

Northwest Biotherapeutics (NWBO-OTC)

NWBO: Proprietary immunotherapy platforms for cancers with promising late stage candidates--initiating with an Outperform rating.

Current Recommendation	Outperform
Prior Recommendation	N/A
Date of Last Change	10/30/2011
Current Price (12/12/11)	\$0.38
Twelve-Month Target Price	\$1.50

OUTLOOK

Northwest Biotherapeutics is a late clinical stage biotech company engaged in the development of cell based cancer immunotherapeutics. We are optimistic with the Company's dendritic cell-based platform technology and its lead program DCVax-L for glioblastoma multiform, which is in a Phase II clinical trial designed and powered as a pivotal trial. Another late stage program is DCVax-Prostate. The Company is looking for a partner to initiate Phase III trials of this program due to scale of resources required for the Phase III trials.

Current valuation is attractive. We encourage investors to accumulate shares of NWBO at current price level.

SUMMARY DATA

52-Week High	\$0.88
52-Week Low	\$0.34
One-Year Return (%)	-34.00
Beta	1.46
Average Daily Volume (sh)	241,337

Shares Outstanding (mil)	94
Market Capitalization (\$mil)	\$47
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
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P/E using 2011 Estimate	N/A
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P/E using 2012 Estimate	N/A
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Zacks Rank	N/A
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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)
2010	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2011	0.00 A	0.00 A	0.01 A	0.00 E	0.00 E
2012					0.00 E
2013					0.00 E

Earnings per Share

(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-\$0.10 A	-\$0.07 A	-\$0.05 A	-\$0.12 A	-\$0.34 A
2011	-\$0.11 A	-\$0.13 A	-\$0.07 A	-\$0.07 E	-\$0.35 E
2012					-\$0.19 E
2013					-\$0.15 E

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

- We are initiating coverage of Northwest Biotherapeutics (NWBO) with an Outperform rating. Our 12-month price target is \$1.50 per share.
- NWBO holds two proprietary platform technologies: dendritic cell (DC)-based immunotherapy (DCVax) and monoclonal antibody for the treatment of various cancers with two promising late stage immunotherapy candidates.
- The Company's DCVax technology holds competitive advantages compared to Dendreon's Provenge and other competitors which include low cost of manufacturing, ease of administration, high concentration of activated dendritic cells and lesser side effects.
- The Company's lead candidate is DCVax-L for the treatment of Glioblastoma. DCVax-L utilizes NWBO's dendritic cells (DC) platform combined with glioblastoma tumor lysate antigens. DCVax-L demonstrated excellent antitumor activity and safety profile in Phase I trials.
- NWBO is conducting a 240-patient Phase II clinical trial (designed and powered as a pivotal trial) for DCVax-L, which could become the second active immunotherapy gaining the FDA approval. The Phase II trial is also working towards recruiting patients in Europe. The Company plans to use the European data together with the US data to seek approval of DCVax-L in the US as well as in Europe if the trial results are similarly compelling as in the prior trials.
- NWBO's DCVax-Prostate vaccine was also cleared by the FDA for a 612-patients Phase III trial for non- metastatic hormone independent prostate cancer patients. The Company is looking for a partner to initiate the Phase III trial due to the scale of resources required for such a large trial.
- Both DCVax-L and DCVax-Prostate have the potential to become blockbusters if approved in our view. NWBO has established an unusually deep pipeline. Its DCVax-Direct technology can target almost every solid tumor. Current targets include liver, head & neck, ovarian and pancreatic cancers.
- Progress has been made in the past few months in terms of clinical trials, business development and balance sheet strengthening. Current valuation is attractive and upside potential is high at current price level.

OVERVIEW

Northwest Biotherapeutics, Inc. (NWBO) is a clinical stage biotechnology company focused on discovery, development and commercialization of **immunotherapy products** to safely generate and enhance immune system responses to effectively treat cancers. The Company holds two technology platforms applicable to cancer therapeutics: **dendritic cell (DC)-based cancer vaccines (DCVax™)**, and **monoclonal antibodies** for cancer therapeutics. The Company's current focus is DCVax dendritic cell-based cancer vaccine programs.

NWBO's **DCVax platform technology** makes use of the same immune cells as Dendreon's prostate cancer vaccine Provenge does. DCVax uses a patient's own dendritic cells (DCs). The dendritic cells are extracted from the body, loaded with tumor antigens, thereby creating a personalized therapeutic vaccine. Injection of these cells back into the patient initiates a potent immune response against cancer cells, resulting in delayed time to progression and prolonged survival.

NWBO has developed three versions of DCVax products which are complementary. **DCVax-L** is developed using the patient's own dendritic cells loaded with antigens from the patient's own tumor lysate. **DCVax-prostate** is developed using the patient's own dendritic cells loaded with a recombinant antigen for prostate cancer. The third version of DCVax is called **DCVax-Direct**, which is developed using the patient's own dendritic cells without any patient tumor tissue. The DCs are activated, but without addition of tumor antigens. The cells adhere to the plastic culture surface, which results in activation. All three versions of DCVax are based on the same DCVax platform technology. Together, these three versions of DCVax can cover almost all solid tumor indications. For example, DCVax-L is used when the patient's tumor can be surgically removed while DCVax-Direct can be used when the patient's tumor cannot be surgically removed.

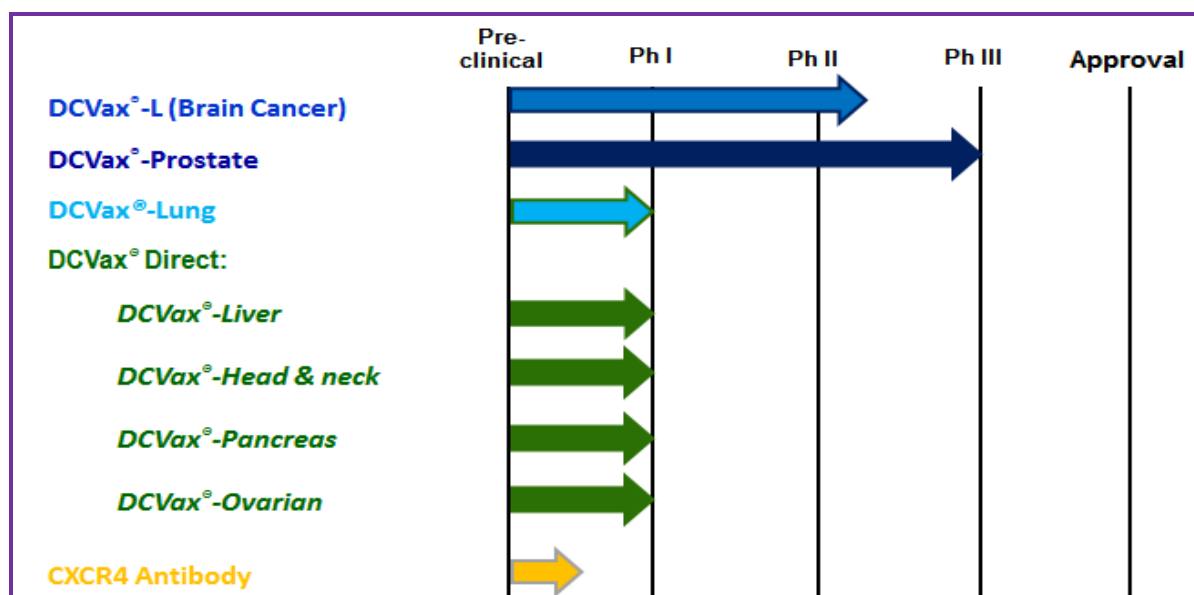
The Company's lead product candidate is **DCVax-L**, which targets Glioblastoma Multiforme (GBM), the most lethal form of brain cancer. DCVax-L has entered a **Phase II** clinical trial, which is designed and powered as a pivotal trial. Following this trial, if the results are again strikingly positive as in the early stage trials, the Company anticipates petitioning the FDA for an early approval of DCVax-L. **DCVax-Prostate**, which targets hormone independent prostate cancer, has also been cleared by the FDA to commence a **Phase III** clinical trial, which is also designed and powered as a pivotal trial. Manufacture of a DCVax product takes approximately 30 days to complete for DCVax-Prostate and approximately 8-10 days for DCVax -L.

Northwest's monoclonal antibody **CXCR4** is an experimental monoclonal antibody therapy that targets the functional chemokine receptor, CXCR4. CXCR4 is highly expressed on many cancer cell types, and is involved in three functional aspects of cancer cells including cell division, migration to distant sites, and in setting up metastatic sites and thus the spread of cancer. These functional aspects make CXCR4 a particularly attractive target for cancer therapeutics. Northwest is not currently focusing on this technology platform.

Northwest completed an initial public offering (IPO) of its common stock on the NASDAQ Stock market in December 2001 and an IPO of its common stock on the Alternative Investment Market (AIM) of the London Stock Exchange in June 2007.

