Zacks Small-Cap Research

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MabVax Therapeutics Holdings, Inc.

(MBVX - Nasdaq)

MBVX: Uplist to Nasdaq Complete; Company Raised $9.4 million; Preliminary Data for HuMab-5B1 Looks Encouraging…

Based on our probability adjusted DCF model that takes into account potential future revenues from HuMab-5B1 in pancreatic cancer as a therapeutic and imaging agent as well as for the company's sarcoma and ovarian cancer vaccines, MBVX is valued at $15/share. This model is highly dependent upon continued clinical success of HuMab-5B1 as well as the results of the ongoing Phase 2 clinical trials of the company's cancer vaccines.

Current Price (08/26/16)	$5.09
Valuation	**$15.00**

OUTLOOK

On August 17, 2016, MabVax Therapeutics Holdings, Inc. (MBVX) announced a 1 for 7.4 reverse split of its common stock, an uplist to the Nasdaq stock exchange, and a public offering that resulted in total gross proceeds of approximately $9.4 million.

The company is currently conducting two Phase 1 clinical trials with the lead antibody assets, MVT-5873 and MVT-2163. MVT-5873 is being tested as a therapeutic agent in patients with advanced pancreatic cancer while MVT-2163 is being tested as an imaging agent in patients with pancreatic cancer. Of nine patients treated with MVT-5873 thus far, five have been treated for longer than three months with some of those exhibiting stable disease.

SUMMARY DATA

52-Week High	**$13.32**
52-Week Low	**$3.40**
One-Year Return (%)	**-54.52**
Beta	**0.07**
Average Daily Volume (sh)	**34,416**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**9**
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	**-1.1**
P/E using 2014 Estimate	**-1.2**

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)
2015	0.2 A	0.1 A	0.1 A	0.8 A	1.3 A
2016	0.1 A	0.0 A	0.2 E	0.2 E	0.7 E
2017					1.0 E
2018					1.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$46.26 A	-$2.18 A	-$1.51 A	-$1.03 A	-$13.44 A
2016	-$1.12 A	-$0.92 A	-$0.74 E	-$0.69 E	-$3.36 E
2017					-$3.76 E
2018					-$4.56 E

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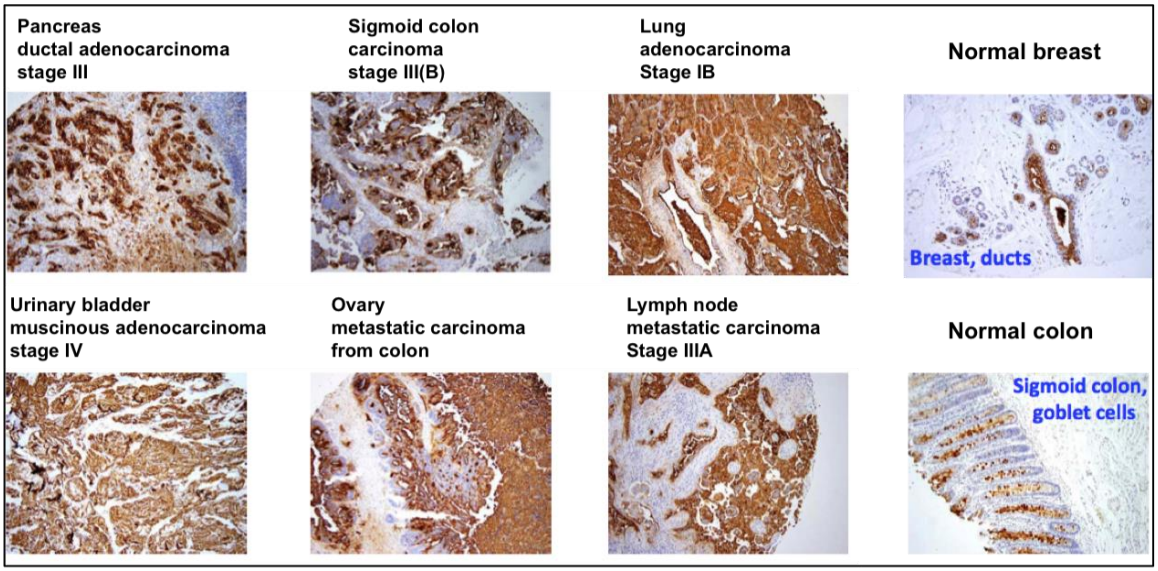
WHAT'S NEW

