Zacks Small-Cap Research

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Northwest Biotherapeutics (NWBO-OTC)

NWBO: *Further progress made for DCVax-L brain cancer clinical trial* --maintain Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (06/18/12)	$0.25
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	**$0.78**
52-Week Low	**$0.19**
One-Year Return (%)	**-64.65**
Beta	**1.43**
Average Daily Volume (sh)	**239,876**
Shares Outstanding (mil)	**159**
Market Capitalization ($mil)	**$41**
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	0.00 E	0.00 E	0.00 E	0.00 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	-$0.05 E	-$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

Further Progress Made For DCVax-L Brain Cancer Clinical Trial

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), the most lethal form of brain cancer.

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.

$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.

Phase II DCVax-L Poised To Proceed in Germany

On April 24, 2012, NWBO and **the Fraunhofer IZI Institute** in Germany announced that the two parties have completed significant milestones in NWBO's DCVax-L program for brain cancer in Germany. As a result, NWBO is poised to move forward in the near term in Germany with both its clinical trial program and Hospital Exemption cases (compassionate use cases).

The two parties have been working closely together over the course of more than 13 months, including the technology transfer of the manufacturing process for DCVax-L, as well as completing the extensive documentation required to apply for manufacturing authorization. The application was submitted to the responsible pharmaceutical supervisory authority, and the 9-month long regulatory process has been completed up to the point of the official acceptance inspection. The parties are now waiting that final inspection, which is the last step required before the manufacturing authorization can be granted and manufacturing can proceed for clinical trials and hospital exemption cases. The inspection is scheduled for **June 2012**.

To date, 24 of the 30 clinical trial sites in Germany have already been selected and are in varying stages of qualification and preparation.

The completions of these processes constitute significant milestones. It has been a very intensive process for well over a year to complete these important milestones in Germany. The Fraunhofer IZI Institute is the largest applied research foundation in Europe, and is a highly respected leader in many areas of technology, including cell and immune therapies. The Institute is assisting NWBO with the applicable regulatory requirements for both clinical trials and compassionate use cases. The Fraunhofer IZI Institute is also helping to select and initiate connections with leading clinical centers on behalf of NWBO and its DCVax products.

DCVax-L Program is also Expanding in Britain for Both Clinical Trial and Compassionate Use

On April 12, 2012, NWBO announced that it is partnering with **King's Health Partners** in London to manufacture NWBO's DCVax-L for both clinical trial and compassionate use in the UK for brain cancer patients as part of its ongoing 240-patient Phase II clinical trial for Glioblastoma multiforme (GBM).

Specialists at **King's College London** will manufacture NWBO's DCVax-L for the Phase II clinical trial, which will take place and involve brain cancer patients at **King's College Hospital** NHS Foundation Trust. Both institutions are part of King's Health Partners.

The collaboration with King's College Hospital includes two important dimensions.

- One such dimension is enabling the Hospital to join NWBO's ongoing, 240-patient randomized, controlled **Phase II clinical trial** for GBM, which is currently under way at more than 30 clinical trial sites across the U.S.

- A second important dimension involves treatment of patients on a **compassionate use** basis, for those who do not fully meet the criteria to enroll on the clinical trial, but may benefit from the treatment. This compassionate use dimension will enable treatment of such patients to proceed while the clinical trial is ongoing.

Cognate BioServices, Inc., NWBO's contract manufacturer, will manage and oversee the processing at King's College (in addition to the production at Fraunhofer in Germany) on an ongoing basis, to ensure consistency and coordination.

The Implications of the Two Partnerships

We think the two partnerships in Germany and Britain are very encouraging news and positive to NWBO in the following aspects:

- The two partnerships will help **accelerate** the Company's ongoing international Phase II clinical trial of DCVax-L for GBM (designed and powered as a pivotal trial). Data from Germany and Britain combined with US clinical sites could form the basis for the submission of a BLA in the US and EU.

- The compassionate use of DCVax-L will help **extend** lives for other patients who are not qualified while the trials are ongoing. It may also bring some additional revenues for the Company although it won't be material in our view.

- The collaborations also **expand** NWBO's manufacturing capacity and flexibility for DCVax® products, without the need for any capital investment by the Company.

