1.00**	**$15.00**	**$75.00**	**$150.00**	**$300.00**
YOY Growth	*4.8%*	*79.7%*	-	-	*-65.6%*	*-77.1%*	*-32.3%*	*1.5%*	-	*400.0%*	*100.0%*	*100.0%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.25	11.25	22.50	45.00
Gross Income	**$0.81**	**$1.45**	**$0.19**	**$0.39**	**$0.20**	**$0.20**	**$0.99**	**$1.00**	**$12.75**	**$63.75**	**$127.50**	**$255.00**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	-	*85.0%*	*85.0%*	*85.0%*	*85.0%*
R&D	$43.91	$85.64	$19.70	$29.43	$23.00	$18.00	$90.14	$50.00	$35.00	$30.00	$35.00	$50.00
% R&D	-	*5889.8%*	*10156.2%*	*7527.9%*	*11500.0%*	*9000.0%*	*9151.0%*	*5000.0%*	*233.3%*	*40.0%*	*23.3%*	*16.7%*
SG&A	$12.36	$16.95	$3.32	$9.81	$4.50	$5.00	$22.63	$25.00	$30.00	$35.00	$40.00	$45.00
% SG&A	-	*1165.7%*	*1710.8%*	*2509.2%*	*2250.0%*	*2500.0%*	*2297.5%*	*2500.0%*	*200.0%*	*46.7%*	*26.7%*	*15.0%*
Other expenses	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($55.5)**	**($101.1)**	**($22.8)**	**($38.9)**	**($27.3)**	**($22.8)**	**($111.8)**	**($74.0)**	**($52.3)**	**($1.3)**	**$52.5**	**$160.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($10.3)	($34.5)	($23.6)	($28.0)	($0.8)	($1.0)	($53.4)	($2.5)	($2.5)	($2.5)	($2.5)	($2.5)
Pre-Tax Income	**($65.8)**	**($135.6)**	**($46.4)**	**($66.8)**	**($28.1)**	**($23.8)**	**($165.2)**	**($76.5)**	**($54.8)**	**($3.8)**	**$50.0**	**$157.5**
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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($65.8)**	**($135.6)**	**($46.4)**	**($66.8)**	**($28.1)**	**($23.8)**	**($165.2)**	**($76.5)**	**($54.8)**	**($3.8)**	**$50.0**	**$157.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	*32.9*	*59.2*	*69.4*	*75.6*	*82.0*	*83.0*	*77.5*	*85.0*	*90.0*	*100.0*	*105.0*	*110.0*
Reported EPS	**($2.00)**	**($2.29)**	**($0.67)**	**($0.88)**	**($0.34)**	**($0.29)**	**($2.13)**	**($0.90)**	**($0.61)**	**($0.04)**	**$0.48**	**$1.43**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$7.45*	*$34.05*	*$23.60*	*$27.99*	*$0.80*	*$1.00*	*$53.39*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($58.3)**	**($101.6)**	**($22.8)**	**($38.9)**	**($27.3)**	**($22.8)**	**($111.8)**	**($76.5)**	**($54.8)**	**($3.8)**	**$50.0**	**$157.5**
Non GAAP EPS	**($1.78)**	**($1.71)**	**($0.33)**	**($0.51)**	**($0.33)**	**($0.27)**	**($1.44)**	**($0.90)**	**($0.61)**	**($0.04)**	**$0.48**	**$1.43**

Source: Company filings and Zacks estimates

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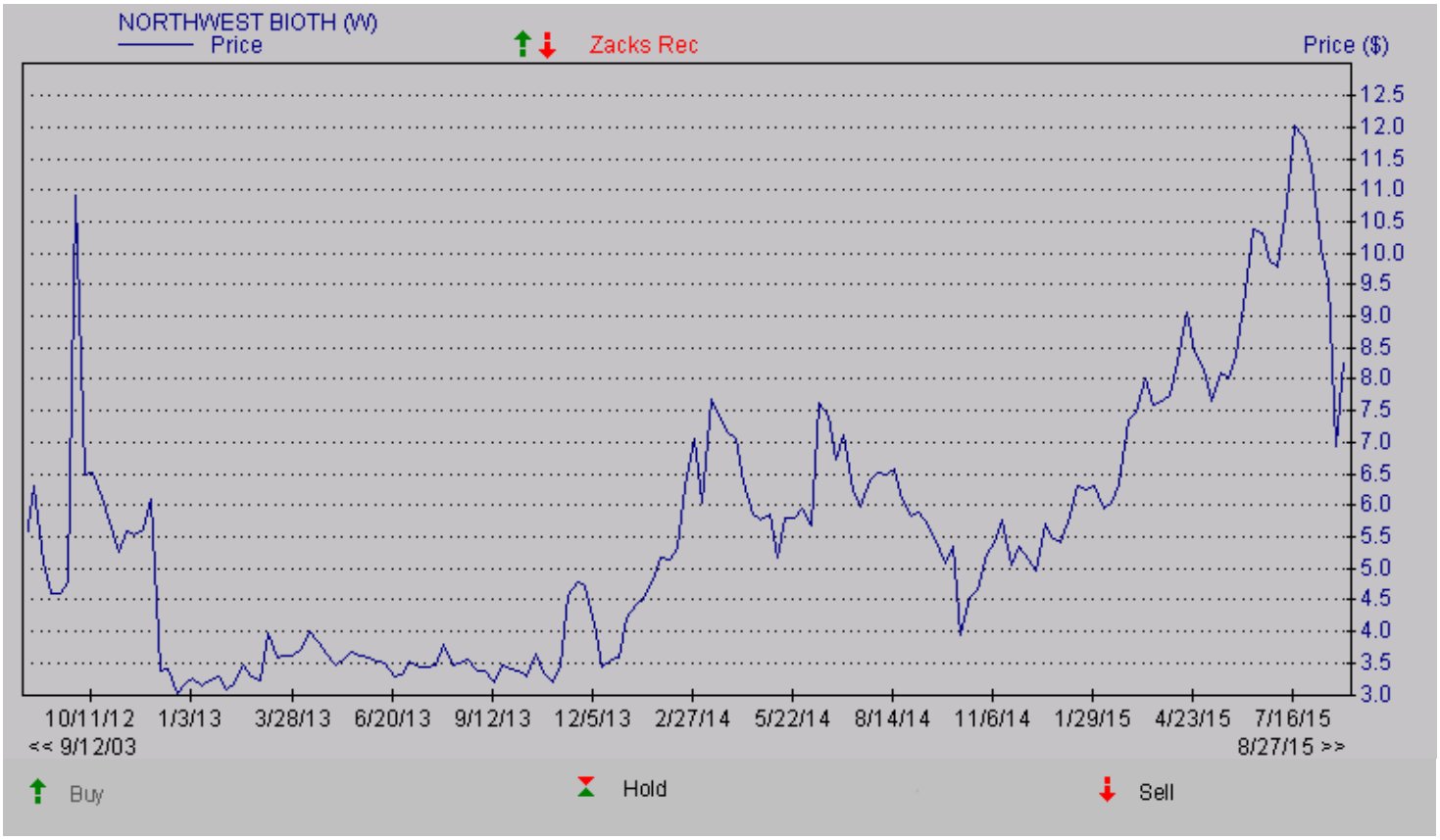
HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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