Business Update

MabVax Therapeutics Holdings, Inc. (MBVX) is a biopharmaceutical company that is developing proprietary human monoclonal antibody products for the diagnosis and treatment of a variety of cancers. The company utilizes a novel antibody discovery platform that identifies potent antibodies targeted to unique cancer-specific antigens. These antibodies are identified from patients immunized with proprietary cancer vaccines that result in robust anti-cancer immune responses. The company's lead antibody asset is HuMab-5B1, which is currently in clinical trials as a potential therapeutic (MVT-5873) and imaging agent (MVT-2163).

HuMab-5B1

MabVax's lead antibody candidate, HuMab-5B1, targets the tumor associated carbohydrate antigen (TACA) sialyl Lewis^a (sLe^a). A diagnostic assay using an antibody (CA19-9) raised to sLe^a is used worldwide to aid in the management of pancreatic cancer, as the antigen is typically shed into the bloodstream by tumors and thus can be monitored over time. 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

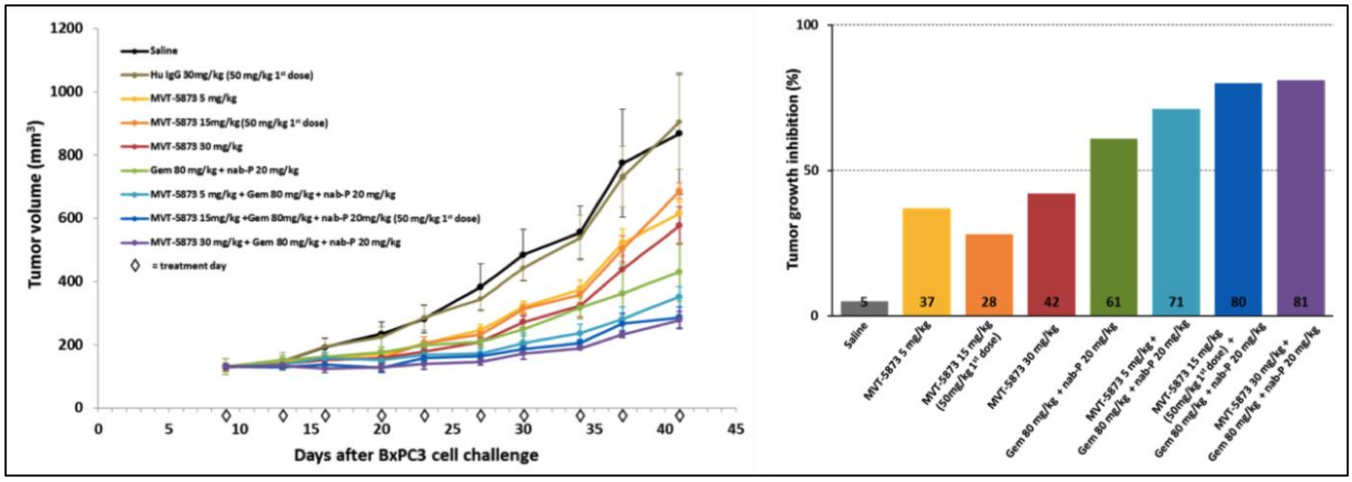
HuMab-5B1 was generated from the company's novel antibody discovery platform, which allows for the generation of fully human antibodies. The antibodies are derived from B-cells extracted from patients immunized with proprietary cancer vaccines. This is the only example we know of where fully human monoclonal antibodies targeting cancer are generated from immunized patients. 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 initially targeting HuMab-5B1 for the treatment of metastatic pancreatic cancer (MVT-5873) and as an imaging agent (MVT-2163) for the detection of pancreatic cancer. There are approximately 49,000 individuals diagnosed with pancreatic cancer each year, and close to 80% have metastatic disease at the time of diagnosis. The 5-year survival rates for patients with pancreatic cancer are dismal (<14%) and are particularly bad for those with metastatic disease (~1%).