NWBO was formed in 1996 and incorporated in Delaware in July 1998.

Figure 1: Development pipeline



Source: Company filings and Zacks Investment Research

INVESTMENT THESIS

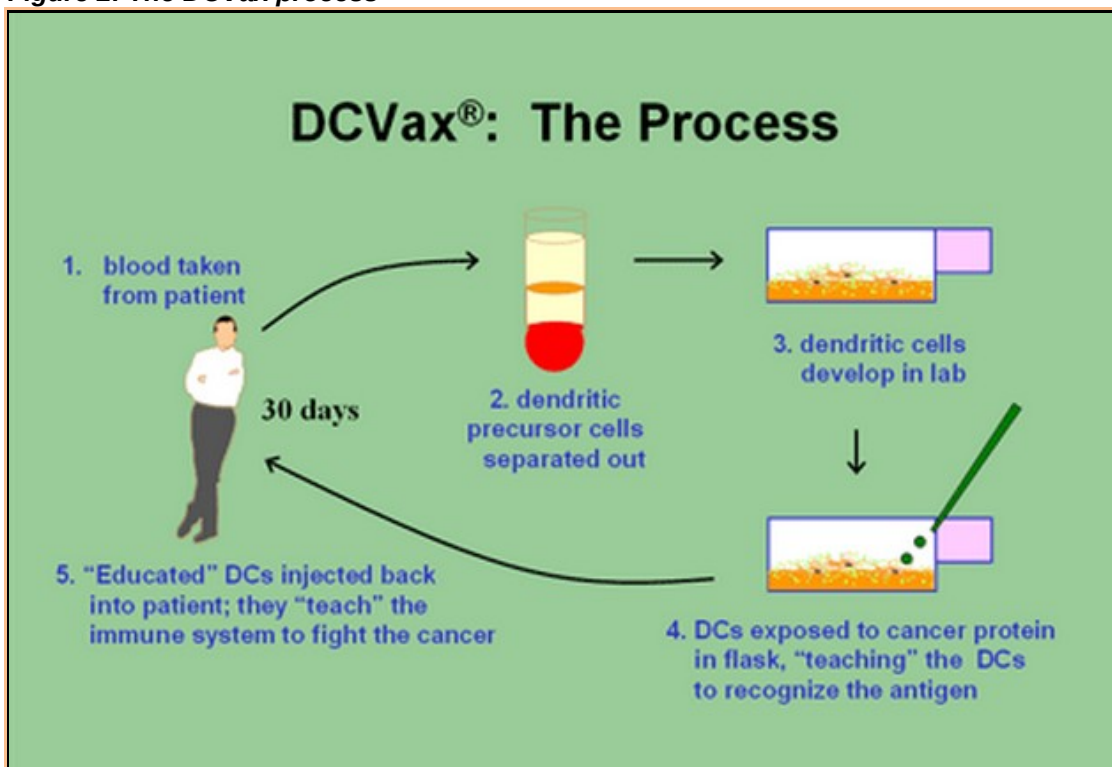
The Dendritic Cell-based DCVax Platform Technology

Northwest is developing a proprietary personalized-dendritic cell (DC) vaccine, **DCVax**, for stimulating and enhancing a patient's natural cellular and humoral (antibody) immune response to cancer. DCVax is a platform technology which may be applicable to most cancers. It combines a patient's own dendritic cells either with a patient's own cancer-related biomarkers (antigens), or with off-the-shelf antigens, to induce immune responses against a patient's cancer cells.

With the approval of Dendreon's first in class **Provenge** by the FDA in April 2010 and the award of the 2011 Nobel Prize in Physiology or Medicine for the discovery of the role and importance of dendritic cells, DC-based cancer vaccine has become the center of attention recently. NWBO's DCVax technology makes use of the dendritic cells as Dendreon's Provenge does to stimulate a patient's own immune system to fight cancer. It takes four steps to produce DCVax.

- First, the patient has surgery to remove their tumor tissue, and that tissue is sent to the manufacturing facility;
- Second, the patient goes to a blood center for a leukapheresis procedure to collect the patient's blood, from which the dendritic cells (DCs) will be obtained;
- Thirdly, at the manufacturing facility, the dendritic cells are isolated, matured and "educated" to recognize the antigens (biomarkers) of that patient's tumor;
- Fourth, the finished DCVax is shipped back to the patient's doctor for delivery into the patient's own body to fight cancer, through a simple injection under the skin in the upper arm.

Figure 2: The DCVax process



Source: company website

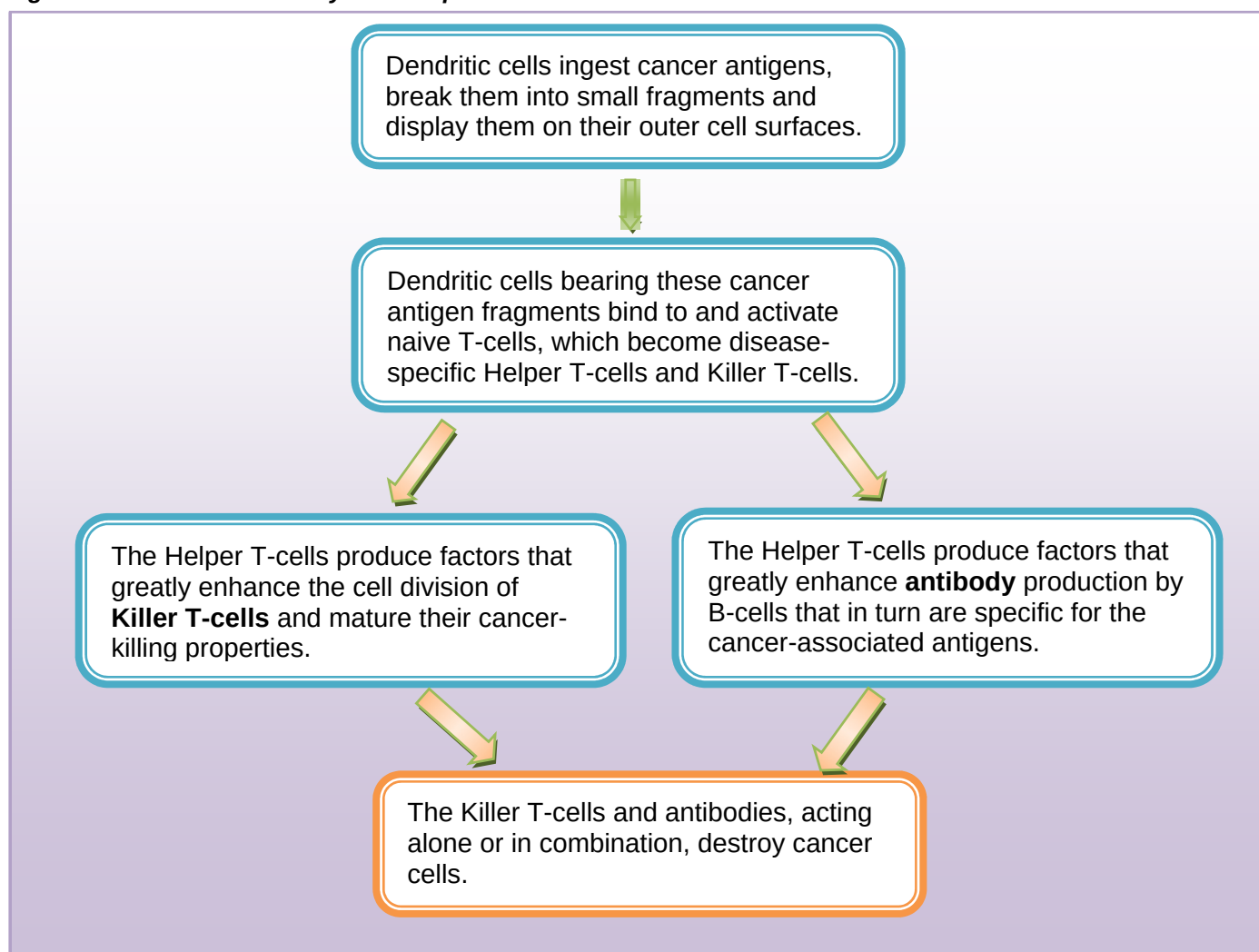
The immune system consists of populations of white blood cells whose components are responsible for initiating the **cellular** immune response, and the **humoral**, or antibody-based, immune response. The Company's DCVax stimulates both arms of the body's immune system to fight cancer.

Dendritic cells, a component of white blood cells, are the **master cells** of the immune system responsible for mobilizing the overall immune response. The dendritic cells stimulate **cellular immune responses** by processing and displaying disease-associated antigen fragments on their outer cell surface, where they are recognized by naive T-cells that have not yet been exposed to antigens. Upon exposure to these antigen fragments, naive T-cells become disease-specific Helper T-cells or Killer T-cells. Helper T-cells then help Killer T-cells to locate and potentially destroy the cells marked by the disease-associated antigen.

