Zacks Small-Cap Research

August 11, 2015
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# MabVax Therapeutics Holdings, Inc. (MBVX - OTC)

## *MBVX: Phase 1 Clinical Trials Set to Get Underway in the First Quarter of 2016…*

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 07/13/2015 |
| Current Price (08/11/15) | $1.91 |
| **Target Price** | **$4.50** |

## UPDATE

On August 10, 2015, MabVax Therapeutic Holdings, Inc. (MBVX) announced financial results for the second quarter of 2015 and provided a business update. The company exited the quarter with $7.2 million, which included $3.5 million received from an escrow account that was held in conjunction with the company's $11.7 million equity financing.

The company is planning to file INDs before the end of the year for the lead asset, HuMab 5B1, as both a therapeutic and diagnostic. We anticipate Phase 1 clinical trials being initiated in each indication in the first quarter of 2016.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$15.00** |
| **52-Week Low** | **$0.85** |
| **One-Year Return (%)** | **-66.37** |
| **Beta** | **-0.37** |
| **Average Daily Volume (sh)** | **99,588** |
| **Shares Outstanding (mil)** | **26** |
| **Market Capitalization ($mil)** | **$49** |
| **Short Interest Ratio (days)** | **1.33** |
| **Institutional Ownership (%)** | **0** |
| **Insider Ownership (%)** | **7** |
| **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 2013 Estimate** | **N/A** |
| **P/E using 2014 Estimate** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

### Revenue

(In millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | 0.1 A | 0.1 A | 0.1 A | 0.1 A | 0.3 A |
| 2015 | 0.2 A | 0.1 A | 0.2 E | 0.2 E | 0.8 E |
| 2016 | | | | | 1.0 E |
| 2017 | | | | | 1.0 E |

### Earnings per Share

(EPS is operating earnings before non-recurring items)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | - A | - A | -$1.54 A | -$1.30 A | -$9.51 A |
| 2015 | -$6.25 A | -$0.29 A | -$0.11 E | -$0.11 E | -$1.69 E |
| 2016 | | | | | -$0.48 E |
| 2017 | | | | | -$0.40 E |

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## WHAT'S NEW

### Financial Update

On August 10, 2015, MabVax Therapeutics Holdings, Inc. (MBVX) announced financial results for the second quarter of 2015 and provided a business update. The company reported revenue of $0.14 million, which was recognized from the $1.5 million Phase II Small Business Innovation Research contract from the National Cancer Institute (NCI) for developing HuMab 5B1 as an imaging agent in pancreatic cancer. The company recognizes the revenue from grants received from the National Institutes of Health (NIH) as expenses that directly relatr to the grant are incurred.

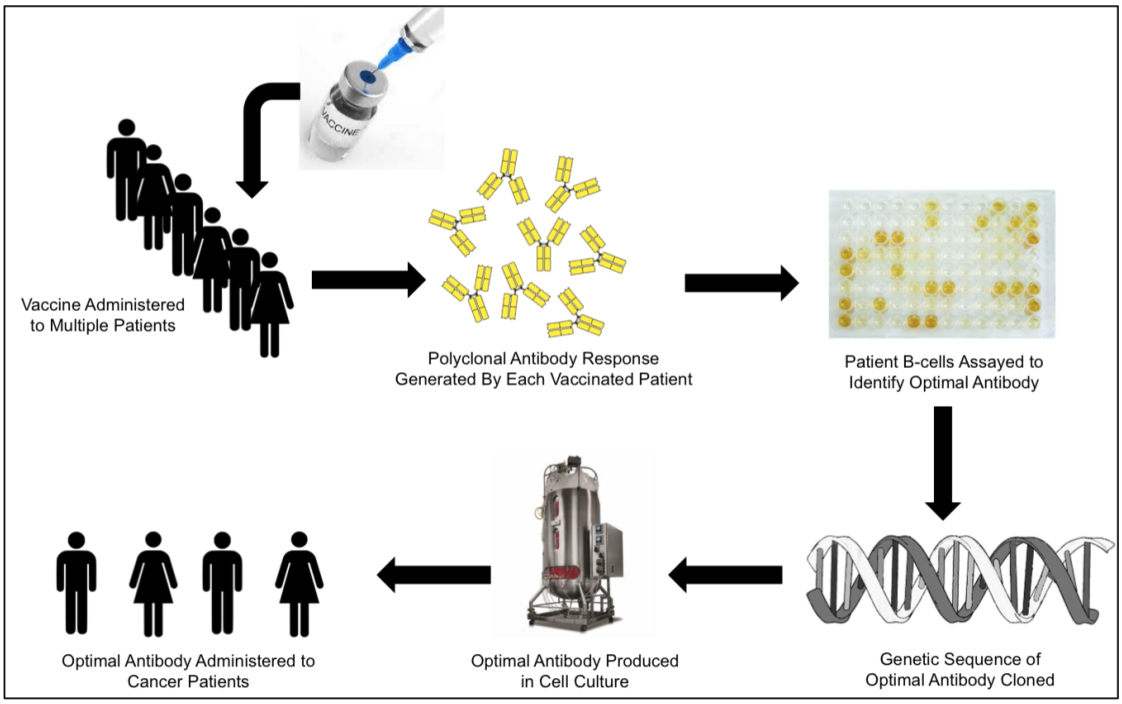
Net loss for the second quarter of 2015 was $6.4 million, or $0.29 per share. R&D expenses for the current quarter were $2.3 million while G&A expenses were $4.2 million. The G&A expenses included investor relations expenses related to restricted stock grants to an investor relations firm. Total cash burn for the quarter was approximately $3.9 million. The company exited the second quarter of 2015 with approximately $7.2 million thanks in part to raising $11.6 million through a private placement led by OPKO Health (NYSE:OPKO) and Dr. Philip Frost, CEO and Chairman of OPKO Health. We anticipate this will be sufficient to fund the company through the first quarter of 2016.

