Zacks Small-Cap Research

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MabVax Therapeutics Holdings, Inc.

(MBVX - Nasdaq)

MBVX: Update on Phase 1 Clinical Trials of MVT-5873 and MVT-2163 …

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 (02/24/17)	$3.07
Valuation	**$15.00**

OUTLOOK

MabVax Therapeutics Holdings, Inc. (MBVX) is developing antibody-based therapeutics for the treatment of cancer. The company is currently conducting two Phase 1 clinical trials centered on its lead antibody product, HuMab-5B1, as a stand-alone therapeutic agent (MVT-5873) and a PET imaging agent (MVT-2163). A third Phase 1 clinical trial will be initiated in the first half of 2017 with the company's radioimmunotherapy agent (MVT-1075).

The company recently announced preclinical data showing improved accumulation of MVT-5873 on tumors in an animal model of pancreatic cancer when administered in combination with Halozyme's (HALO) PEGPH20, a recombinant human hyaluronidase enzyme.

SUMMARY DATA

52-Week High	**$6.14**
52-Week Low	**$2.57**
One-Year Return (%)	**-12.66**
Beta	**-0.06**
Average Daily Volume (sh)	**110,934**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
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	0.0 A	0.0 E	0.1 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	-$0.86 A	-$0.69 E	-$3.49 E
2017					-$3.01 E
2018					-$2.93 E

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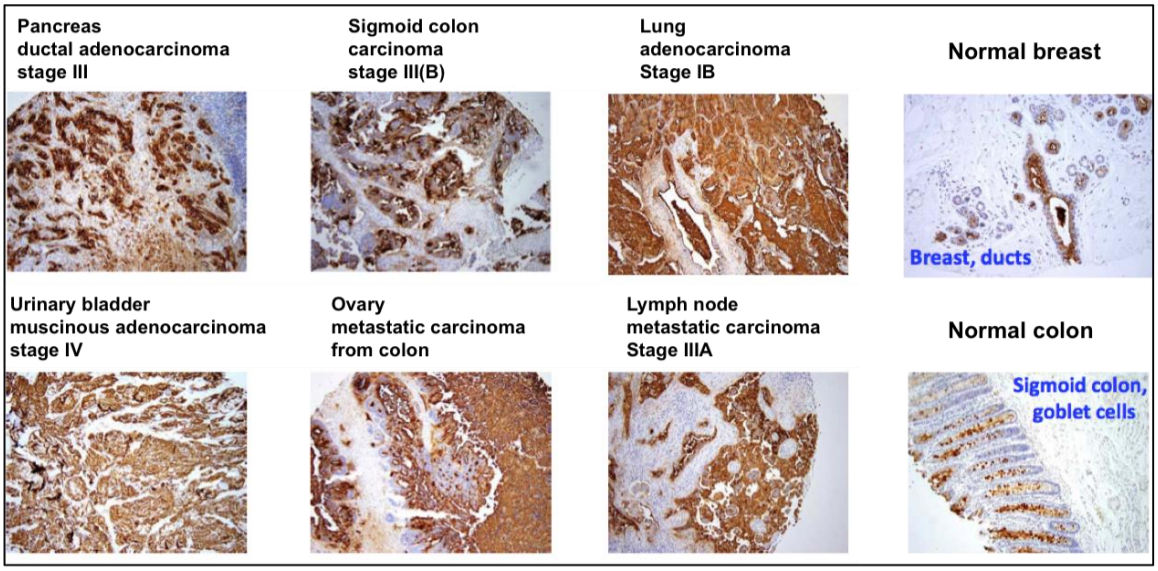
WHAT'S NEW

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 Phase 1 clinical trials as a potential therapeutic (MVT-5873) and imaging agent (MVT-2163). A third Phase 1 clinical trial is expected to initiate in the first half of 2017 for the radioimmunotherapy product MVT-1075.