MVT-5873 Synergizes with Pancreatic Cancer SOC

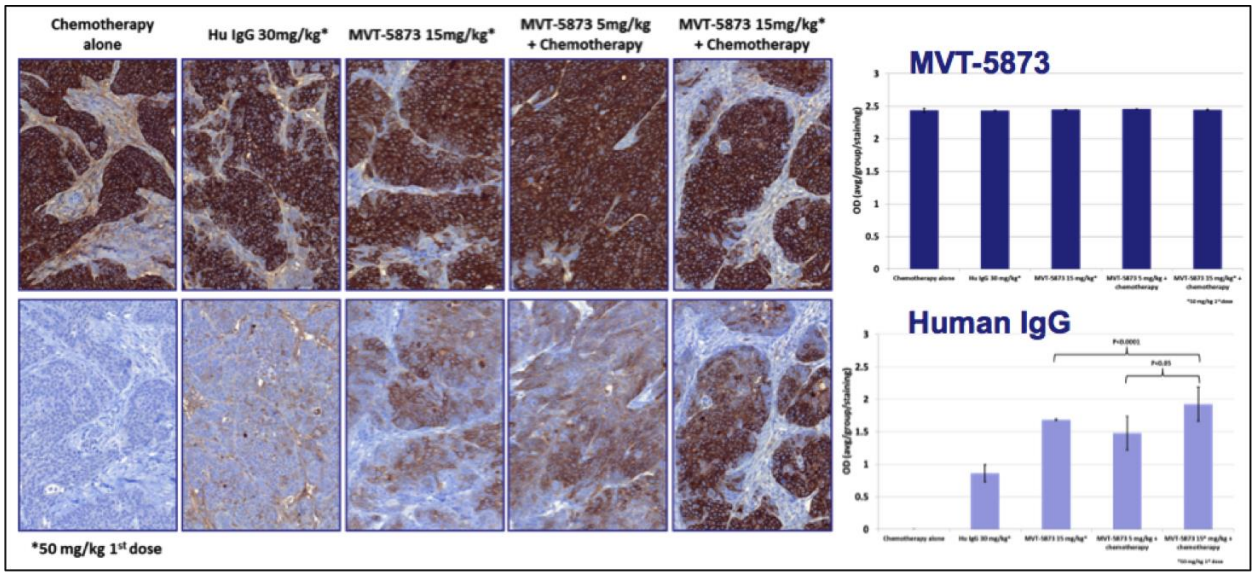
On May 16, 2016, MabVax announced a poster presentation at the American Association for Cancer Research (AACR) Special Conference on Pancreatic Cancer. The study examined the effect of MVT-5873 in a BxPC3 human pancreatic cancer xenograft model that included an analysis of antibody activity both as a monotherapy and in combination with the standard of care (SOC) chemotherapeutic agents gemcitabine and nab-paclitaxel (Abraxane®).

Mice were inoculated with $1x10^6$ BxPC3 cells and the tumors were allowed to reach approximately 130 mm^3 in size (approximately Day 9). The mice were divided into ten treatment groups of five mice each and treated twice weekly for five weeks with varying doses of MVT-5873 with and without various doses of the chemotherapeutic agents gemcitabine and nab-paclitaxel. The following graph shows tumor growth in each of the treated groups. MVT-5873 as a monotherapy showed moderate tumor growth inhibition, however this effect was potentiated when it was combined with gemcitabine and nab-paclitaxel.



Source: Ragupathi *et al*., 2016

Following treatment, tumor tissue was stained for the presence of sLe^a using MVT-5873 as a probe. In addition, tumor tissue was stained for the presence of human IgG as a means of quantitating the level of MVT-5873 that had bound to the tumor during treatment. The top panel of pictures in the following figure shows that there is extensive expression of sLe^a and that the expression level did not change over the course of the experiment due to differences in treatment. The bottom panel shows that MVT-5873 was not detected in the sample treated only with chemotherapy (negative control) and that uptake of the antibody was dose-dependent and appeared to be enhanced by the addition of chemotherapy.