Dendritic cells also stimulate **humoral immune response** by mobilizing B-cells. Such B cells contribute to the immune response by binding to disease-associated antigens on the surface of various cell types, producing disease-specific antibodies. Helper T-cells also enhance B-cell production of disease-specific antibodies. These antibodies bind to and initiate the destruction of cells marked by the associated disease-specific antigens.

A small population of activated Helper T-cells, Killer T-cells, and antibody-producing B-cells survive for long periods of time, retaining the memory of what the disease fragment looks like. These cells can respond very rapidly to subsequent exposure to disease-specific antigens and fragments. The most effective natural immune response is one in which both Helper and Killer T-cells and antibody-producing B-cells are activated.

Figure 3: How the immune system responds to cancer



Source: Company filings and Zacks Investment Research

In cancer patients, the signaling through which the DCs are activated is impaired. The DCVax technology, therefore, involves delivering the necessary signals to activate the DCs outside the patients' body. After receiving these signals, the DCs will be able to function normally and mobilize the full immune response in the natural manner.

NWBO's DCVax Technology Holds Competitive Advantages

Through over 10 years of extensive lab research and development work, Northwest has developed a superior DCVax technology compared to its competitors.

A key advantage is **clinical outcomes**: length of overall survival. In NWBO's early stage trial, patients who received DCVax lived much longer than the patients who received Provenge in Dendreon's Phase III trials. Although NWBO's early stage trial results will have to be confirmed in its Phase III trial, the difference in survival with DCVax in NWBO's Phase I/II trial compared with survival with Provenge in Dendreon's Phase III trials was substantial enough to be noteworthy. In NWBO's Phase I/II trial, patients with metastatic, hormone independent prostate cancer (the same patient population as in Dendreon's Provenge trials) who received DCVax had median survival of 38.7 months, while such patients in Dendreon's Phase III trials with Provenge had median survival of about 25.9 months. (The "control group" patients who received current standard of care in Dendreon's trials had median survival of about 19 months.)

Another important advantage for DCVax is its **low cost**. Since the approval of Dendreon's Provenge in April 2010, sales have been disappointing. One of the major reasons is the high price and concerns about reimbursement mechanics. Provenge is priced at \$93,000 for one month of treatment while NWBO's DCVax will be priced in the range of \$37,000 per year for up to 3 years of treatments. The pricing of DCVax will also be substantially below the price range of most antibody drugs and targeted drugs for cancer. Such drugs are typically priced at \$60,000-80,000 per year, and can easily exceed \$100,000 per year. Such drugs also carry significant side effects, and often only extend survival for as little as 10 weeks.

The key to the substantial pricing advantage of DCVax is NWBT's proprietary **batch manufacturing process** together with its **cryopreservation technology** for frozen storage of the finished vaccine. NWBT has spent a decade developing and improving its manufacturing and cryopreservation processes. The manufacturing of personalized, living cell products is expensive. But the frozen storage of living cells is quite low-cost – once the specialized freezing technology is worked out for a particular type of cells (the culture conditions, rate of freezing, density of cells and many other factors).

NWBT's manufacturing methods produce – in a single manufacturing run – a large batch of personalized DCVax product for 3 years of treatments that are much less costly than separate manufacturing runs for each treatment. The technology for freezing the master immune cells (dendritic cells) which comprise DCVax enables these cells to remain frozen for years and, when needed, to be thawed and "come back to life" with full potency. This approach makes DCVax an "off the shelf" product for several years of treatments for the particular patient after just one manufacturing run. In contrast, Dendreon must do a separate manufacturing run for each one month of treatments. In addition, Dendreon's Provenge is fresh and not cryopreserved, which limits its shelf life to at most a few weeks.

Manufacturing has been a key commercial bottleneck for cancer immunotherapeutic market. NWBO's cost advantage is a highly differentiating factor key to its product pricing and margins. Using the Company's unique batch manufacturing process and cryopreservation technology, it is possible to manufacture 3 years (sometimes even more) of DCVax products from a single manufacturing run, therefore giving NWBO a key commercial advantage.

One more important advantage of DCVax is its simplicity and **ease of administration**. DCVax is delivered as a small intra-dermal injection under the skin, similar to a flu shot. As such, it can be administered in any physician's office or clinic. There is no lengthy intravenous infusion, with the

attendant patient discomfort, cost and need for a specialty infusion center. In contrast, Dendreon's Provenge is delivered by intravenous infusion.

The fourth advantage of DCVax is its **higher purity of dendritic cells** (greater than 80%). Provenge has less than 15% activated dendritic cells and the rest are various other cell types which are not needed for immunization. Therefore, a much smaller dosage of DCVax is required for vaccination, making intra-dermal injection possible, and reducing side effects.

Table 1: NWBO's DCVax versus Dendreon's Provenge

	DCVax	Provenge
Active Drug	High Concentration > 80% pure	Low concentration ≤ 15%
Delivery	intra-dermal, similar to flu shot	IV infusion, invasive, cumbersome
Costs	1 manufacturing run=3 year treatment, approximate \$37k/year	1 manufacturing run=1 month treatment, \$93k for one month

Source: Company presentation

The DCVax-L Brain Cancer Program: Impressive Clinical Data

Northwest's lead therapeutic program is **DCVax-L**. DCVax-L uses the Company's DCVax platform in combination with the patient's own glioblastoma **tumor cell lysate antigens**.

The tumor from surgery is shipped to a manufacturing facility, as is the blood from a leukapheresis, in order to prepare the DCVax-L. The finished DCVax-L is then shipped frozen to the clinic for administration to the patient. DCVax-L is usually manufactured in sufficient quantities for treatment of 3 years. Manufacture of DCVax-L takes approximately 8-10 days to complete (followed by quality control testing for release of the product).

Northwest's clinical collaborators at UCLA completed **two Phase I** clinical trials to assess the safety and efficacy of DC-based immunotherapy for Glioblastoma multiforme (GBM). In the first Phase I clinical trial, DCVax-L was administered to 12 newly diagnosed and recurrent patients and in the second Phase I clinical trial it was administered to 17 newly diagnosed patients. The patients in both trials were treated with DCVax-L being administered as an adjuvant to the standard of care. Standard of care is defined as surgery followed by 6 weeks of radiation and daily temodar chemotherapy combination and a further 6 months of temodar chemotherapy in monthly cycles.

The data from the two Phase I clinical trials have shown very impressive positive results of DCVax-L. Newly diagnosed GBM patients treated with DCVax-L had a delay in the median time to recurrence or progression of disease from 6.9 months with standard of care treatments to 2 years in patients treated with DCVax-L ($p = 0.00001$; $n=20$). DCVax-L increased median overall survival from 14.6 months with standard of care to 3 years in patients treated with DCVax-L ($p < 0.0004$; $n=20$).

In addition, according to the latest long term follow-up data as of July 2010, 33% of the patients had reached or exceeded 4-year survival; 27% of the patients had reached or exceeded 6-year survival, and the longest surviving patient to date had exceeded 10 years. Five of the 20 patients remained alive for periods ranging, to date, from 40 to 128 months, with seven patients having lived for over 45 months without cancer recurrence.

Similarly, in recurrent (late stage) patients, DCVax-L has increased median survival from 6.4 months for those receiving standard of care to 11.9 months for patients receiving DCVax-L.

DCVax-L is well tolerated by all patients. There were no toxicities such as are seen with chemotherapies.

When compared to other two similar brain cancer vaccines **ICT-107** and **Rindopepimut**, DCVax-L also shows favorable or similar efficacy data. Both ICT-107, developed by ImmunoCellular Therapeutics, and Rindopepimut, developed by Celldex Therapeutics, are targeting patients with newly diagnosed glioblastoma. ICT-107 is in Phase II clinical trial and Rindopepimut will enter into Phase III clinical trial at the end of 2011.

Table 2: Phase I DCVax-L efficacy data are impressive

	Standard of care	DCVax-L (NWBO)	ICT-107 (IMUC)	Rindopepimut (CLDX)
Median PFS*	6.9 months	24 months	17 months	15 months
Median OS*	14.6 months	36.0 months	> 30 months	25 months
24-month OS (%)	26.5	68	80.2	50

Source: Zacks Investment Research, PFS*: progression free survival, OS*: overall survival

Based on the positive Phase I clinical data, in **December 2006**, NWBO commenced recruiting patients with newly diagnosed GBM in a 141 patient **Phase II** DCVax-L clinical trial. The Company planned to carry out the study at 12 to 15 clinical sites. The study was designed as a randomized study in which patients received either DCVax-L in addition to standard of care or standard of care alone. The study was not blinded because there was no available approach for making a placebo that was indistinguishable from the DCVax-L. Almost 50 patients were screened at 4 clinical sites. However, patients were reluctant to enroll in the study when faced with a 33% chance of being randomized into the control arm of the study under which they will receive standard of care alone. In addition, even patients who did enroll were reluctant to stay in the study if they were assigned to the control arm. Since the study was not blinded, patients were able to know which arm of the study they were assigned to. So, the Company stopped and undertook a development program to develop a placebo that would be indistinguishable from DCVax-L, and would not show activity of its own.

