Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-NASDAQ)

NWBO: Phase III of DCVax-L remains on track; Phase I portion of DCVax-Direct completed; Positive data reported-- *Outperform*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (03/20/15)	$7.63
Twelve-Month Target Price	**$12.00**

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.

Positive data from Phase I/II study of DCVax-Direct reported.

Current valuation is attractive. We maintain our Outperform rating.

SUMMARY DATA

52-Week High	**$8.97**
52-Week Low	**$3.94**
One-Year Return (%)	**3.58**
Beta	**2.81**
Average Daily Volume (sh)	**745,114**
Shares Outstanding (mil)	**80**
Market Capitalization ($mil)	**$550**
Short Interest Ratio (days)	**29.20**
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	0.50 E	0.50 E	0.50 E	0.50 E	2.00 E
2016					2.50 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	-$0.37 E	-$0.34 E	-$0.32 E	-$0.29 E	-$1.32 E
2016					-$0.88 E
2017					-$0.61 E

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

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WHAT'S NEW

- ***NWBO reports financials for 2014;***
- ***Phase III of DCVax-L enrolling patients in the US, UK, Canada and Germany;***
- ***Phase I portion of Phase I/II trial finished enrollment, Encouraging preliminary data reported;***
- ***We maintain Outperform rating and reiterate our PT of $12.00;***

NWBO Reports Financials for 2014

Total revenue was $1.5 million for 2014, which was from Grant and other source. This compared to $0.8 million for 2013.

R&D expense was $85.6 million for 2014, compared to $43.9 million for 2013.

G&A expense was $17.0 million for 2014, compared to $12.4 million for 2013.

Operating loss was $101.1 million ($1.71 per share) for 2014, compared to an operating loss of $55.5 million ($1.69 per share) for 2013.

On November 19, 2014, NWBO announced two financings totaling $35 million. The first financing was a $25 million equity investment by UK based C.F. Woodford Equity Income Fund, and the second was a $10 million mortgage on the Company's recently acquired UK facility.

Woodford purchased $25 million of unregistered shares of the Company's common stock at $5.79 per share, for a total of 4,317,790 shares. The $10 million mortgage was secured solely by a UK facility acquired by the Company for its previously announced expansion of manufacturing capacity in Europe. The mortgage has a two-year term and interest-only payments until maturity. The mortgage funding will be used to continue building manufacturing capacity for the Company's growing programs in Europe: both the clinical trials and the early access programs.

The company raised total of $79 million in equity and debt financing in 2014.

Proceeds from these financings were, and will be used to further expand and accelerate the Phase III DCVax-L clinical trial in GBM brain cancer, the Company's DCVax-Direct Phase II trials and the Company's early access programs.

We are pleased to see that NWBO completed these new financings, which not only boost the company's balance sheet, but also validate the company's immunotherapy platform technology as well as the company's clinical programs.

As of December 31, 2014, NWBO held $14.3 million in cash and restricted cash.

Update on Phase III DCVax®-L Trial

According to NWBO, the Phase III trial of DCVax-L for glioblastoma multiforme (GBM) brain cancer is progressing on track. The Phase III trial is enrolling patients at over 50 trial sites in the **US** and a number of sites in the **UK** and **Germany**.

In Feb, 2015, the Phase III trial was approved to proceed in Canada at two sites, which are under way screening patients for enrollment.

The Phase III trial has reached late stage in patient enrollment. As of February 28, 2015, 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, with more sites expected to become operational during 2015, particularly in Europe.

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 is modifying 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.

NWBO anticipates that the Phase III trial will reach its first interim analysis for efficacy during 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**.

Update on Phase I Trial of DCVAX®-Direct

In July, 2014, NWBO completed the **36-patient target recruitment** in the Phase I portion of the Company's Phase I/II DCVax-Direct clinical trial. Treatment will finish in **2Q15**. While treatment of the patients is ongoing, the Company is now underway with preparations for the Phase II portion of this trial, as well as expansion of DCVax-Direct manufacturing.

As a reminder, in June, 2013, NWBO initiated its **60-patient Phase I/II** clinical trial of DCVax-Direct for all inoperable **solid tumor** 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. The DCVax-Direct treatment regimen in the clinical trial includes a total of 6 injections: initially at Day 0, Day 7 and Day 14, followed by injections at Week 8, Week 16 and Week 32.

The Phase I portion of the trial has involved testing of 3 different dose levels, and a diverse range of cancers. The patients enrolled in Phase I will continue to receive treatments in accordance with the protocol.

With the closing of Phase I, the Company is now preparing to initiate the **Phase II** portion of the trial. At least **2 Phase II trials** in parallel with 2 different cancers will be initiated. Additional trial sites are being brought on to facilitate and expedite enrollment.