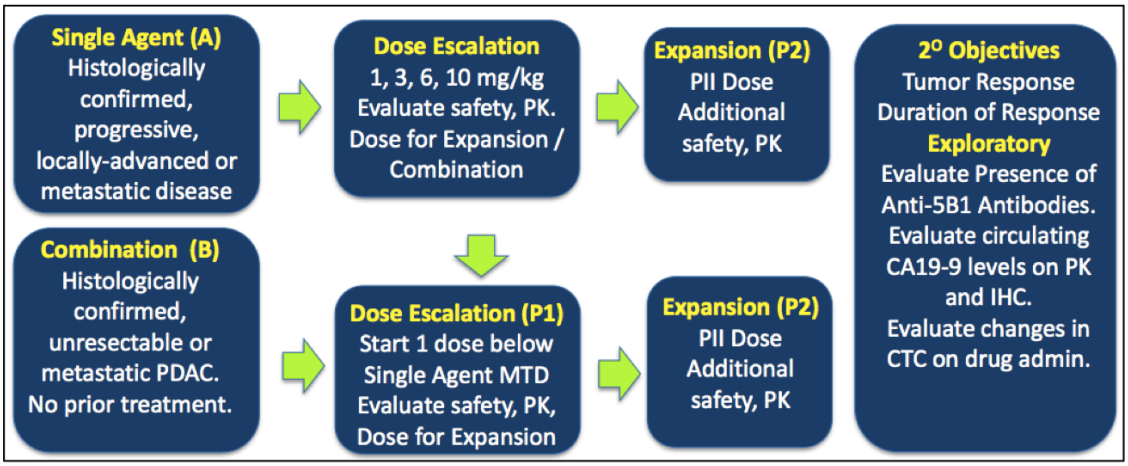


Source: Ragupathi *et al*., 2016

Phase 1 Clinical Trial of MVT-5873

On March 21, 2016, MabVax announced the initiation of a Phase 1 clinical trial of MVT-5873 in patients with pancreatic cancer. This is an open label, multi-center, dose escalation clinical trial that is designed to determine the safety, maximum tolerated dose (MTD), and pharmacokinetics (PK) of MVT-5873. An evaluation of tumor response rate based on RECIST 1.1 and the duration of response of MVT-5873 as a single agent or in combination with the standard of care chemotherapy agent gemcitabine will also be evaluated.

The initial cohort of patients will be treated with 1, 3, 6 or 10 mg/kg of MVT-5873 to determine the MTD. This dose will then be utilized in an expansion cohort of approximately 10 subjects to examine additional safety and PK parameters. For the combination study, the first cohort will be treated with one dose below the MTD with escalation up to the MTD. This dose will then be utilized in an expansion study where MVT-5873 will be administered alongside the standard of care chemotherapeutic agent gemcitabine. An overview of the Phase 1 protocol is given in the following figure.

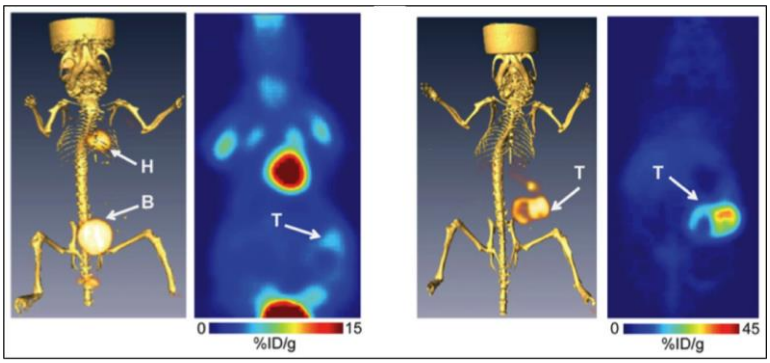


Source: MabVax Therapeutics

In the 10-Q filing for the second quarter of 2016, the company disclosed that "Of the nine patients who have been dosed to date, five have been treated for three or more months and investigator observations have noted stable disease for a subset of those patients." This is very encouraging, and we are looking forward to reviewing additional data as the company releases it.