With the placebo developed the Company redesigned the study as a **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 study size has been increased from 141 to 240 patients and 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.

As of May 3, 2011, 33 patients have already been enrolled in this ongoing 240-patient GBM brain cancer trial and its information arm, and have been proceeding through the treatment regimen and follow-up. Currently 21 medical centers across the U.S. are actively recruiting patients. The Company is continuing to add clinical trial sites in the U.S., and is working toward adding sites in Europe. Northwest expects to have 25 sites in the U.S. open and active by the end of 2011, with further growth expected into 2012. It takes about 18-24 months to reach primary endpoint.

Further, on May 18, 2011, NWBO announced that it is partnering with Germany's the **Fraunhofer Institute for Cell Therapy and Immunology IZI** for production of DCVax-L for clinical trials and compassionate use cases in Europe. Fraunhofer 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 Fraunhofer is assisting NWBO with the applicable regulatory requirements for both clinical trials and compassionate use cases. The Fraunhofer IZI is also selecting and initiating connections with leading clinical centers on behalf of NWBO and its DCVax products.

This partnering arrangement provides a solid foundation upon which NWBO can proceed with clinical trials in Europe, and with compassionate use treatments of patients in parallel with such clinical trials. In addition, NWBO is eligible for certain grants through the German government which, if approved, can amount to as much as €2 to 3 million (\$2.8 to 4.2 million).

The Company plans to petition for early product approval in both the U.S. and the European Union if the international 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. DCVax-L is the Company's top priority. DCVax-L received orphan drug status in both the US and EU.

Huge Market Opportunities for DCVax-L

Glioblastoma multiforme (GBM), also called glioblastoma, is the most common and most aggressive type of primary brain tumor and accounts for approximately 50% to 60% of all primary brain tumors.

According to National Cancer Institute (NCI), it is estimated that 22,020 men and women (11,980 men and 10,040 women) will be diagnosed with and 13,140 men and women will die of cancer of the brain and other nervous system each year in the US. Worldwide, approximately 176,000 new cases of brain and other CNS tumors were diagnosed each year, with an estimated mortality of 128,000.

Glioblastomas are among the most aggressively malignant human neoplasms. The median survival time from the time of diagnosis without any treatment is only a little over 1 year. Despite multimodality treatment consisting of open craniotomy with surgical resection of as much of the tumor as possible, followed by concurrent or sequential gamma knife radiotherapy, chemoradiotherapy, targeted therapy, and symptomatic care with corticosteroids, median survival is about 14.6 months. The overall 5-year survival is less than 3% with the standard of care today. Increasing age (> 60 years of age) carries a worse prognostic risk. Death is usually due to cerebral edema or increased intracranial pressure.

It is very difficult to treat glioblastoma due to several complicating factors

- The tumor cells are very resistant to conventional therapies
- The brain is susceptible to damage due to conventional therapy
- The brain has a very limited capacity to repair itself
- Many drugs cannot cross the blood-brain barrier to act on the tumor

Current treatments for GBM include surgery, radiation and chemotherapy. Such treatments are often used in various combinations and/or sequences and have significant adverse side effects such as bleeding, seizures, nausea and collateral tissue damage. Following initial treatment, virtually all cases of this cancer recur, with a life expectancy of approximately six months following recurrence. Few, if any, effective therapies exist for these patients.

Current options of chemotherapy (including targeted therapy) for glioblastoma are very limited. Although the addition of chemotherapy to radiation improves survival in many cancer types, with glioblastoma, the chemotherapy only adds about 10 weeks of survival, in a portion of the patients who take it. Most studies showed no benefit from the addition of chemotherapy to radiation for glioblastoma patients. However, currently, two chemotherapeutic agents (including one targeted therapy) approved by the FDA are frequently used for the treatment of glioblastoma in combination with radiation therapy. They are **Temodar** (temozolomide) from Merck/Schering Plough for newly diagnosed GBM and **Avastin** from Roche for recurrent GBM.

The current **standard of care** for GBM was established in a 573 patient study as set out by Stupp, et al. in N Engl J Med 352; 10. The standard of care established in the Stupp trial for GBM patients consists of

surgery followed two weeks later by radiation therapy with concomitant daily low-dose **Temodar** chemotherapy, followed by six monthly cycles of full-dose Temodar chemotherapy. In this study, patients treated with the standard of care had a median time to progression of 6.9 months and median overall survival of 14.6 months. While the group who received the same treatment regimen without Temodar survived for only 12.1 months – a difference of about 10 weeks. This standard of care treatment regime has a 26% survival at two years. In comparison, when DCVax-L was added to this standard of care in NWBOs early stage trials, over 70% of patients survived at two years.

The US FDA recently approved **Avastin** (bevacizumab) to treat patients with recurred glioblastoma (but not newly diagnosed GBM which is DCVax's initial target) after standard therapy based on the results of 2 studies that showed Avastin reduced tumor size in some glioblastoma patients. In the first study, the efficacy of Avastin was demonstrated by an objective response rate of 25.9%. Median duration of response was 4.2 months. In the second study, the efficacy of Avastin was supported by an objective response rate of 19.6%. Median duration of response was 3.9 months.

A third chemotherapeutic agent on the market for glioblastoma is Bristol Myers Squibb's **Carmustine** injection and Eisai's Carmustine wafer, which are less frequently used.

Clearly, there are unmet medical needs for the treatment of glioblastoma. DCVax may be able to address these unmet medical needs in a unique way. DCVax is specifically designed to target glioblastoma cells by activating the patient's own immune system. So far, data from DCVax are encouraging for the treatment of glioblastoma compared to marketed products and products under development.

The glioblastoma market is a multibillion dollar business. Worldwide sales of Temodar reached \$1 billion in 2009. If DCVax ultimately reaches the market, it will command a huge market share of the GBM market due to its outstanding efficacy data and safety profile in our view. Peak sales could reach \$1 billion for DCVax-L. This market potential means a lot to a small biotech company like Northwest, even if it turns out to be a few hundred million dollars in sales.

DCVax-Prostate: Targeting Unmet Medical Needs

DCVax-Prostate targets hormone independent (late stage) prostate cancer. **DCVax-Prostate** combines the Company's DCVax platform with the cancer-associated antigen "prostate specific membrane antigen" (PSMA). **PSMA** is located on the surface of prostate cells. It is expressed at very low levels on benign or healthy prostate cells, and at much higher levels on prostate cancer cells. Because PSMA is over-expressed in virtually all prostate cancers, it represents an effective target for prostate cancer therapeutics.

DCVax-Prostate is designed to be used in the whole patient population; therefore, the Company does not need to screen patients. In contrast, the use of other cancer vaccines in development may be limited to part of the patient population and require screening of patients.

Northwest completed a **Phase I/II** clinical trial for DCVax-Prostate to treat late-stage prostate cancer patients for whom hormone therapy was no longer effective (**initiated in 1999**). This trial, which was carried out at the M.D. Anderson Cancer Centre and at UCLA, involved the administration of DCVax-Prostate to 33 evaluable patients with non-metastatic and metastatic hormone independent prostate cancer in order to establish the safety of three different dosage levels of DCVax -Prostate. Of a total of 33 patients who have been treated in this trial, 11 were non-metastatic hormone independent prostate cancer patients (group A) and 22 were metastatic hormone independent prostate cancer patients (group B).

In group A (hormone independent patients without metastasis), there has been an increase in survival from 36 months for the natural course of the disease to >54 months for DCVax-Prostate treated patients. The median had not yet been reached as of the end of 2005 (the latest date to which long-term data is so far available). In this group the time to metastases under the natural course of the disease is 28 to

34 weeks. This time was lengthened to 59 weeks in patients who received DCVax -Prostate. In group A, none of the 11 patients had progressed at 28 weeks and only five had progressed at 59 weeks. The group A patient population is the patient population in planned Phase III clinical trial. Currently, there is no FDA approved treatment for non-metastatic hormone independent prostate cancer patients.

	Natural Course of Disease	DCVax-Prostate
Median Time to Disease Progression	28-34 weeks	59 weeks
Median Survival	36 months	> 54 months

In group B (hormone independent patients with metastases), there was an increase in median overall survival from 18.9 months for standard of care to 38.7 months for DCVax-Prostate treated patients. Patients in this study had a six-times greater chance of being alive at 36 months compared to patients treated with the standard of care. DCVax -Prostate has been shown to elicit a specific PSMA antibody response and a specific and strong T-cell response in about 80 percent of patients. In contrast, many cancer therapeutics elicit a clinical response in only a small fraction of patients. DCVax-Prostate also compares favorably with Dendreon's **Provenge**. DCVax-Prostate had a median survival of 38.7 months in NWBO's Phase I/II trial compared to 25.9 months for Provenge in Dendreon's Phase III trials. Three-year overall survival for DCVax-Prostate is 64% vs Provenge's 33%.