### Business Update

On August 5, 2015, MabVax published a letter from CEO David Hansen to stockholders. In the letter, Mr. Hansen provided an overview of the company's antibody pipeline, vaccine pipeline, HuMab 5B1, and upcoming development milestones.

***MabVax's Novel Antibody Discovery Platform***

MabVax has generated >100 fully human antibody leads from the use of a novel antibody discovery platform. Instead of using transgenic mice or phage display, MabVax generates fully human antibodies from B-cells extracted from patients immunized with proprietary cancer vaccines. This is the only example we know of where fully human monoclonal antibodies targeting cancer are generated from immunized patients.



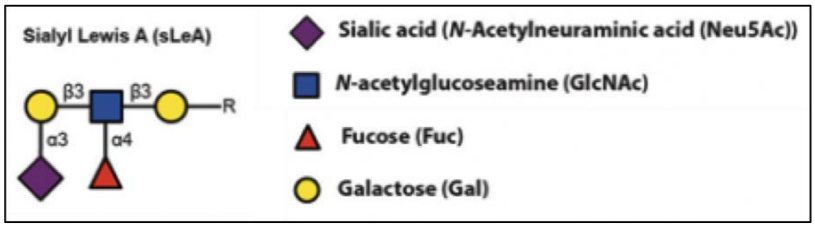

*Source*: Zacks SCR

Deriving fully human monoclonal antibodies from vaccinated patients is a novel approach to generating therapeutic antibody candidates and comes with a number of advantages over traditional antibody discovery programs. These advantages include:

1) There is no need to genetically modify a murine derived antibody or perform any type of *in vitro* affinity maturation, as the patient's immune system has already performed that work.
2) The self-censoring mechanism of the human immune system prevents that production of "self-harming" antibodies. Thus, any antibodies derived from a vaccinated patient that responds well to the vaccine are less likely to result in unwanted side effects.
3) A "proof-of-concept" experiment has already been performed; a source patient who had a positive clinical outcome provides anecdotal evidence for clinical activity of any derived antibodies.

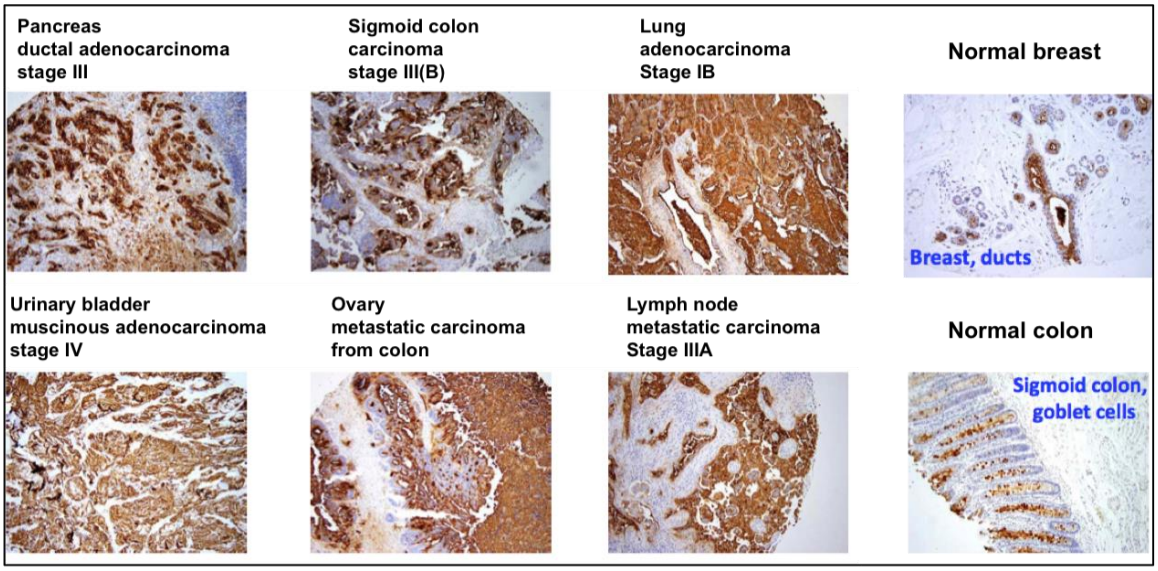
***Lead Antibody Candidate Targets Sialyl Lewis$^a$ Antigen***