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

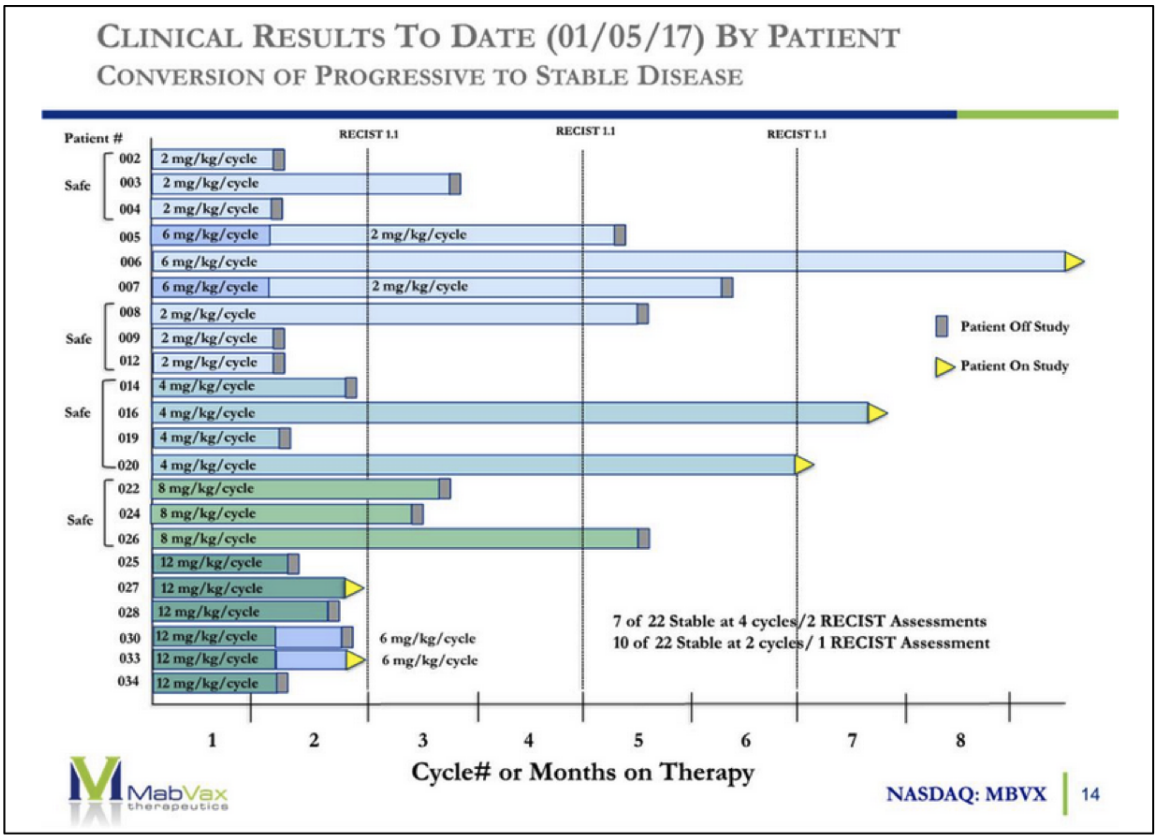
HuMab-5B1 was generated from the company's novel antibody discovery platform, which allows for the generation of fully human antibodies. The antibodies are derived from B-cells extracted from patients immunized with proprietary cancer vaccines. HuMab-5B1 was derived from a patient with Stage IV breast 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 and as an imaging agent 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%).

Update on MVT-5873

MabVax is currently conducting an open label, multi-center, dose escalation Phase 1 clinical trial that is designed to determine the safety, maximum tolerated dose (MTD), and pharmacokinetics (PK) of MVT-5873 (NCT02672917). An evaluation of tumor response rate based on RECIST 1.1 and the duration of response of MVT-5873 as a single agent (Part 1) or in combination with standard of care chemotherapy (Part 2) will also be evaluated.

The following chart shows the clinical trial results as of Jan. 5, 2017. A total of 22 patients have been treated with varying doses of MVT-5873 and five patients remain on study. Three patients have made it through at least 6 cycles of treatment and 10/22 patients were stable after two cycles of treatment.



Source: MabVax Therapeutics Holdings, Inc.

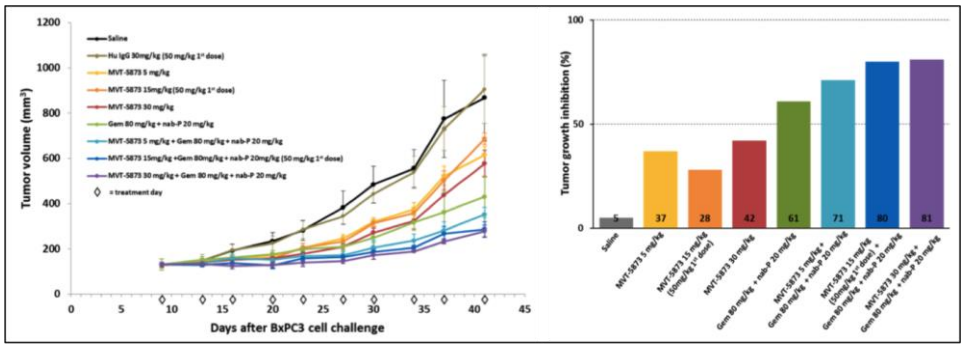
The company has established a sufficient dosage safety margin to initiate Part 2 of the Phase 1 study (discussed below), which will combine MVT-5873 with standard of care chemotherapy in newly diagnosed treatment naïve patients. However, the company will continue to recruit patients in Part 1 of the study to establish a recommended dose for a Phase 2 study of MVT-5873 as a monotherapy.