- Overall, the partnerships with King's Health Partners and the Fraunhofer IZI Institute **provide** solid foundation for NWBO's programs in Europe upon which NWBO can proceed with clinical trials in Europe, and with compassionate use treatments of patients in parallel with such clinical trials.

- The Company plans to petition for early product approval in the U.S. and/or the European Union if the Phase II 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.

Two Experienced Directors Added to the Board

NWBO recently added Dr. Navid Malik and Mr. Jerry Jasinowski to the Company's Board of Directors. The two members bring to the NWBO Board longstanding, deep experience in the life sciences industry, advanced manufacturing, and corporate operations and governance.

Dr. Navid Malik is the Head of Life Sciences Research for Cenkos Securities Plc. in the UK, and has been one of the most influential analysts in the UK and Europe over the last decade, covering the life sciences industry worldwide. In 2011, Dr. Malik was awarded two Starmine Awards: Number One Stock Picker in the European Pharmaceutical Sector, and Number Two Stock Picker in the UK and Ireland Healthcare Sector. Dr. Malik has built life science teams and franchises at multiple large financial institutions in London, which completed IPOs and secondary stock offerings for small biotech and life sciences companies totaling over $700 million in recent years, and which also initiated research coverage on dozens of small life sciences companies in addition to covering large pharmaceutical, biologics and healthcare companies. Dr. Malik holds a PhD in Drug Delivery within Pharmaceutical Sciences, as well as degrees in Biomedical Sciences Research (M.Sc.) and Biochemistry and Physiology (B.Sc., joint honors). Dr. Malik also holds an MBA in finance.

Mr. Jasinowski is a nationally recognized chief executive who headed up the largest industrial trade association in the US (the National Association of Manufacturers) for fourteen years, and has decades of experience in leading public and private organizations. He also has extensive board experience across a wide range of manufacturing, technology, and financial firms, including Fortune 1000 and Fortune 500 companies. His board service includes experience on financial, audit and nominating committees. Mr. Jasinowski was also the founder and longtime President of the Manufacturing Institute, providing information and services to the nation's manufacturers. He has extensive experience in economic and strategic analysis, and has authored two books about US-based manufacturing and business. He is extremely knowledgeable about Washington, DC policy and regulatory affairs relating to a wide range of industries.

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 $0.25 per share which values the Company at about $41 million based on 159 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 $120 million in market cap based on the 159 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 December 31, 2011, the Company had only $24,000 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 II 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 $26 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.

Clinical and Regulatory Risks Remain High

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.

In NWBO's case, the Company plans to rely on current DCVax -Brain Phase II clinical trial as a single study in support of regulatory approval. This may be risky. While under certain circumstances, both EMEA and the FDA will accept a Phase II study as a single study in support of approval, it is not yet known whether they will do so in this case.

In the case of DCVax-Prostate, we don't think the Company will go ahead with the Phase III clinical trials of DCVax-Prostate except with a partner, due to the scale of resources required for this large Phase III trial ($50 million or more).

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	Q2E	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	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$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**
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**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$4.44	$3.47	$3.56	$1.98	$13.45	$3.58	$4.00	$4.50	$5.50	$17.58	$14.50	$12.00	$10.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$2.32	$5.56	$2.80	$2.66	$13.34	$2.18	$2.50	$2.50	$2.50	$9.68	$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)**	**($6.5)**	**($7.0)**	**($8.0)**	**($27.3)**	**($26.0)**	**($24.5)**	**($24.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($1.7)	($3.3)	$6.8	($7.9)	($6.0)	($4.4)	($2.5)	($2.5)	($2.5)	($11.9)	($7.5)	($5.0)	($5.0)
Pre-Tax Income	**($8.4)**	**($12.3)**	**$0.5**	**($12.6)**	**($32.8)**	**($10.1)**	**($9.0)**	**($9.5)**	**($10.5)**	**($39.1)**	**($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)**	**($9.0)**	**($9.5)**	**($10.5)**	**($39.1)**	**($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*	*165.0*	*185.0*	*220.0*	*180.9*	*230.0*	*260.0*	*310.0*
Reported EPS	**($0.11)**	**($0.15)**	**$0.00**	**($0.08)**	**($0.30)**	**($0.07)**	**($0.05)**	**($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)**	**($9.0)**	**($9.5)**	**($10.5)**	**($39.1)**	**($33.5)**	**($29.5)**	**($29.0)**
Non GAAP EPS	**($0.11)**	**($0.13)**	**($0.07)**	**($0.04)**	**($0.32)**	**($0.07)**	**($0.05)**	**($0.05)**	**($0.05)**	**($0.22)**	**($0.15)**	**($0.11)**	**($0.09)**