MabVax has focused its initial antibody discovery work against tumor associated carbohydrate antigens (TACAs), as they are consistently over-expressed across a wide range of cancer types while being less expressed on normal tissue (Dabelsteen, 1996). The TACA sialyl Lewis$^a$ (sLe$^a$) was discovered in the early 1980's and a diagnostic assay using an antibody (CA19-9) raised to sLe$^a$ is used worldwide to aid in the management of pancreatic cancer (Magnani *et al*., 2004). The American Society of Clinical Oncology discourages the use of CA19-9 as a screening test for cancer due to a high number of both false positives and false negatives (Locker *et al*., 2006), however CA19-9 is useful in determining whether a pancreatic tumor is secreting sLe$^a$ and if so, how the tumor is responding to treatment through the rise and fall of sLe$^a$ serum levels.




*Source*: Glycopedia.eu

sLe$^a$ is over-expressed on a number of different epithelial tumor types including pancreatic, colon, stomach, ovarian, breast, and small-cell lung cancers. The following figure shows significant homogeneity and staining intensity of sLe$^a$ on different types of cancer cells along with limited staining of normal tissue. The expression of sLe$^a$ on normal breast, colon, and pancreatic tissue is restricted to cells of the secretory ducts and lumen, which are inaccessible to the immune effector mechanisms.



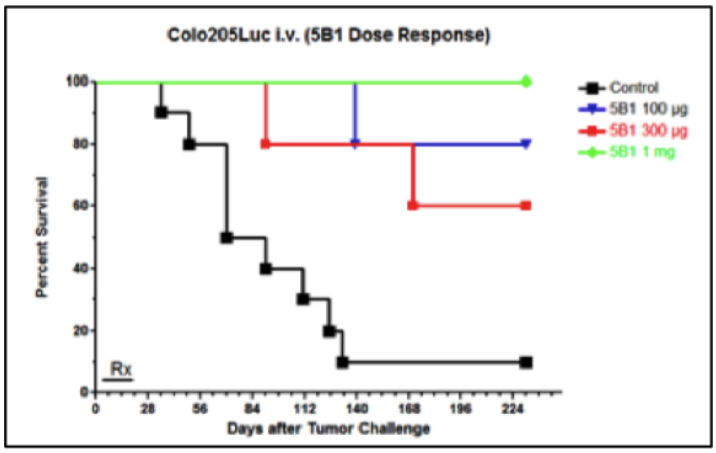

*Source*: MabVax Therapeutics, Inc. / MSKCC

Circulating cells from those tumors typically over-express sLe$^a$, and as a ligand for E selectin (a protein expressed in the inner lining of blood vessels) this antigen facilitates interactions between tumor cells and tissues that are key events for tumor metastasis. Colorectal cancer cells that express high levels of sLe$^a$ metastasize more efficiently than cells that express low levels of sLe$^a$ (Ben-David *et al*., 2008). In addition, the loss of sLe$^a$ expression was shown to inhibit metastasis of human gastrointestinal tract cancer cells (Kawamura *et al*., 2005).

The lead antibody in MabVax's pipeline is HuMab-5B1, which has demonstrated exceptionally high affinity (Kd = 140 pM) and specificity for sLe$^a$. HuMab-5B1 was derived from a patient with Stage IV breast cancer who was originally vaccinated with a sLe$^a$ vaccine at the end of 2008. A total of seven patients were vaccinated at that time with the sLe$^a$ vaccine and six of them are still alive today. The patient from whom 5B1 was derived remains disease free to this day. MabVax is targeting HuMab-5B1 for the treatment of metastatic pancreatic and colorectal cancer, as these two diseases have very low 5-year survival rates and improved therapeutic options are clearly warranted.

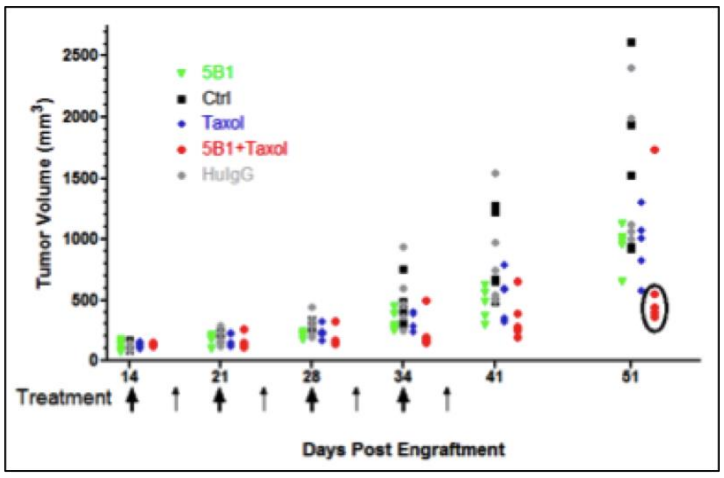
***HuMab 5B1 is Effective in Pre-Clinical Cancer Models***

MabVax has tested HuMab 5B1 (MVT-5873) in multiple pre-clinical tumor xenograft models. The first model involved the use of colo205 cells, which are a human colorectal cancer cell line. The following figure shows the effect of treating mice inoculated with colo205-luc cells with MVT-5873 at varying concentrations. Mice were treated twice a week for the first two weeks and then once a week for the next 7 weeks. All mice treated with MVT-5873 at 1 mg per injection survived the experiment.