Early Data from DCVax-Direct Phase I/II Trial Very Encouraging

In June, 2014, NWBO announced positive results from the ongoing Phase I/II clinical trial of DCVax-Direct for all types of inoperable solid tumors.

As of the reporting date, 20 patients have received at least 3 of the 6 total injections, and 13 of these 20 patients are showing tumor cell death, tumor shrinkage, substantial accumulation of immune cells in the tumors, and/or stabilization of their disease.

All 9 out of 9 patients who have received 4 of the 6 planned injections are showing tumor cell death, tumor shrinkage, substantial immune cell accumulation in their tumors and/or stabilization (i.e., stopping the progression) of their advanced cancer.

Also, in a new finding, biopsies taken in 3 of these 9 patients now show no live tumor cells in the tumor that was injected. These 3 cases include diverse, advanced and particularly aggressive cancers: 1 metastatic pancreatic cancer case, 1 metastatic colon cancer case and 1 metastatic sarcoma case. These patients' tumors showed some enlargement on imaging scans, but the biopsies showed that live tumor cells are no longer detectable and immune cells were found there. Each of these 3 patients was treated with the lowest dose level (2 million cells per treatment).

In these 3 patients, as well as the other patients in the trial, only one of their tumors has been injected with DCVax-Direct. The Company plans to inject multiple tumors in its further studies of DCVax-Direct.

The Company plans to report more details when the patients are further along in the treatment regimen. The first 3 injections are given in the first 2 weeks of the 32-week treatment regimen (at Day 0, Day 7 and Day 14).

We think the initial data are very encouraging. Though in early stage, the Phase I trial already demonstrated that over 65% patients are already showing positive response, and as of the 4th injection in week 8 of the treatments, 100% of the patients (9 of 9) have shown some positive effects. It's **especially excited** to see such responses while these patients are still only part way through their treatment and with only one tumor being injected with DCVax-Direct.

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.

DCVax®-L Hospital Exemption Program under Way in Germany

In mid-October, 2014 NWBO announced that the first patient with Glioblastoma multiforme (GBM) brain cancer began the treatment process under the Hospital Exemption Program. Additional patients are being assessed and a waiting list has been established.

As a reminder, in March, 2014, Northwest received **approval** from the German Health Authority of a "**Hospital Exemption**" early access program. Under this Hospital Exemption, Northwest may provide DCVax-L to patients for the treatment of **any glioma** brain cancers (both Glioblastoma multiforme and lower grade gliomas), both newly diagnosed and recurrent, outside of the Company's clinical trial and charge full price. The patients may be from Germany or elsewhere. This approval has a term of five years, and can be re-applied for and re-issued at the end of that period.

Meanwhile, the German reimbursement authority has determined that DCVax-L treatments for glioma brain cancers are **eligible to obtain reimbursement** from the Health Insurers of the German healthcare system. Applications for such reimbursement eligibility may only be submitted to the Health Insurers by German hospitals, not by a company.

NWBO's DCVax-L is the first immune therapy to be granted a Hospital Exemption approval under the German Drug Law. **We view the two approvals and the initiation of the program in Germany a significant milestone for NWBO in the following aspects**.

- First, the approvals will allow the company to record product revenue as early as in 2014. The revenue may not be meaningful, but this marks the first time in the company's history that product sales will be booked for revenue.

- **More importantly**, the approvals further **validate** the company's DCVax immunotherapy platform technology.

- Furthermore, the German approvals also provide NWBO the opportunity to begin practicing for future commercial operations.

DCVax-L is the first product of its kind to receive Hospital Exemption approval from the German regulators, in the following key ways:

- the first immunotherapy;
- the first product which exerts pharmacological effects;
- the first product that has never previously been on the market commercially;
- the first product developed by a non-German company, not previously under the German regulators' oversight; and
- the first "somatic" cell therapy product (a somatic cell is any cell of the body other than a reproductive or embryonic cell).

Furthermore, **the scope** of the Hospital Exemption granted for DCVax-L is broader than the scope of the ongoing Phase III clinical trial. The Hospital Exemption for DCVax-L applies to all glioma brain cancers, including both the most severe grade (Grade IV, Glioblastoma multiforme or GBM) and lower grade gliomas, while the clinical trial includes only GBM. The Hospital Exemption also includes both newly diagnosed and recurrent gliomas, while the clinical trial includes only newly diagnosed.

DCVax-L Designated as a "Promising Innovative Medicine" in UK

On September 16, 2014, NWBO announced that its DCVax-L is the first product to receive formal designation as a "Promising Innovative Medicine" (**PIM**) under the new "Early Access to Medicines Scheme" (EAMS) launched in the UK in April 2014.