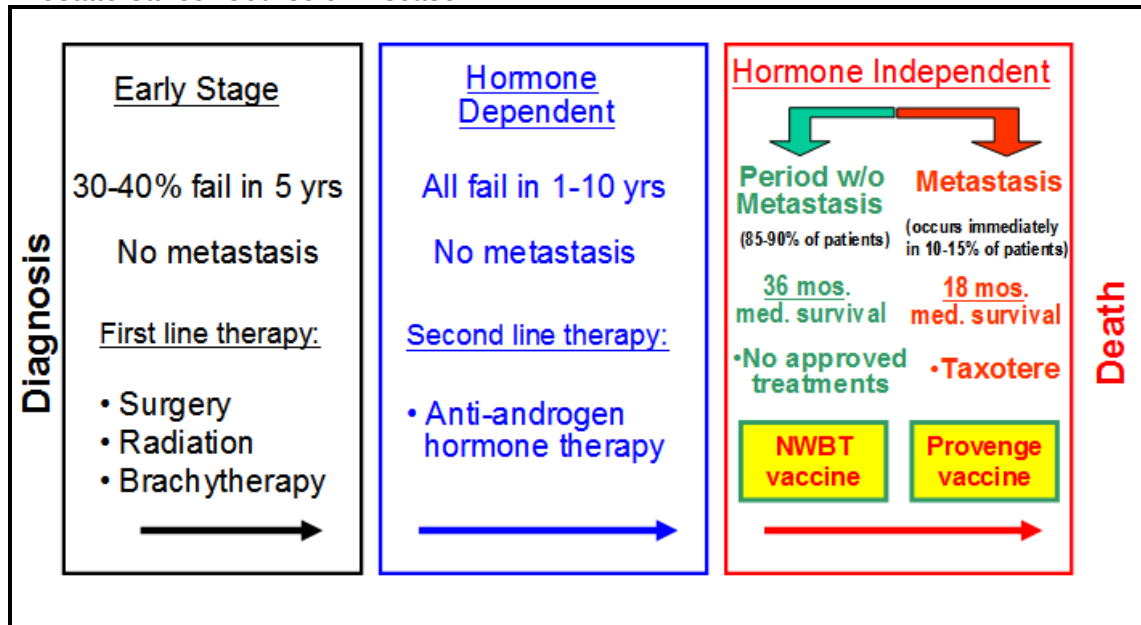
	Standard of Care (Taxotere)	DCVax-Prostate	Provenge
Median Survival	18.9 months	38.7 months	25.9 months
Overall Survival (3 years)	11%	64%	33%

The Phase I/II clinical results are encouraging. Based on these positive data, DCVax-Prostate was cleared by the FDA for a **Phase III** clinical trial in about 600 patients in January 2005. The patient population is **non-metastatic hormone independent prostate cancer**. The Company currently intends to separate the 600 patient Phase III trial into two Phase III clinical trials in non- metastatic hormone independent prostate cancer patients with about 300 patients per trial. Due to large expenses associated with the Phase III study, the Company is looking for partners to conduct the Phase III trial.

Market Opportunities for DCVax-Prostate

Other than skin cancer, prostate cancer is the most common cancer in American men. The American Cancer Society estimates that about 217,730 new cases of prostate cancer were diagnosed in 2010. About 32,050 men died of prostate cancer in 2010. About 1 man in 6 will be diagnosed with prostate cancer during his lifetime. More than 2 million men in the United States who have been diagnosed with prostate cancer at some point are still alive today. Prostate cancer is the second leading cause of cancer death in American men, behind only lung cancer. About 1 man in 36 will die of prostate cancer.

Prostate Cancer Course of Disease



Source: Company presentation

Northwest's DCVax-Prostate targets **non-metastatic hormone independent prostate cancer** which consists of approximately 100,000 patients per year in the US. The target population in Europe for DCVax-Prostate is similar to the numbers in the US.

Existing treatments for localized (i.e. newly-diagnosed) prostate cancer include **surgery** and/or various forms of **radiation therapy**. The current standard of care for treating patients who fail primary therapy is **hormone therapy** through which the effect of male hormones is blocked. Although this therapy achieves temporary tumor control, prostate cancer patients eventually fail hormone treatments, meaning that blocking of hormones no longer keeps the cancer under control. The United States National Cancer Institute's 1989-1996 five-year survival rate for metastatic prostate cancer is only 32 percent. Moreover, hormone therapy may cause significant adverse side effects, including bone loss, hot flashes and impotence. Disease progression despite hormone therapy occurs on average in two years, and is then classified as hormone independent prostate cancer. Approximately 55 percent of patients with hormone independent prostate cancer will die within two years of its onset. For a long time, the only FDA approved treatments for hormone independent prostate cancer are chemotherapy and radioactive pharmaceuticals, which can alleviate cancer-related symptoms but may cause significant toxic side effects and only prolong survival by approximately two and a half months.

Recently, the FDA approved Dendreon's **Provenge**, an autologous immunotherapy, for the treatment of metastatic hormone independent prostate cancer. The approval of Provenge was based on a Phase III IMPACT trial which was a multi-center, randomized, double-blind, placebo-controlled study which enrolled 512 patients with metastatic androgen-independent prostate cancer. The final results from the study showed that Provenge extended median survival by 4.1 months compared to placebo (25.8 months versus 21.7 months), and improved 3-year survival by 38% compared to placebo (33% versus 21%). The study also achieved a p-value of 0.032.

DCVax-Prostate is similar to Provenge, but holds some advantages over the latter. Both vaccines are autologous immunotherapy for the treatment of prostate cancer using the patient's own dendritic cells, but they use different prostate cancer specific antigens. Provenge uses **PAP-GM-CSF** as the antigen which combines prostatic acid phosphatase (PAP) with generic GM-CSF, which is commercially available. DCVax-Prostate uses prostate specific membrane antigen (**PSMA**). Dendreon's target, PAP, is not expressed on some 30% of prostate cancers, so Dendreon must screen its patients. NWBO's target,

PSMA, is expressed essentially in all prostate cancer, so NWBO does not need to screen patients and can treat all of them.

Another significant advantage of DCVax-Prostate results from a manufacturing advantage. NWBO's manufacturing process produces a finished vaccine with more than 80% purity of activated, "educated" dendritic cells – which are the active ingredient of the vaccine. In contrast, Dendreon's manufacturing process produces a finished vaccine with only 15% dendritic cells. As a result of this difference, NWBO's dose consists of a few drops and is administered as a simple injection under the skin. Dendreon's dose must be delivered through intravenous infusion.

In addition to advantages of low cost, ease of administration and high concentration of DCs, the cost effectiveness of NWBT's DCVax-Prostate is further enhanced by the fact that DCVax-Prostate is targeting a portion of the prostate cancer market that is **4 times the size of the market segment** that Dendreon's Provenge is currently targeting. The late stage prostate cancer market breaks down into two groups of patients: those who do not yet have metastases, which constitutes 80-85% of the market, and those who already have metastases, which constitutes about 15-20% of the market. Dendreon's Provenge is approved for and targeted to the patients with metastases (i.e., the 15-20% portion of the market). In contrast, NWBT's prior Phase I/II trial treated both groups of patients, and NWBT's Phase III trial design is focused on the much bigger market: patients without metastases (i.e., 80-85% of the market).

NWBO's DCVax-Prostate vs Dendreon's Provenge

	DCVax-Prostate	Provenge
Target	PSMA (attractive)	PAP
Active Drug	High Concentration > 80% pure	Low concentration ≤ 15%
Delivery	intra-dermal, similar to flu shot	IV infusion, invasive, cumbersome
Costs	1 manufacturing run=3 year treatment, approximate \$37k/year	1 manufacturing run=1 month treatment, \$93k for one month
Addressable Market	80-85%	15-20%

Source: Company presentation and Zacks Investment Research

The standard of care for metastatic hormone independent prostate cancer was established in a 674 patient study as set out by Petrylak, et al. in N Engl J Med 351; 15 and resulted in a median overall survival rate of 18.9 months. This standard of care consists of taxotere (chemotherapy) being administered as a single dose every three weeks or in a weekly regime. Other drugs, such as mitoxantrone and prednisone, are also administered to patients for pain derived from bone metastasis.

A large proportion (80-85%) of hormone independent patients does not yet have objective metastatic disease as measured by bone and CT scans at the time when they become hormone independent. There is no established standard of care for non-metastatic hormone independent prostate cancer as there is no FDA approved therapeutic product for this type of prostate cancer.