Potential clinical applications for MVT-5873 as a monotherapy are 1) in the adjuvant setting for patients who have completed a successful chemotherapy regimen or after surgery; 2) patients with poor performance status who can't tolerate gemcitabine; and 3) patients that are refractory to gemcitabine and/or Abraxane®. A clinical trial to test MVT-5873 in these patients would likely require fewer than 200 subjects and would be relatively short in duration, as almost all pancreatic cancer recurrences occur within six months and the median overall survival for these patients is <1 year.

MVT-5873 + Standard of Care Chemotherapy

MabVax has initiated Part 2 of the Phase 1 study, which is the addition of MVT-5873 to standard of care chemotherapy (gemcitabine and nab-paclitaxel) in newly diagnosed patients with unresectable or metastatic pancreatic cancer. We anticipate results from Part 2 of the study to be reported in 2017.

Previous preclinical results showed a synergistic effect between MVT-5873 and standard of care chemotherapy in a mouse model that utilized BxPC3 human pancreatic cancer cells. The following graph shows MVT-5873 as a monotherapy had moderate tumor growth inhibition, however this effect was potentiated when it was combined with gemcitabine and nab-paclitaxel. This data strongly supports the rationale for combining MVT-5873 with standard of care chemotherapy.

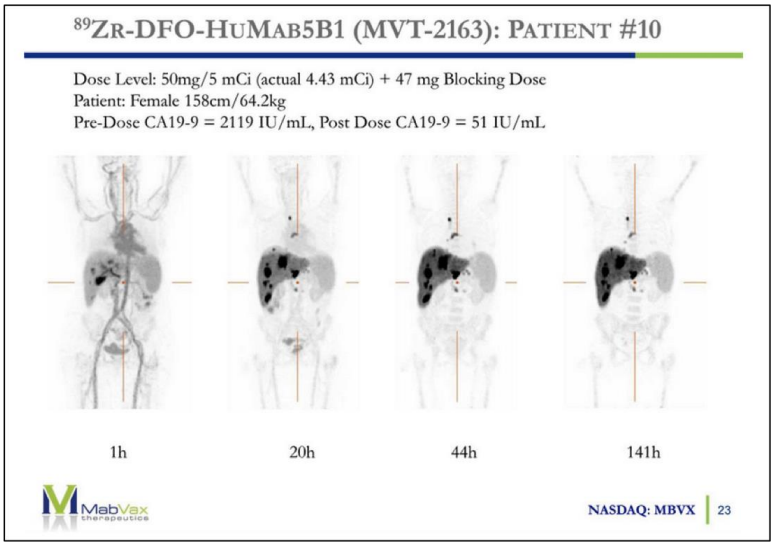


Source: Ragupathi *et al.*, 2016

MVT-2163 Interim Phase 1 Data

The company is continuing work on the Phase 1 trial of MVT-2163, the company's next-generation diagnostic PET imaging agent that combines HuMab-5B1 with the radionuclide ^{89}Zr using a clinically validated linking agent (DFO). The trial is designed to establish the safety, pharmacokinetics, biodistribution, and the amount of MVT-5873 to be used as a "blocking agent" to optimize the PET scan images. Two cohorts of patients have been dosed thus far: the first cohort received MVT-2163 alone while the second cohort received MVT-2163 following administration of MVT-5873. The use of MVT-5873 as a blocking agent is intended to neutralize any circulating CA19.9 antigen, thus allowing for increased binding of MVT-2163 on tumor cells.

The initial PET images that have been obtained thus far demonstrate that the antibody is binding specifically to tumors, as the images correlate with those obtained by conventional CT scans. Administration of MVT-5873 improves the biodistribution of MVT-2163, which is similar to what is seen with the use of a blocking agent with other antibody-based PET agents. The following images show PET scans from a patient dosed with MVT-2163 following a blocking dose of MVT-5873, with scans taken one, 20, 40, and 141 hours following dosing. The liver metastases are clearly visible as soon as one day following dosing.



Source: MabVax Therapeutics Holdings, Inc.

The company will continue to dose patients to establish the optimal blocking dose of MVT-5873 as well as to establish the optimal time after administration of MVT-2163 for obtaining the PET image, which we anticipate to be completed in the 1H17. The company is also planning to initiate an expansion cohort study in newly diagnosed pancreatic cancer patients, as there is a critical need for correct staging in these patients prior to surgery. MVT-

2163 has shown the ability to identify small metastatic sites, which is important since many metastatic lesions are less than 1 cm in length, the resolution limit for CT scans.