A PIM is the first step in a 2-step process for early access approval under the EAMS. The PIM designation for DCVax-L covers all malignant gliomas, which include both Glioblastoma multiforme as well as less malignant grades, and would include both newly diagnosed and recurrent gliomas.

The EAMS is an important new initiative in the UK to lead the way in accelerating patients' access to innovative new medicines for serious diseases. The **first step** under the EAMS is the evaluation of whether a product candidate meets three criteria for a PIM designation:

- the product is for a serious disease or condition with high unmet medical need;
- the product is likely to offer a major advantage over treatments available today; and
- the potential adverse effects of the product are outweighed by the potential benefits.

NWBO's DCVax-L has become the first product to earn this PIM certification. There is no expiration on the PIM certification.

The second step under the EAMS is the determination of a Scientific Opinion about the product candidate's benefits and risks, based on available clinical data. The Scientific Opinion will be delivered within 90 days after a party submits an application for Step 2 of the EAMS process. A positive or negative Scientific Opinion will be judged by the same three criteria as for the PIM designation, as well as a fourth criterion:

- the Company's ability to manufacture the product to rigorous "GMP" (clinical grade) standards.

If the Scientific Opinion is positive, the product candidate may then be prescribed by physicians and provided to (and paid for by) patients before the product is formally licensed and while it is still in clinical development.

We think the PIM designation is another important milestone for DCVax-L to be approved in the UK for a similar early access program in Germany. Together with German approval, the early access program of DCVax-L will provide great opportunity for NWBO to practice commercial operations.

We Maintain Our Outperform Rating on NWBO Shares

We maintain our Outperform rating on NWBO and reiterate our 12-month price target of $12.00 per share.

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 has finished the enrollment of the Phase I portion of a Phase I/II clinical trial for its third candidate DCVax-Direct for solid tumors and initial data have been very encouraging.

Currently, the Company shares are trading at about $7.50 per share which values the Company at about $600 million based on 80 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 2010 and EPS will be $1.43. We think a 30x P/E multiple is appropriate for NWBO, and then we come up with our $12 price target using 30% discount for 5 years.

Our price target of $12.00 per share values NWBO at $960 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

	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	$0.50	$0.50	$0.50	$0.50	$2.00	$2.50	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.81**	**$1.45**	**$0.50**	**$0.50**	**$0.50**	**$0.50**	**$2.00**	**$2.50**	**$15.00**	**$75.00**	**$150.00**	**$300.00**
YOY Growth	*4.8%*	*79.7%*	*-*	*-*	*-14.1%*	*-42.7%*	*37.6%*	*25.0%*	*-*	*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**	**$0.50**	**$0.50**	**$0.50**	**$0.50**	**$2.00**	**$2.50**	**$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	$21.00	$20.00	$19.00	$18.00	$78.00	$50.00	$35.00	$30.00	$35.00	$50.00
% R&D	*-*	*5889.8%*	*4200.0%*	*4000.0%*	*3800.0%*	*3600.0%*	*3900.0%*	*2000.0%*	*233.3%*	*40.0%*	*23.3%*	*16.7%*
SG&A	$12.36	$16.95	$5.00	$5.20	$5.30	$5.50	$21.00	$25.00	$30.00	$35.00	$40.00	$45.00
% SG&A	*-*	*1165.7%*	*1000.0%*	*1040.0%*	*1060.0%*	*1100.0%*	*1050.0%*	*1000.0%*	*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)**	**($25.5)**	**($24.7)**	**($23.8)**	**($23.0)**	**($97.0)**	**($72.5)**	**($52.3)**	**($1.3)**	**$52.5**	**$160.0**
Operating Margin	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
Other Net	($10.3)	($34.5)	($0.5)	($0.6)	($0.8)	($1.0)	($2.9)	($2.5)	($2.5)	($2.5)	($2.5)	($2.5)
Pre-Tax Income	**($65.8)**	**($135.6)**	**($26.0)**	**($25.3)**	**($24.6)**	**($24.0)**	**($99.9)**	**($75.0)**	**($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)**	**($26.0)**	**($25.3)**	**($24.6)**	**($24.0)**	**($99.9)**	**($75.0)**	**($54.8)**	**($3.8)**	**$50.0**	**$157.5**
YOY Growth	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
Net Margin	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
Diluted Shares Out	*32.9*	*59.2*	*80.0*	*81.0*	*82.0*	*83.0*	*81.5*	*85.0*	*90.0*	*100.0*	*105.0*	*110.0*
Reported EPS	**($2.00)**	**($2.29)**	**($0.33)**	**($0.31)**	**($0.30)**	**($0.29)**	**($1.23)**	**($0.88)**	**($0.61)**	**($0.04)**	**$0.48**	**$1.43**
YOY Growth	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
One time charge	*$7.45*	*$34.05*	*$0.50*	*$0.60*	*$0.80*	*$1.00*	*$2.90*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($58.3)**	**($101.6)**	**($25.5)**	**($24.7)**	**($23.8)**	**($23.0)**	**($97.0)**	**($75.0)**	**($54.8)**	**($3.8)**	**$50.0**	**$157.5**
Non GAAP EPS	**($1.78)**	**($1.71)**	**($0.32)**	**($0.30)**	**($0.29)**	**($0.28)**	**($1.19)**	**($0.88)**	**($0.61)**	**($0.04)**	**$0.48**	**$1.43**