Imaging Study of MVT-2163 Underway

On July 18, 2016, MabVax announced the initiation of patient enrollment in a Phase 1 clinical trial of MVT-2163, the company's next-generation diagnostic PET imaging agent in patients with pancreatic cancer that combines the sLe^a specific antibody HuMab-5B1 with 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). Previous *in vitro* studies performed with MVT-2163 showed very little background and clear uptake by BxPC3 tumor cells (lower right), particularly in comparison to the currently used PET imaging agent FDG (lower left).

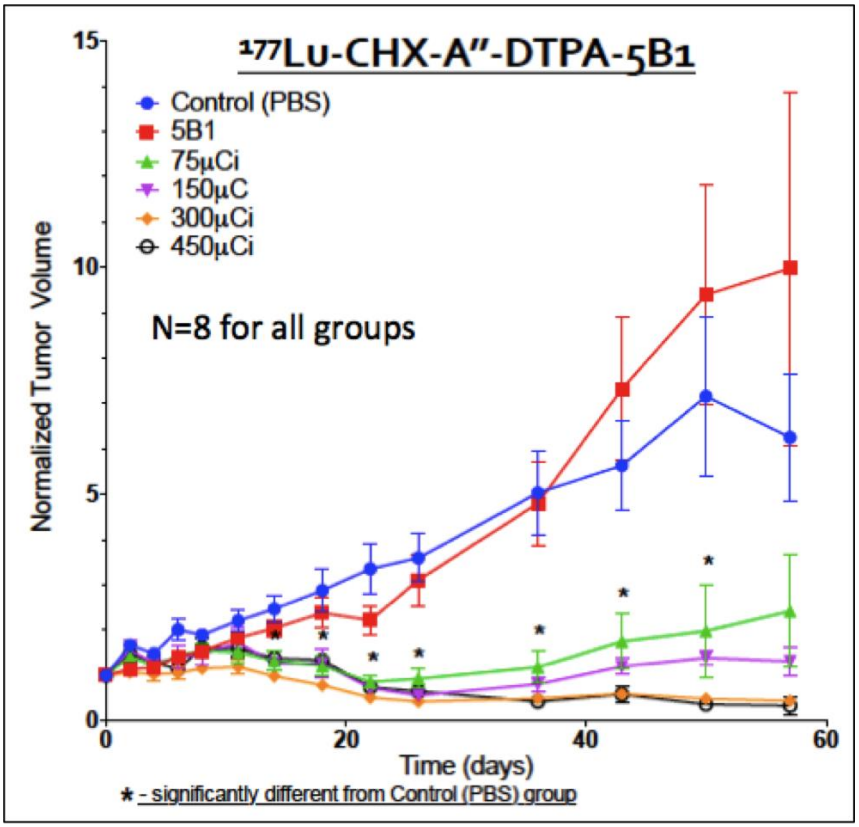


Source: Viola-Villegas *et al*., 2013

The Phase 1 trial of MVT-2163 will likely include approximately 20 patients with pancreatic cancer. The goal of the Phase 1 study will be to determine the safety, pharmacokinetics, and biodistribution of MVT-2163. In addition, the trial will help determine the optimal amount of "cold", or unlabeled antibody, to be administered before the radiolabeled antibody as well as the optimal time following injection of MVT-2163 to obtain the image. The target of HuMab-5B1, sLe^a, is shed by growing tumors into the bloodstream. Injecting non-labeled HuMab-5B1 binds this circulating sLe^a allowing for more radiolabeled antibody to reach the tumor, which helps to enhance tumor imaging as well as reduce the background. In the 10-Q filing for the second quarter of 2016, the company disclosed "The first patient in the trial was dosed with MVT-2163 in early July and received PET scans on days 1, 2, 4, and 7. Investigator observations showed scans potentially highlighting smaller metastatic sites not seen on standard CT scans." This initial result is quite promising, and we anticipate the company releasing additional preliminary data from the trial during the third quarter of 2016, with full results available in 2017.