Source: Company filings and Zacks Investment Research estimates

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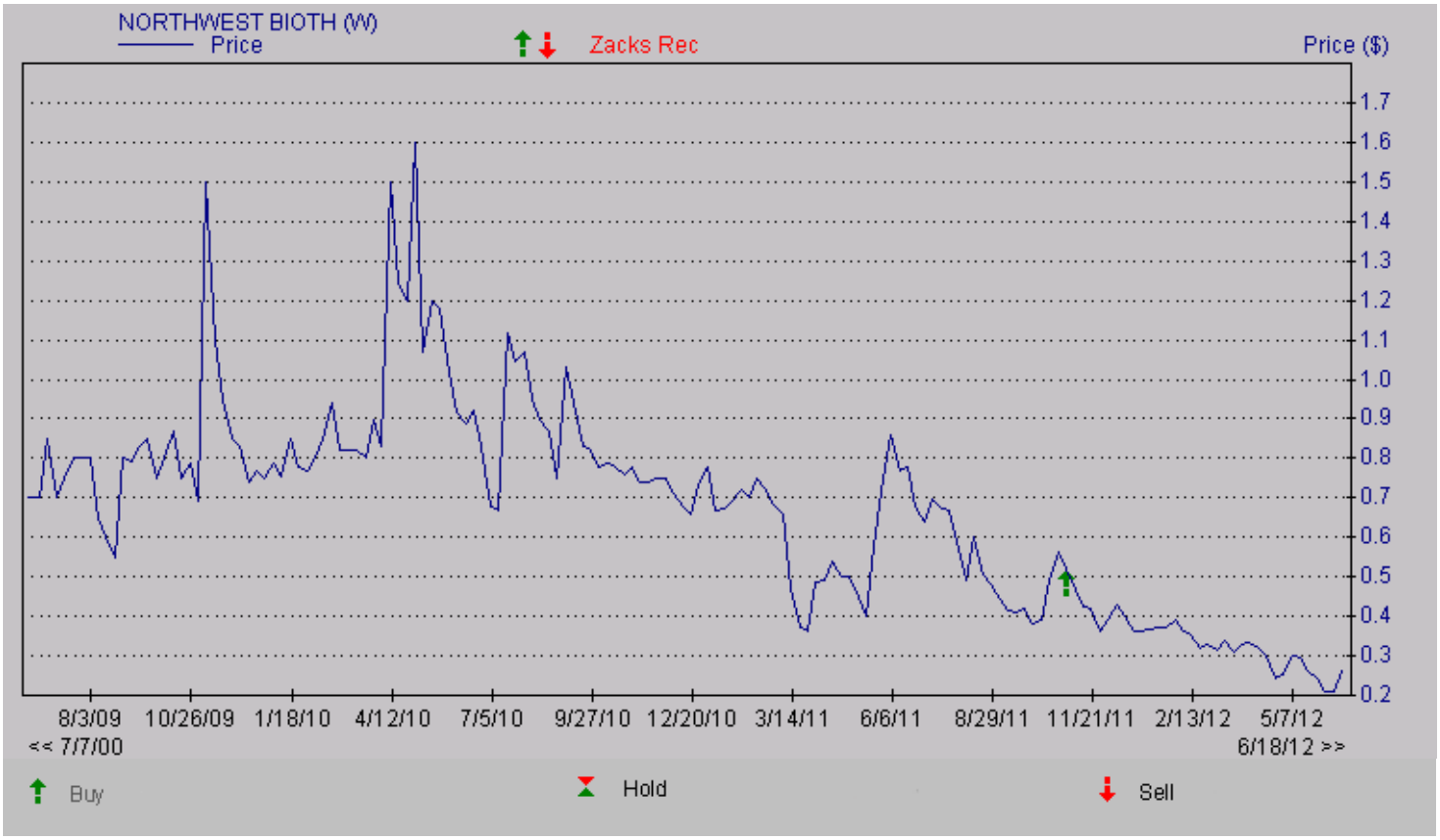
HISTORICAL ZACKS RECOMMENDATIONS



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