We believe that DCVax-Prostate has the potential to address this critical unmet medical need. The DCVax-Prostate treatment regimen offers a potential new standard of care, and does not require a change in clinical practices.

DCVax-L for Solid Tumors

DCVax-L targets any kind of **solid tumor cancer** and it combines the Company's DCVax platform with patient specific **tumor lysate**. Following surgery, the tumor is prepared as a lysate (i.e. the tumor tissue is finely chopped and proteins are extracted) for loading into autologous dendritic cells. The patient's tumor lysate contains cancer specific biomarkers which will be added to the patient's own dendritic cells to "educate" them and the educated DCs are subsequently injected back into the patient to elicit a cancer specific immune response.

The Company commenced a **Phase I/II** study using DCVax-L for metastatic ovarian cancer at the University of Pennsylvania in 2007. This trial treated "no option" patients who had already been treated with most or all major drugs currently available for recurrent, metastatic **ovarian cancer** (including carboplatin, paclitaxel, docetaxel, abraxane, gemcitabine and topotecan), and whose cancer had still continued to progress.

In the trial, 6 patients were treated and 3 of the 6 were still alive at the last data update with survival times of 316, 330 and 783 days. The 3 patients who died had survival times of 401, 428 and 601 days. Two of the treated patients who received DCVax-L treatment were classified as partial responders, 3 stable disease and one progressive disease. Partial response is defined by the tumor shrinking by 20-25% or combined with remaining the same size and not growing, or by disappearing. The patients did not experience any toxicity or debilitating side effects.

This study was funded by the Ovarian Cancer Vaccine Initiative (OCVI), a private philanthropic organization.

Standard therapy of ovarian cancer includes surgical debulking, followed by chemotherapy with a taxane/platinum combination for six to eight cycles. Of the patients who present with advanced stage disease (stage III or IV), 70 percent will have an initial clinical remission following surgery and chemotherapy, with no evidence of disease by physical examination, radiographic imaging (such as CT or MRI) or normalization of the CA125 tumor marker. However, for most of these patients, the ovarian cancer will recur within two years. The median time to progression is approximately 20 months even for patients who received total or near-total surgical removal of the initial tumor and is approximately 14 months for patients with less complete surgical removal of the initial tumor. Once ovarian cancer has recurred, it is not considered curable and progression to death is usually inevitable, despite aggressive chemotherapy strategies. The overall five year survival for advanced ovarian cancer remains at only 20 to 30 percent.

Metastatic ovarian cancer poses a particularly serious and urgent unmet medical need. In most patients, the disease is not discovered until it is already late stage, because ovarian cancer typically causes little or no symptoms until it is late stage. When this cancer has metastasized, the cancer usually progresses rapidly and aggressively. In other recent clinical trials in recurrent ovarian cancer, only limited clinical responses were obtained in the treated patients. In other recent clinical trials testing various drugs and drug combinations for recurrent ovarian cancer, the treated patients have generally attained less than 3 or 4 months without progression of their cancer, and have experienced serious side effects (including gastro-intestinal perforation, a life-threatening condition).

Northwest's DCVax-L may address the issues related to metastatic ovarian cancer with increased efficacy and fewer side effects.

DCVax- Lung Cancer

NWBO also has a product (DCVax-LB) designed for **non-small cell lung cancer**, the largest cause of cancer deaths in both the U.S. and Europe. DCVax-LB combines the Company's DCVax platform with isolated and killed **lung cancer cells as antigens**. The autologous DCs used to formulate DCVax-LB are activated through a process similar to that used in the manufacturing of DCVax-Prostate.

Northwest had an investigational new drug application cleared by the FDA in **May 2006** for a **Phase I** clinical trial using DCVax-LB in non-small cell lung cancer.

Lung cancer (both small cell and non-small cell) is the second most common cancer in both men (after prostate cancer) and women (after breast cancer). It accounts for about 15% of all new cancers.

The American Cancer Society estimates that about 222,520 new cases of lung cancer will be diagnosed each year. Approximately 80 percent of these cases are expected to be attributable to non-small cell lung cancer. There will be an estimated 157,300 deaths from lung cancer accounting for about 28% of all cancer deaths. Lung cancer is by far the leading cause of cancer death among both men and women. More people die of lung cancer than of colon, breast, and prostate cancers combined.

In Europe, approximate 374,764 new cases of lung cancer will be diagnosed each year. Deaths from lung cancer in Europe are estimated at 341,595 each year.

Existing treatments for non-small cell lung cancer include surgery and radiation therapy, which are used in various combinations. These treatments have significant toxic side effects and have limited clinical benefit. The American Cancer Society has reported that only 16 percent of patients diagnosed with non-small cell lung cancer survive after five years. Following initial treatment, virtually all cases of this cancer recur, with a life expectancy of approximately one year following recurrence.

Clearly, there is an unmet medical need for non-small cell lung cancer. Northwest's DCVax-Lung cancer may address this need with better efficacy and fewer side effects.

DCVax –Direct, A Unique DCVax Technology With Potential For Any Solid Tumor

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.

Several scientific studies have shown that DCs injected into solid tumors in animal models can result in tumor regression. **Pre-clinical** animal studies have demonstrated the ability of activated DCs, when injected directly into just a single tumor of mice bearing multiple tumors, to cause all tumors to regress. In these studies, subsequent challenge of these now tumor-free mice with the injection of additional tumor cells was met with total rejection of tumor growth demonstrating an immunization of the mouse against regrowth of the tumor. The DCs used in the formulation of DCVax-Direct are activated through a process similar to that used for DCVax-L and DCVax-Prostate, although they are not loaded with tumor antigens prior to injection. Rather, the antigen loading takes place in vivo after injection of the DCVax-Direct DCs into the tumor tissue, typically following radiation therapy, chemotherapy, or other treatments that kill tumor cells.

Phase I clinical trial protocol was cleared by the FDA for the treatment of several cancers, including **head and neck cancer**, in the third quarter of 2006, and re-submitted to FDA with a broader scope (for solid tumor cancers) this year and was cleared by FDA, with that broader scope, in the third quarter this year. The Company intends to address a range of cancers in this trial, including liver and pancreatic cancers.

Current treatments for solid tumors typically involve cytotoxic therapy aimed at killing tumor cells. Such treatments include radiation therapy, chemotherapy, or other cell killing treatments such as cryotherapy. These treatments can still be used along with DCVax-Direct as they can potentially prepare the tumor tissue for the injection of DCVax-Direct. The ability to still use conventional cytotoxic agents along with

DCVax-Direct will enable DCVax-Direct to be adopted in the market without requiring any change of existing clinical practice if so desired.

Therapeutic Antibody Product Candidate

In addition to dendritic cell immunotherapy platform technology, NWBO also has intellectual property and did pre-clinical work to develop therapeutic monoclonal antibodies to a particularly valuable target: **CXCR4**.

CXCR4 is a receptor protein for **chemokines**. CXCR4 is a protein that plays a key role in the progression of primary cancers and in the metastatic process. CXCR4 is over-expressed in more than 75 percent of cancers including non- small cell lung cancer, breast cancer, GBM, colon cancer, melanoma, prostate, pancreatic, kidney, ovarian, and certain blood cancers. In all of these cancers CXCR4 is centrally involved in all three phases of disease progression: proliferation of the primary tumor, migration of cancer cells out of the primary tumor, and establishment of distant metastatic sites. These functional aspects make CXCR4 a particularly attractive target for cancer therapeutics.

The Company has completed substantial research and **pre-clinical** testing phases with two versions of CXCR4 antibodies. The Company intends to consider further development work at an appropriate time.

Balance Sheet Has Been Boosted

Management has been making every effort to beef up the Company's balance sheet and has been successful to seal a few deals in the past few months.

On June 28, 2011, NWBO secured a \$4.55 million equity investment by The Richard M. Schulze Family Foundation. The Foundation has been focused for a number of years on game-changing medical research and treatment breakthroughs. The Foundation has been a major supporter of basic research at universities, and clinical programs at medical centers such as the University of Minnesota and the Mayo Clinic. NWBO is the first company chosen by the Schulze Foundation for a biotech investment, and the decision followed a full year of due diligence by teams of experts.

On June 5, 2011, NWBO announced that it has put in place a series of financing arrangements with Whitebox Advisors, a multi-billion dollar hedge fund group headquartered in Minneapolis, Minnesota, including a \$3 million investment already received. In addition, NWBO announced that it had entered into an agreement for access to up to \$25 million of further funding on fixed, specified and favorable terms, at such times and in such amounts as the Company chooses through an equity line similar to a shelf registration. The facility will be administered by Toucan Partners, a longtime shareholder and supporter of NWBO, in order to ensure that the facility is handled in a manner that is beneficial and not toxic to NWBO.

On November 17, 2011, NWBO announced an additional \$5.4 million in funding arrangements, being provided by another longtime shareholder and supporter of the Company who is not an affiliate. The arrangements consist of a \$2.4 million note and \$3 million commitment to purchase newly issued shares under the equity facility.