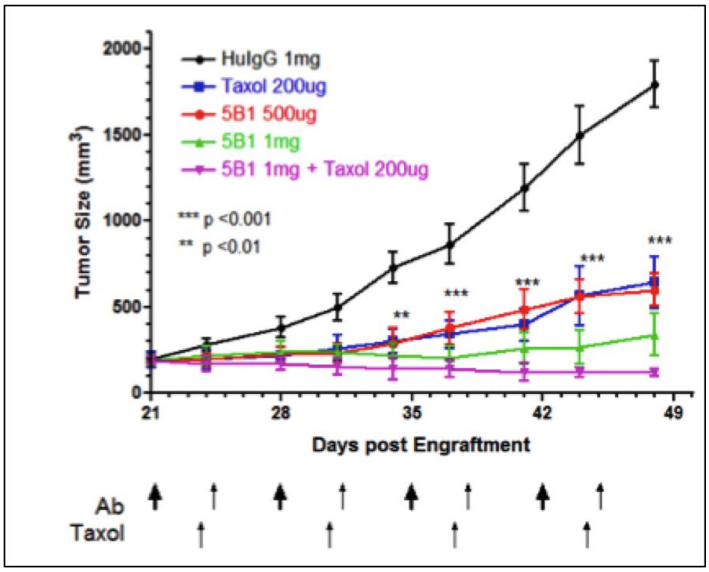

*Source*: MabVax Therapeutics, Inc.

Another experiment was performed with BxPC3 cell line, which is a human pancreatic cancer cell line. BxPC3 cells were injected into mice and the tumors were allowed to grow for 14 days (>100 mm$^3$) before commencing treatment. Mice were treated twice per week with either MVT-5873 or control human IgG and taxol was administered once a week for four weeks. Results show that either MVT-5873 or taxol reduced tumor growth over control and the combination of MVT-5873 and taxol significantly reduced tumor growth compared to either treatment alone.




*Source*: MabVax Therapeutics, Inc.

MVT-5873 has also been tested in a human small-cell lung cancer model using the DMS79 cell line. After allowing the tumors to grow for three weeks, treatment was begun with MVT-5873 and taxol either alone or in combination. Results showed that MVT-5873 treatment coupled with taxol inhibited tumor growth while MVT-5873 treatment alone resulted in only modest tumor growth.




*Source*: MabVax Therapeutics, Inc.

In summary, MVT-5873 has shown activity in pre-clinical models using human colorectal, pancreatic, and small-cell lung cancer xenografts, exactly as would be predicted based on the expression of $sLe^a$ on those tumor types. In addition, the data support the use of MVT-5873 in combination with chemotherapeutic agents since MVT-5873 was able to increase the effectiveness of taxol in two separate models.

***MabVax to Investigate HuMab 5B1 Effector Mechanisms***

On August 6, 2015, MabVax announced a research collaboration with The Rockefeller University's Laboratory of Molecular Genetics and Immunology, which is headed by Dr. Jeffrey Ravetch. Dr. Ravetch is a leading researcher of antibody-mediated effector responses and how alterations to the antibody constant region impact those responses. Alterations to the amino acid sequence of an antibody's constant region can have a large impact on how the antibody interacts with other components of the immune system, including various receptors and complement proteins, which can then lead to a varied immunological response. Probable outcomes of this collaboration are to engineer next-generation therapeutics with HuMab 5B1 that have enhanced tumor cell killing capabilities. Examples of Dr. Ravetch's work can be found on his website.

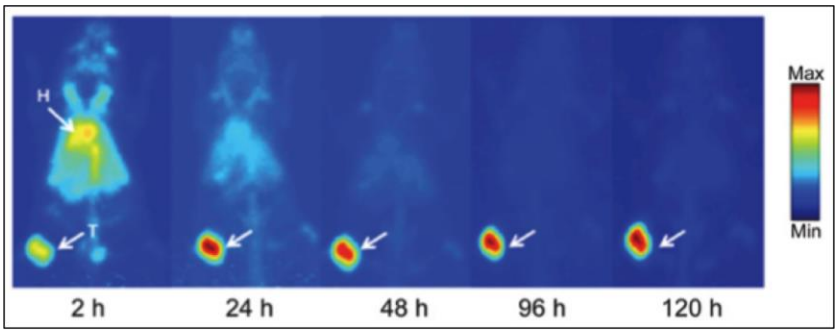
***MVT-5873 Development Plan in Metastatic Cancer***

MabVax is planning to file an investigational new drug (IND) application with the FDA for MVT-5873 before the end of 2015 and initiate a Phase 1 clinical trial to examine the safety and pharmacokinetics in a group of patients with different cancer types in the first quarter of 2016. We anticipate preliminary results from this study being available in the second half of 2016.