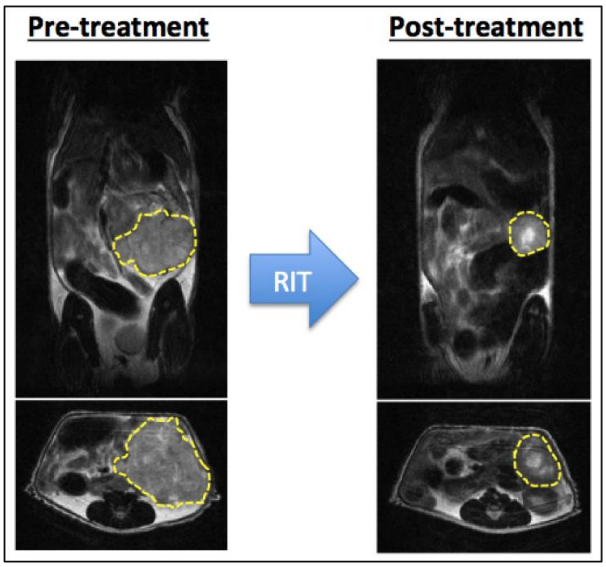
HuMab-5B1 Radioimmunotherapy IND to be Filed in 4Q16

Since HuMab-5B1 has shown such promising results as a PET agent through uptake of the antibody by tumor cells, MabVax has constructed HuMab-5B1 as a radioimmunotherapy (MVT-1075) by attaching the antibody to the radionuclide ^{177}Lu. The following figure shows the results of treating mice with BxPC3 xenografts (after tumors had reached approximately 100 mm^3) with one dose of differing amounts of MVT-1075 (based on radioactivity). At the higher radiation doses, MVT-1075 showed tumor *regression*, not just inhibition or slowing of tumor growth. It should be noted that 5B1 without a radionuclide was added in an equivalent mass dosage and was not optimized as a single agent for this study, hence the reason that there was no anti-tumor activity of the antibody with no radionuclide attached.



Source: MabVax Therapeutics Holdings, Inc.

MVT-1075 also appears to be equally effective in an orthotopic pancreatic cancer model. As opposed to a xenograft, in which the cancer cells are injected subcutaneously, in an orthotopic model the cancer cells are injected into the tissue from which the tumor cells were derived (i.e., BxPC3 pancreatic cancer cells are injected into the mouse pancreas and allowed to grow). This has the advantage of being a more clinically relevant model. The following images again show tumor *regression*, not just growth inhibition, following administration of 300 µCi of MVT-1075.



Source: MabVax Therapeutics Holdings, Inc.

The preclinical results with MVT-1075 are very encouraging, particularly since it was successful using both a xenograft and an orthotopic model. The small error bars for mice showing regression of tumor means that all the mice showed tumor regression and it was not just a subset of those treated. This is important, as the combination of gemcitabine and nab-paclitaxel (Abraxane®) is only able to cause tumor regression in a subset of mice with human pancreatic cancer xenografts (Van Hoff *et al*., 2011). MabVax is hoping to quickly follow up on these successful preclinical results by filing an Investigational New Drug (IND) application with the FDA for MVT-1075 by the end of 2016 and initiating a Phase 1 clinical study in the first half of 2017.

Financial Update

On August 11, 2016, MabVax filed form 10-Q with financial results for the second quarter of 2016. The company did not report any revenues in the quarter, compared to $0.1 million in the same period last year. The decrease in revenue was due to the completion of the NIH imaging contract during the first quarter of 2016. Net loss for the second quarter was $3.8 million, or $0.12 per share, and consisted of $1.6 million in R&D expenses and $1.9 million in G&A expenses. Total cash burn for the second quarter was approximately $2.5 million. The company exited the second quarter with approximately $3.0 million in cash and cash equivalents.

Subsequent to the end of the quarter, the company enacted a 1-for-7.4 reverse split of its common stock, uplisted to the Nasdaq Capital Market, and raised $9.4 million in gross proceeds from a public offering of common stock and Series F Preferred Stock sold at $4.81 per share. Each share of stock also included one Class A warrant exercisable at $5.55 per share and one Class B warrant exercisable at $6.29 per share. We estimate that the company will exit the third quarter of 2016 with approximately $9 million.