On December 2, 2011, NWBO announced the implementation of a major clean-up of its balance sheet, under which the Company's liabilities were reduced from \$48 million to \$16.5 million. Moreover, only about \$2.3 million of the remaining \$16.5 million involves trade payables (which are being maintained on a current basis), and the rest of the \$16.5 million involves investor debt which is mostly held by longtime supporters of the Company and expected to convert into equity in due course.

This series of financing arrangements, as well as other such transactions on an ongoing basis, will provide a strong financial foundation for completion of the Company's ongoing 240-patient clinical trial of

DCVax-L for the treatment of glioblastoma, and will also provide for certain other programs in the Company's near term pipeline.

As mentioned above, Toucan Partners has agreed to help provide an equity facility, similar to a shelf registration, to enable NWBO to issue registered, tradable shares for future financings of up to \$25 million over a 30-month period. The shares involved in this equity facility will be registered in several tranches, and the 30-month period will begin on the effective date of the first registration statement.

As of September 30, 2011, the Company held \$1.6 million in cash.

Management Has Been Enhanced

Northwest recently made changes and substantially expanded its management team, adding several highly experienced executives.

Ms. Linda Powers, Chairperson and CEO.

Ms. Powers has served as Chairman of NWBT for the last 4 years, and brings more than 25 years' experience in corporate transactions and operations, including more than a decade specializing in building biotech companies through Toucan Capital. Ms. Powers is particularly well known for her experience in building biotech companies that are developing cell therapies, including both immune cell therapies (such as NWBT's DCVax) and adult stem cell therapies. The cell therapy companies which Ms. Powers has been involved in building over the last decade, both in the US and abroad (in Asia, Europe and Israel), are at the forefront of clinical trials and early commercialization. Ms. Powers has served for years on a number of related boards, including the M2Gen Board of the Moffitt Cancer Center, the Board of the Trudeau Institute (a world leader in immunology research) and others. As Chairman of NWBT, she has brought her lengthy experience to bear in helping to shape NWBT's overall strategy and programs. As CEO, she will now undertake operational responsibilities in addition to continuing her duties as Chairman.

Anthony Maida, PhD, Chief Operating Officer

Dr. Maida, a well-known senior executive in the field of cancer immune therapies, joined NWBT as Chief Operating Officer on June 20th, 2011.

As the newest member of the management team, Dr. Maida brings more than 20 years' experience in building oncology companies, with expertise in the business and financial aspects, the clinical and regulatory aspects, and the underlying science. Over these two decades, Dr. Maida has held positions as Chairman, CEO, COO, CSO, CFO and VP Business Development, and has raised nearly \$200 million in financings for these oncology companies. Among these experiences, he served for a period as CEO of CancerVax, an early leader in cancer vaccines. In that role, he raised the company's first \$30 million of funding, and was responsible for conducting multi-hundred patient, multi-center clinical trials with the company's cancer vaccines. Prior to joining NWBT as COO, Dr. Maida was serving as global head of Oncology for a leading contract research organization that manages clinical trials in the US and internationally.

Dr. Maida has been responsible for negotiating partnering and licensing transactions with many premier pharmaceutical companies and academic centers of excellence, including, among others, Eli Lilly, Novartis, RCT Corporation, Astra Zeneca, Pfizer, Bristol Myers Squibb, MD Anderson, Yale University, Stanford University, University of California San Francisco and Davis, and the Wistar Institute. Dr. Maida's already strong scientific expertise was further strengthened as he recently completed and in 2010 received a PhD in Tumor Immunology. On the financial front, Dr. Maida has served for years as a key adviser to many large institutional investors for their oncology investments. Dr. Maida serves on several boards in the oncology field, including Spectrum Pharmaceuticals and others. Earlier in his career, Dr. Maida served for a number of years as the Chief Financial Officer of a large public company's subsidiary and Senior Financial Controller of a \$1.7 billion division of that company (Lockheed).

Alton Boynton, PhD, Chief Scientific Officer

Dr. Boynton is the scientific founder of NWBT, and was the first in the world to conduct a clinical trial with dendritic cells, which are the cells used in NWBT's DCVax products. During the 1990s, when little was known about dendritic cells and their roles, Dr. Boynton's research lab was an early leader in identifying the important clinical capabilities of the dendritic cells and their potential for fighting cancer. Within this academic setting, during the 1990s Dr. Boynton treated over 100 prostate cancer patients with the DCVax technology, prior to commencing formal clinical trials in the Company. Since that time, Dr. Boynton served as the Chief Scientific Officer of the Company until 2007, at which time he became CEO. Prior to founding NWBT, Dr. Boynton headed the Molecular Oncology research lab at the Pacific Northwest Research Foundation (the original foundation of Bill Hutchinson, from which the Fred Hutchinson Cancer Center was spun off), focusing on dendritic cells, and he established and headed the Molecular Oncology research department at Northwest Hospital in Seattle (where the first clinical trial with dendritic cells took place in 1995). Earlier in his career, Dr. Boynton was Associate Director of the University of Hawaii Cancer Center, and a professor of Genetics and Molecular Biology. He has authored over 150 peer-reviewed research publications, and is the inventor on numerous issued and pending patents relating to dendritic cells. Dr. Boynton is resuming his position as Chief Scientific Officer of NWBT.

Mr. Les Goldman, Sr. VP of business development

Mr. Goldman was a partner at the law firm of Skadden, Arps for over 30 years, specializing in a wide array of advanced technologies and their commercialization. He helped build one of the preeminent global practices in this area. He was responsible for advising on financing, regulatory strategies, and public outreach relating to his clients' development of numerous cutting edge technologies, bringing to bear a diverse range of deal-making skills. He has taken a special early retirement from Skadden, Arps to enable him to undertake an executive role at NWBT. Mr. Goldman also serves as an advisor to a number of other breakthrough technology companies. In addition, for 8 years, Mr. Goldman has served as Chairman of the Board of a group of TV Stations in 4 mid-size cities across the country. Mr. Goldman is joining NWBT as Senior VP Business Development.

Marnix Bosch, PhD, Chief Technical Officer

Dr. Bosch joined NWBT in 2000, and has been serving as Chief Technical Officer for a number of years. In this capacity, he plays a key role in the preparation and submission of the Company's regulatory applications, as well as ongoing development of the Company's product lines, and ongoing development and/or acquisition of new technologies. Dr. Bosch led the process of designing the protocols, and managed the successful preparation and submission of the Company's INDs for prostate cancer, brain cancer and five other cancers. He also led the processes for other regulatory submissions in both the US and abroad. He spearheaded the development of the Company's manufacturing and quality control processes, and is working with the Company's contract manufacturer, Cognate BioServices, on next-generation further development of these processes. Prior to joining NWBT in 2000, Dr. Bosch worked at the Dutch National Institutes of Health (RIVM) as head of the Department of Molecular Biology, as well as in academia as a professor of Pathobiology. He has authored more than 40 peer-reviewed research publications in immunology and virology, and is an inventor on several patent applications on dendritic cell product manufacturing. Dr. Bosch is continuing in his capacity as Chief Technical Officer of NWBT.

INDUSTRY OUTLOOK

Our Outlook For The Biotech Industry Is Positive In General

We think there are a number of strong secular growth drivers that still power the biotech industry—namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent

breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership remain the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think those with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;
- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

VALUATION AND RECOMMENDATION

We are initiating coverage of Northwest Biotherapeutics with an Outperform rating. Our 12-month price target is \$1.50 which values the Company at \$220 million in market capitalization.

Our call is based on the Company's relatively strong fundamentals.

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 scientists in the area of immunotherapy.

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.

We admit that it's always difficult to value a development stage biotech company, NWBO is no exception. We don't think absolute valuation such as free cash flow method is appropriate for NWBO since generating positive cash flow is still years away. Without revenue and operating income in the foreseeable future, it's also very difficult to come up with a value using a relative valuation metrics. However, we do think that NWBO should be worth more than current value of \$40 million in market cap by comparing the Company with its peers in the same industry.

Currently, the Company shares are trading at about \$0.40 per share which values the Company at about \$59 million based on 148 million shares outstanding. This is certainly a huge 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 middle to late stage development biotech company, and its lead candidate DCVax-L is under a Phase II clinical trial designed and powered as a pivotal trial. Another lead candidate DCVax-Prostate is also cleared for a Phase III trial. Market potential is huge for either product.

We noticed recent acquisition of private BioVex by Amgen. The deal was valued at \$1 billion with \$425 million in upfront and up to \$575 million in additional payments upon the achievement of certain regulatory and sales milestones. BioVex is developing OncoVex, an oncolytic vaccine in Phase III clinical development, for the treatment of melanoma and head and neck cancer. Although BioVex's OncoVex is in more advanced trials (Phase III) than NWBO's DCVax products (Phase II), we noticed that NWBO has a much deeper pipeline. Therefore, this transaction convinces us that NWBO is undervalued.