Following the Phase 1 study, MabVax is planning to initiate a Phase 2 clinical trial that will enroll approximately 150 patients and require two to three years to complete. The program will likely be eligible for Orphan Drug Designation since pancreatic cancer only affects approximately 50,000 individuals each year. The Phase 2 study would likely require $10 million to complete, however the MVT-5873 program has garnered the interest of several larger biopharmaceutical companies based on the positive pre-clinical testing, xenographic animal model experiments, and toxicology results generated thus far and the company would consider partnering after the Phase 1 study is complete if acceptable terms can be established. The robust pipeline of follow-on antibodies already generated means the company can partner MVT-5873 early on as a means of generating non-dilutive capital.

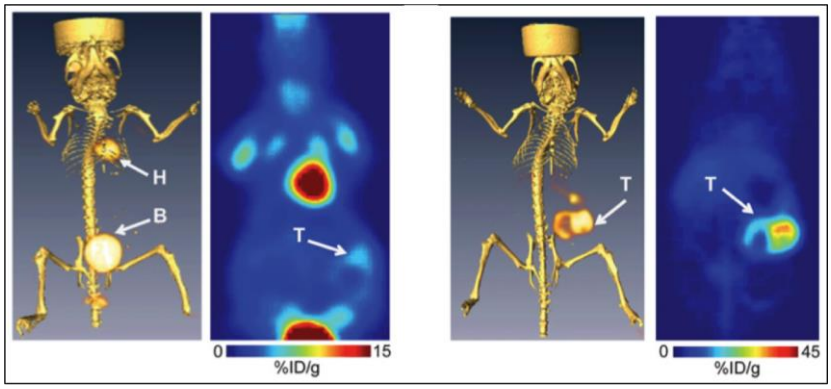
***HuMab-5B1 (MVT-2163) as a PET Tracer in Pancreatic Cancer Imaging***

In order to test the hypothesis that targeting sLe[a] would be a useful imaging tool, HuMAb-5B1 (MVT-5873) was coupled to the radionuclide $^{89}$Zr using a clinically validated linking agent (DFO). $^{89}$Zr is known to offer good quality imaging data based on previous pre-clinical and clinical data (Ulmert *et al*., 2012; Holland *et al*., 2010). A small imaging study was then performed with $^{89}$Zr-DFO-HuMab-5B1 (MVT-2163) in mice bearing a subcutaneous BxPC3 pancreatic cancer xenograft on the left hind leg. PET imaging showed impressive delineation of the tumor by MVT-2163 with normal tissue binding activity disappearing at 24 hours post injection (Viola-Villegas *et al*., 2013). The following figure shows high tumor localization at 24 hours, which increases up to 120 hours post injection.




*Source*: Viola-Villegas *et al*., 2013

Next, MVT-2163 was tested in a more clinically relevant tissue microenvironment. BxPC3-luc cells (which express the luciferase gene allowing for monitoring of tumor growth by bioluminescence) were injected directly into the pancreas of immuno-deficient mice. After the tumors had grown for two weeks, all mice received FDG PET and a subset of mice then received MVT-2163. The following figure shows combined PET/CT analysis for a representative mouse that received FDG PET (left) and MVT-2163 PET (right). The images show that FDG PET has a high degree of background as shown by the intense signal at the heart and bladder and minimal uptake by the tumor. In contrast, the MVT-2163 PET image shows very little background and clear uptake by the tumor.




*Source*: Viola-Villegas *et al*., 2013

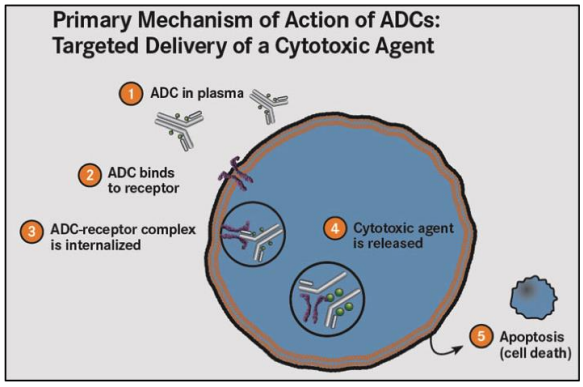
***Opportunity and Development Plan for MVT-2163***

We believe that MVT-2163 is the only human derived imaging agent currently in development for improving imaging of pancreatic cancer and if proven effective would be welcome by patients and physicians. The opportunity for MVT-2163 is significant in a number of ways since accurately diagnosing, staging, and assessing treatment outcomes in pancreatic cancer, along with accurate determinations on the extent of disease and resectability, are essential to improving care for patients with the disease.