The company could also receive a second tranche of $5 million from the loan and security agreement entered into with Oxford Finance, LLC in January 2016. According to the terms of the loan agreement, the second tranche will be funded upon MabVax "achieving positive interim data on the Phase 1 HuMab-5B1 antibody trial in pancreatic cancer and successfully uplisting to either the NASDAQ Stock Market or NYSE MKT." MabVax has already successfully uplisted to the Nasdaq, and the preliminary data disclosed by the company from the Phase 1 study appears promising, thus we anticipate the second tranche of $5 million being funded.

Following the 1 for 7.4 reverse split and the public offering, we estimate the company has 6.0 million shares of common stock outstanding, 2.3 million shares upon conversion of the Series D Preferred shares, 0.5 million shares upon conversion of the Series E Preferred shares, 0.6 million stock options, 0.2 million restricted stock grants, and 5.1 million warrants for a fully diluted share count of 14.7 million.

Conclusion

The initial data disclosed by the company about the ongoing Phase 1 studies of MVT-5873 and MVT-2163 are encouraging, and we look forward to the release of additional data later in the third quarter and the full data sets in 2017. With the recent financing, the company now has sufficient funds to complete the ongoing Phase 1 clinical trials and initiate the clinical trial of MVT-1075.

With so few options available, a successful treatment for pancreatic cancer could easily become a blockbuster drug. The current standard of care for patients with metastatic pancreatic cancer includes gemcitabine combined with either erlotinib or nab-paclitaxel (Abraxane®). Gemzar® (gemcitabine) is now available as a generic, however prior to losing patent protection the drug generated peak revenues of approximately $700 million in the U.S. for Eli Lilly (EvaluatePharma). Tarceva® (erlotinib), which is approved for the treatment of metastatic non-small cell lung cancer and metastatic pancreatic cancer, is marketed by Roche and Astellas and sales of the drug generated $1.2 billion in revenue in 2015 (EvaluatePharma). Abraxane® (nab-paclitaxel), which was approved for the treatment of breast cancer in 2005 and non-small cell lung cancer in 2012, was approved by the FDA in 2013 for the treatment of metastatic pancreatic cancer. Sales of Abraxane® totaled $1.1 billion in 2015 for all indications (EvalatePharma). Our model estimates peak revenues for MVT-5873 of $1 billion in the U.S.

MabVax continues to execute on its business plan, and we continue to be very positive about the company. Our probability adjusted discounted cash flow model leads to a valuation for MabVax of $15, and we believe that positive results from the company's ongoing clinical trials could drive the share price much closer to our valuation.

PROJECTED FINANCIALS

MabVax Therapeutics, Inc.
Income Statement

MabVax Therapeutics, Inc.	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E
MVT-5873	$0.0	$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	$0.0
YOY Growth	-	-	-	-	-	-	-	-
MVT-1075	$0.0	$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	$0.0
YOY Growth	-	-	-	-	-	-	-	-
Pentavalent Vaccine - Ovarian Cancer	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$1.3	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$1.3**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$9.6	$1.7	$1.6	$1.7	$1.7	$6.7	$16.0	$22.0
General & Administrative	$9.8	$2.7	$1.9	$2.3	$2.4	$9.3	$11.0	$13.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($18.1)	($4.204)	($3.525)	($4.000)	($4.1)	($15.8)	($27.0)	($35.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.2)	($0.3)	($0.0)	($0.0)	($0.5)	($0.1)	($0.1)
Pre-Tax Income	($18.1)	($4.4)	($3.8)	($4.0)	($4.1)	($16.3)	($27.1)	($35.1)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	($17.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Accretion of Preferred Stock Dividends	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($36.1)**	**($4.4)**	**($3.8)**	**($4.0)**	**($4.1)**	**($16.3)**	**($27.1)**	**($35.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($13.44)**	**($1.12)**	**($0.92)**	**($0.74)**	**($0.69)**	**($3.36)**	**($3.76)**	**($4.56)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.682	3.947	4.129	5.405	5.946	4.857	7.200	7.700

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

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