Our price target of \$1.5 per share values NWBO at \$220 million in market cap based on the 148 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 A Concern, But Has Been Relieved Some By Recent Transactions

The Company has experienced recurring losses from operations. As of September 30, 2011, the Company had only \$1.6 million in cash and had a working capital deficit of \$44.3 million (including the \$16.6 million recorded as a liability relating to securities in excess of the authorized number, which has been eliminated when the Company increased its authorized number of common stock in November 2011).

In order to boost its balance sheet, NWBO has conducted a series of financing arrangements, including new funding from investors and major balance sheet cleanup in the past few months. These transactions, as well as other such transactions on an ongoing basis, will provide a strong financial foundation for completion of the Company's ongoing 240-patient clinical trial of DCVax-L for the treatment of glioblastoma, and will also provide for certain other programs in the Company's near term pipeline.

Even with 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 soar, not to mention the costs of other clinical programs. According to our model, the Company will incur operational loss of \$29 million in fiscal 2011

alone. Although current financing plan provides some cushion, we believe the Company still needs to tap the capital market in a regular basis in the next few years. 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.

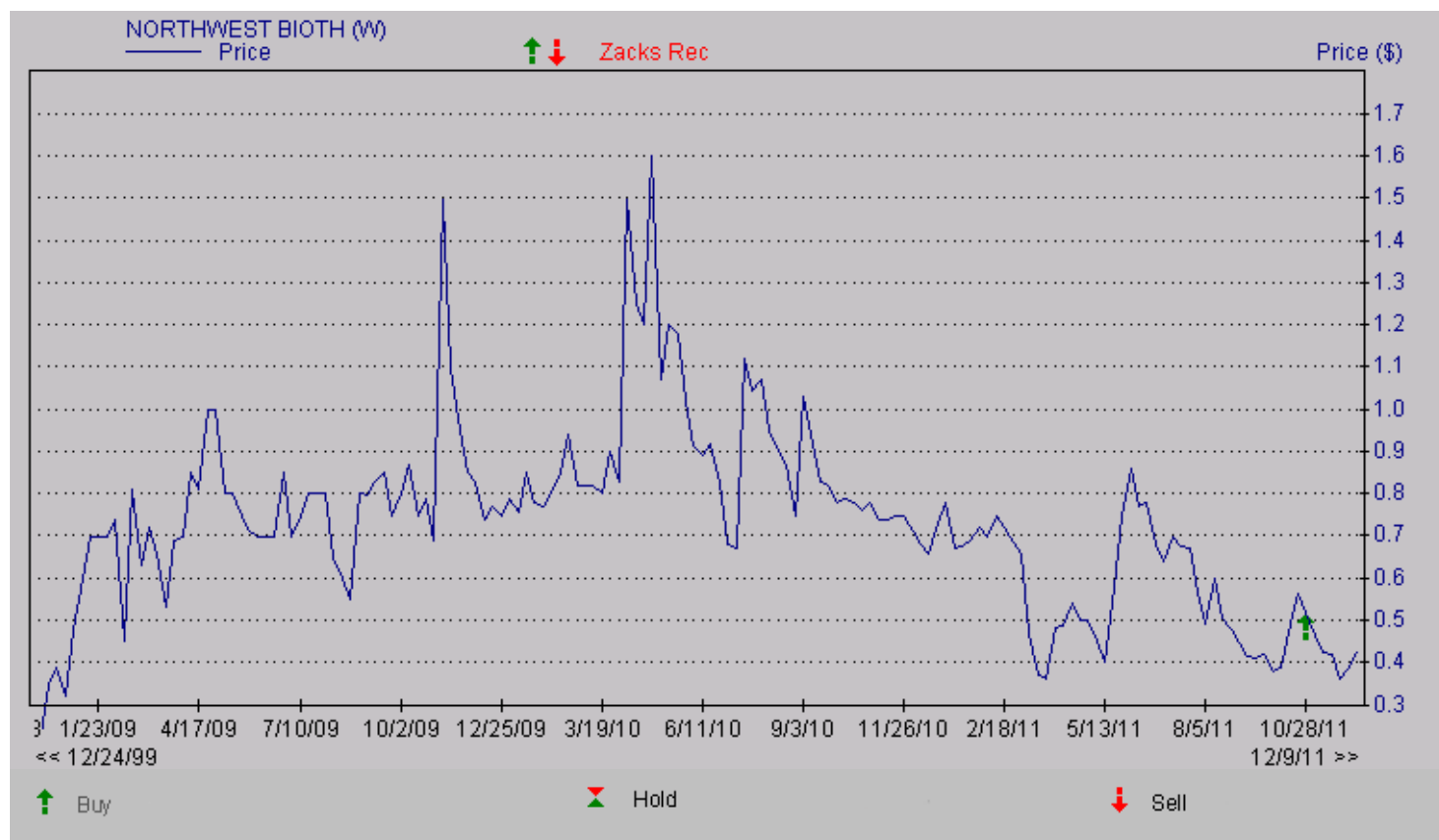
In the case of DCVax-Prostate, we don't think the Company will go ahead with the Phase III clinical trials of DCVax-Prostate except with a partner, due to the scale of resources required for this large Phase III trial (\$40 million or more).

PROJECTED INCOME STATEMENT

	2010A (Dec)					2011E (Dec)					2012E (Dec)	2013E (Dec)	2014E (Dec)	2015E (Dec)
\$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
Research material sales	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$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	\$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	\$0.00
Total Revenues	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$0.00
YOY Growth	-	-	-	#DIV/0!	0.0%	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$0.00	\$0.00	\$0.01	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$0.00
Gross Margin	-	-	100.0%	-	100.0%	-	-	-	-	-	-	-	-	-
R&D	\$1.99	\$1.19	\$1.61	\$5.11	\$9.90	\$4.44	\$3.47	\$3.56	\$4.00	\$15.47	\$17.50	\$14.50	\$12.00	\$10.00
% R&D	-	-	16060.0%	-	-	-	-	-	-	-	-	-	-	-
SG&A	\$1.36	\$1.91	\$1.41	\$0.78	\$5.46	\$2.32	\$5.56	\$2.80	\$3.00	\$13.68	\$10.00	\$11.50	\$12.50	\$14.00
% SG&A	-	-	14120.0%	-	-	-	-	-	-	-	-	-	-	-
Other expenses	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.01	\$0.00	\$0.00	\$0.00	\$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	(\$3.3)	(\$3.1)	(\$3.0)	(\$5.9)	(\$15.4)	(\$6.8)	(\$9.0)	(\$6.4)	(\$7.0)	(\$29.1)	(\$27.5)	(\$26.0)	(\$24.5)	(\$24.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	(\$2.5)	(\$5.6)	(\$0.63)	(\$3.3)	(\$12.0)	(\$1.7)	(\$3.3)	\$6.8	(\$3.0)	(\$1.1)	(\$10.0)	(\$7.5)	(\$5.0)	(\$5.0)
Pre-Tax Income	(\$5.8)	(\$8.7)	(\$3.6)	(\$9.2)	(\$27.4)	(\$8.4)	(\$12.3)	\$0.5	(\$10.0)	(\$30.3)	(\$37.5)	(\$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	\$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	(\$5.8)	(\$8.7)	(\$3.6)	(\$9.2)	(\$27.4)	(\$8.4)	(\$12.3)	\$0.5	(\$10.0)	(\$30.3)	(\$37.5)	(\$33.5)	(\$29.5)	(\$29.0)
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	59.9	63.9	70.4	74.1	67.1	77.1	83.9	123.1	148.5	108.2	200.0	230.0	260.0	310.0
Reported EPS	(\$0.10)	(\$0.14)	(\$0.05)	(\$0.12)	(\$0.41)	(\$0.11)	(\$0.15)	\$0.00	(\$0.07)	(\$0.28)	(\$0.19)	(\$0.15)	(\$0.11)	(\$0.09)
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	\$0.00	\$4.52	\$0.00	\$0.15	\$4.67	\$0.00	\$1.46	(\$9.21)	\$0.00	(\$7.75)	\$0.00	\$0.00	\$0.00	\$0.00
Non GAAP Net Income	(\$5.8)	(\$4.2)	(\$3.6)	(\$9.0)	(\$22.7)	(\$8.4)	(\$10.9)	(\$8.7)	(\$10.0)	(\$38.0)	(\$37.5)	(\$33.5)	(\$29.5)	(\$29.0)
Non GAAP EPS	(\$0.10)	(\$0.07)	(\$0.05)	(\$0.12)	(\$0.34)	(\$0.11)	(\$0.13)	(\$0.07)	(\$0.07)	(\$0.35)	(\$0.19)	(\$0.15)	(\$0.11)	(\$0.09)

Source: Company filings and Zacks Investment Research estimates

HISTORICAL ZACKS RECOMMENDATIONS



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