Source: Company filings and Zacks Investment Research estimates

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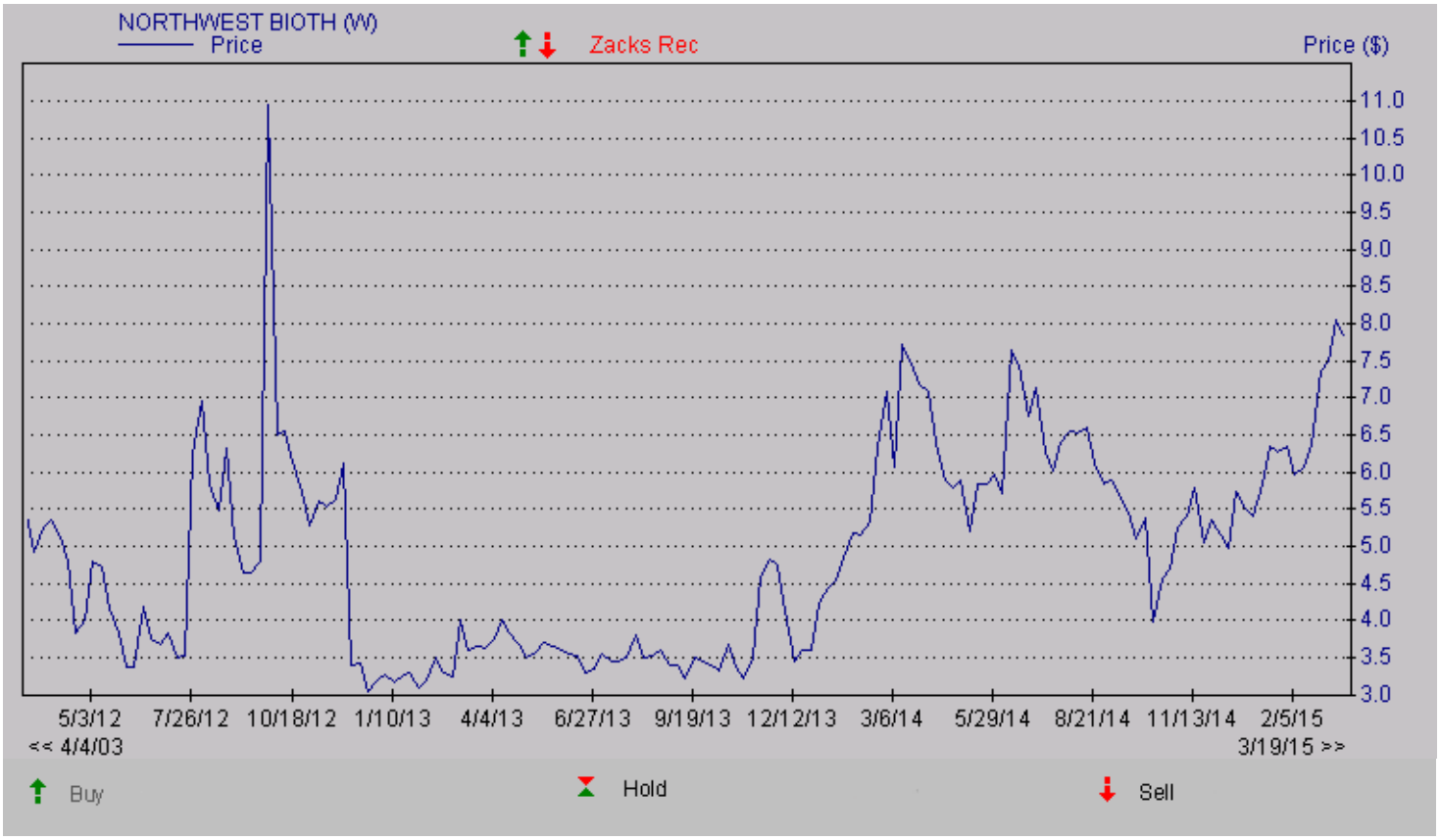
HISTORICAL ZACKS RECOMMENDATIONS



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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.6%, Hold/Neutral- 76.5%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.