The regulatory pathway for a diagnostic agent is considerably less expensive and time consuming than for a therapeutic agent as it requires less intensive clinical trials. New diagnostic agents must be compared to validated standard diagnostic testing techniques. Initial work is performed in limited Phase 1 and 2 studies with a portion of the validation work coming from comparing published data from the standard technologies to the new product data. This approach can allow for more rapid development and approval of a new diagnostic agent. MabVax is planning to file an IND prior to the end of 2015 and initiate a Phase 1a clinical trial in the first quarter of 2016. We estimate a total of 50 patients will be necessary to get MVT-2163 through Phase 2 trials at a total cost of approximately $5 million.

***HuMab 5B1 as an Antibody-Drug Conjugate***

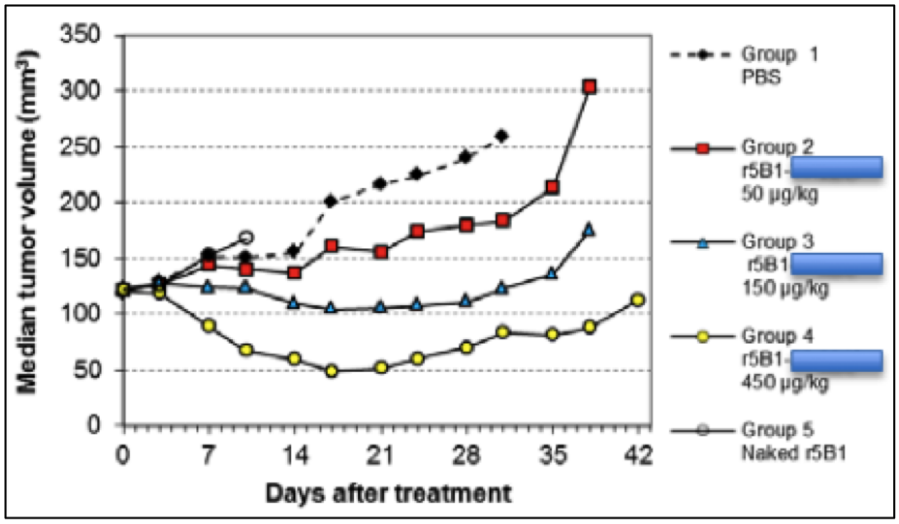
Antibody-drug conjugates (ADC's) are monoclonal antibodies that are conjugated to a cytotoxic agent through a stable, chemical linker (Ducry *et al*., 2010). The compounds work through the ability of a monoclonal antibody to delivery a cytotoxic payload to a cancer cell through its specific binding of a tumor antigen (such as sLe$^a$ for MVT-5873). Binding between the monoclonal antibody and the cell causes the internalization of the antibody along with the attached cytotoxic agent. Once inside the cell, the cytotoxic agent is released and the cancer cell is killed.




*Source*: onclive.com

There are currently two ADC products approved by the FDA: brentuximab vedotin (Adcetris®), for the treatment of Hodgkin lymphoma and systemic anaplastic large cell lymphoma, and trastuzumab emtansine (Kadcyla®), for the treatment of HER2 positive metastatic breast cancer.

The largest challenge in developing additional ADC products is the production of viable linkers that prevent premature off-loading of the cytotoxic agent before the antibody reaches the cancer cell. MabVax has entered into collaboration with Heidelberg Pharm, a company with its own proprietary linker and toxin technology, and as part of the collaboration Heidelberg has performed initial pre-clinical experiments utilizing HuMab-5B1-toxin ADC candidates. Results show the ability to successfully conjugate a linker and toxin to HuMab-5B1 with no apparent loss of binding specificity or affinity between HuMab-5B1 and sLe$^a$. This HuMab-5B1-toxin ADC shows potent *in vitro* and *in vivo* activity, as shown by the following figure where a single dose of HuMab-5B1-toxin ADC at varying concentrations limits the growth of BxPC3 xenografts.




*Source*: MabVax Therapeutics, Inc.

The company plans to continue preclinical testing and select the optimal linker by the end of 2016. In 2017, the company will perform GMP manufacturing of HuMab-5B1-toxin ADC and file an IND such that Phase 1 studies can be initiated.

## Vaccine Program

Dr. Philip Livingston, who is the company's Chief Scientific Officer and former Head of the Laboratory of Tumor Vaccinology at Memorial Sloan-Kettering Cancer Center (MSKCC), has been developing a series of monovalent (targeting a single tumor antigen) cancer vaccines for the last 30 years that target carbohydrate antigens on neuroectodermal and epithelial cancers. MabVax has licensed exclusive rights to vaccines that cover 11 validated target antigens from MSKCC. The license agreement calls for MSKCC to complete all preclinical and Phase 1 clinical trial work at MSKCC's expense at which point the IND would be transferred to MabVax for continued development.

MabVax has three cancer vaccines under active development targeting recurrent sarcoma, ovarian cancer, and neuroblastoma. We invite investors to review our previous research report for an in-depth overview of the company's vaccine program. The vaccines targeting recurrent sarcoma and ovarian cancer are currently in proof of concept Phase 2 clinical trials, while the neuroblastoma vaccine has completed an initial Phase 1 trial at MSKCC and a Phase 2 trial should commence in 2016. We anticipate results from the sarcoma and ovarian cancer trials and the Phase 2 neuroblastoma trial to commence in 2016.

## Conclusion and Recommendation

MabVax has compiled a considerable amount of pre-clinical data on HuMab 5B1 as a therapeutic and diagnostic agent. The company is planning to file an IND for each indication before the end of 2015 and subsequently initiate Phase 1 clinical trials in the first quarter of 2016. The Phase 1 trial for the therapeutic indication will likely be a safety and pharmacokinetic study involving late-stage cancer patients with multiple types of solid tumors. Data from this study should begin to be available in the second half of 2016, and will be used to guide optimal dosing for a Phase 1b clinical trial later in 2017. The Phase 1 trial for the diagnostic indication will likely enroll up to 30 patients in both the dose escalation and expansion arms of the trial. We estimate it will take approximately one year to fully enroll the trial and obtain all results, however important safety and targeting specificity readouts are likely to come much sooner, perhaps by mid to late-2016.

The company is currently investigating two cancer treatment vaccines in Phase 2 clinical trials for preventing recurrence of sarcoma and ovarian cancer. Both trials are fully enrolled and overall survival data from each of the studies should be available in 2016. In addition, an IND will be filed for the neuroblastoma vaccine in the first half of 2016 with a Phase 2 trial likely to begin shortly thereafter.

### *Valuation Methodology*

We value MabVax using a probability-adjusted discounted cash flow model that takes into account potential future revenues from MVT-5873 as a therapeutic in pancreatic and colorectal cancer, MVT-2163 as a diagnostic in pancreatic cancer, and the cancer treatment vaccines for sarcoma, ovarian cancer, and neuroblastoma. The following table summarizes our valuation model.

| Compound | Indication | Approval | Peak Sales U.S. ($millions) | Peak Sales E.U. ($millions) | Discount Rate | Probability | NPV $millions |
|---|---|---|---|---|---|---|---|
| MVT-5873 | Pancreatic Cancer | 2021 | $800 | $900 | 20% | 20% | **$48** |
| MVT-5873 | Colorectal Cancer | 2021 | $1,900 | $1,800 | 20% | 20% | **$77** |
| MVT-2163 | Pancreatic Cancer | 2020 | $60 | $60 | 20% | 25% | **$29** |
| Trivalent Vaccine | Sarcoma | 2020 | $125 | $180 | 20% | 15% | **$20** |
| Pentavalent Vaccine | Ovarian Cancer | 2020 | $300 | $500 | 20% | 15% | **$50** |
| Bivalent Vaccine | Neuroblastoma | 2021 | $45 | $30 | 20% | 10% | **$3** |
| *Source:* Zacks SCR | | | | | | **Total** | **$227** |

Combining the total sum of parts with the company's current cash position, the cash that could be brought in from warrants, and estimate capital expenditures gives a net present value for the company of $225 million. Dividing this by the company's fully diluted share count of 50.3 million shares leads to a fair value of approximately $4.50. We think that investors with a longer investment horizon could be handsomely rewarded as clinical success over the next year leads the share price higher.

## PROJECTED FINANCIALS

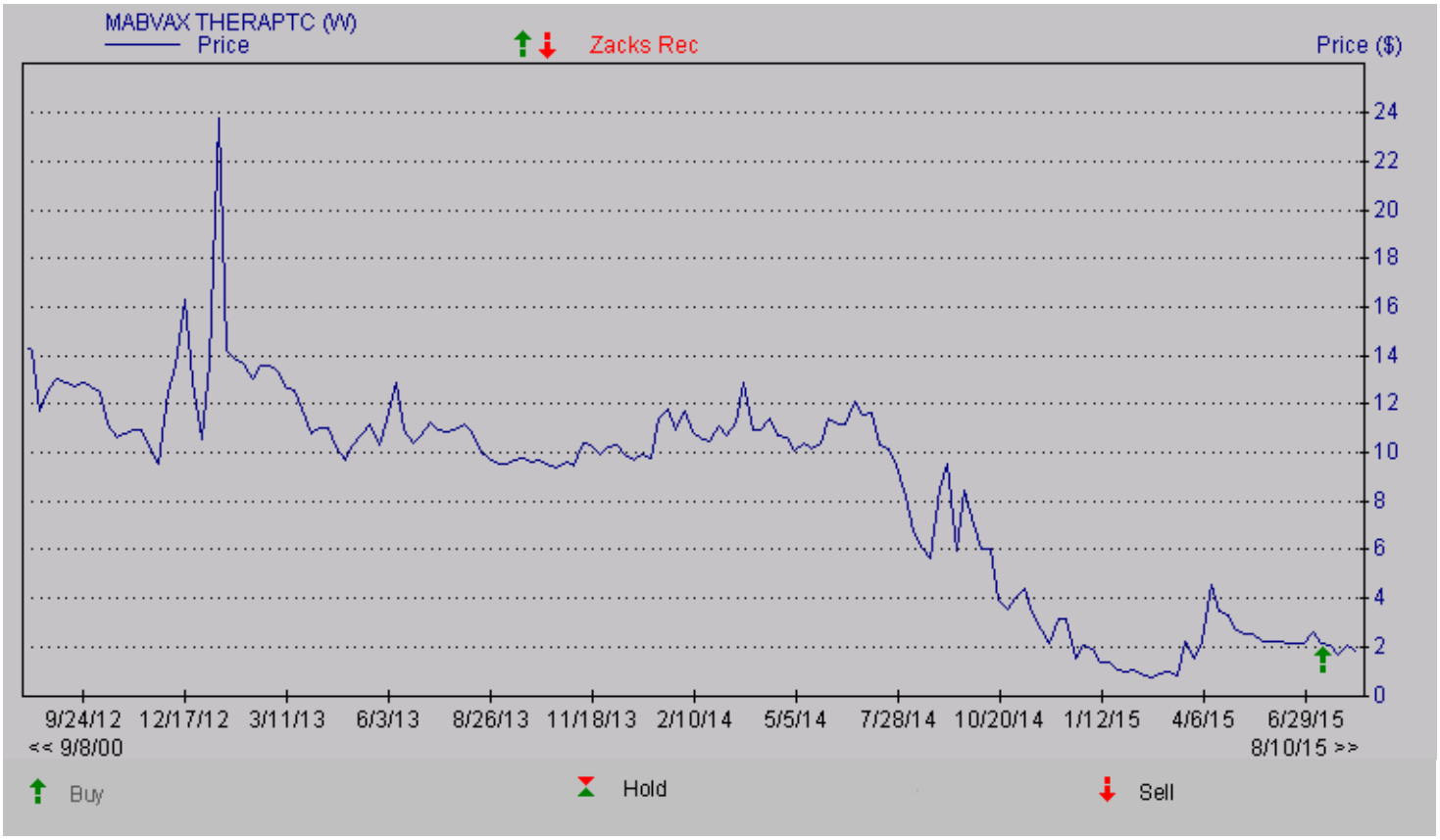
**MabVax Therapeutics, Inc.**
Income Statement

| MabVax Therapeutics, Inc. | 2014 A | Q1 A | Q2 A | Q3 E | Q4 E | 2015 E | 2016 E |
|---|---|---|---|---|---|---|---|
| **MVT-5873** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **MVT-2163** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **HuMab - ADC** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **Trivalent Vaccine - Sarcoma** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **Pentavalent Vaccine - Ovarian Cancer** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **Bivalent Vaccine - Neuroblastoma** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **Grants & Collaborative Revenue** | $0.3 | $0.2 | $0.1 | $0.2 | $0.2 | $0.8 | $1.0 |
| *YOY Growth* | - | - | - | - | - | - | - |
| **Total Revenues** | **$0.3** | **$0.2** | **$0.1** | **$0.2** | **$0.2** | **$0.8** | **$1.0** |
| *YOY Growth* | - | - | - | - | - | - | - |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | - | - | - | - | - | - | - |
| Research & Development | $3.503 | $1.726 | $2.326 | $1.800 | $1.900 | $7.752 | $9.5 |
| General & Administrative | $5.204 | $0.981 | $4.207 | $1.000 | $1.200 | $7.861 | $8.5 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($8.393) | ($2.467) | ($6.396) | ($2.600) | ($2.9) | ($14.8) | ($17.0) |
| *Operating Margin* | - | - | - | - | - | - | - |
| Non-Operating Expenses (Net) | $0.475 | $0.020 | $0.000 | $0.010 | $0.010 | $0.040 | $0.1 |
| Pre-Tax Income | ($7.918) | ($2.4) | ($6.4) | ($2.6) | ($2.9) | ($14.8) | ($16.9) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Deemed Dividends | ($2.21) | ($17.85) | $0.00 | $0.00 | $0.00 | ($17.85) | $0.00 |
| Accretion of Preferred Stock Dividends | ($0.44) | ($0.09) | $0.00 | ($0.10) | ($0.10) | ($0.29) | $0.00 |
| **Net Income** | **($10.578)** | **($20.393)** | **($6.396)** | **($2.690)** | **($2.990)** | **($32.943)** | **($16.900)** |
| *Net Margin* | - | - | - | - | - | - | - |
| **Reported EPS** | **($9.51)** | **($6.25)** | **($0.29)** | **($0.11)** | **($0.11)** | **($1.69)** | **($0.48)** |
| *YOY Growth* | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 1.112 | 3.263 | 21.695 | 25.000 | 28.000 | 19.490 | 35.000 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

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