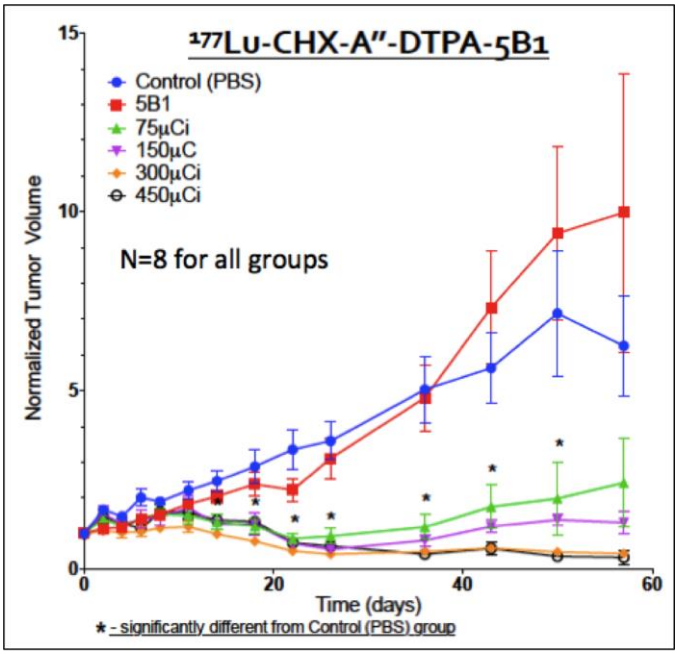
MVT-5873 + PEGPH20

On February 13, 2017, MabVax announced the results of a preclinical study that tested MVT-5873 in combination with Halozymes Therapeutics's PEGPH20, which is currently in Phase 3 clinical testing with ABRAXANE® for the treatment of pancreatic cancer. PEGPH20 is a pegylated recombinant human hyaluronidase, which is an enzyme that temporarily degrades hyaluronan, a naturally occurring complex carbohydrate that is a major component of the extracellular matrix and tumor microenvironment. Degradation of hyaluronidase potentially allows for increased blood flow to tumors and increased access of co-administered cancer drug therapies.

MabVax reported increased accumulation of MVT-5873 on tumors in animal models of pancreatic cancer when administered with PEGPH20. These data are encouraging and additional preclinical studies will be conducted to follow up on these results. The results could also provide support for testing PEGPH20 with both MVT-2163 and MVT-1075.

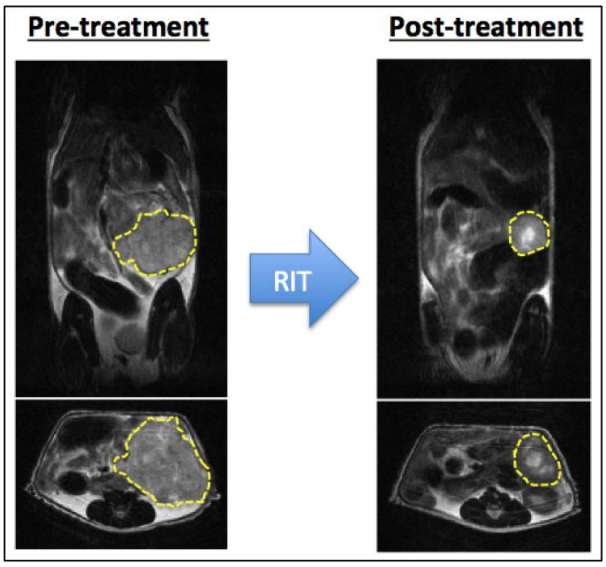
MVT-1075 Phase 1 Trial to Initiate in 1H17

Since HuMab-5B1 has shown great promise in specifically targeting tumor cells while have very limited binding to normal tissue, 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 is only able to cause tumor regression in a subset of mice with human pancreatic cancer xenografts (Van Hoff *et al*., 2011).

On February 23, 2017, MabVax announced that the FDA has authorized the company to proceed with a Phase 1 clinical trial with MVT-1075, which will evaluate its safety, dosimetry, and pharmacokinetics in patients with recurrent locally advanced or metastatic pancreatic cancer. We anticipate the trial initiating in the first half of 2017 and initial results to be available by the end of 2017.

Conclusion

MabVax is continuing to execute on its business plan and to generate exciting preliminary data. Now that the safety of MVT-5873 has been thoroughly shown, we are looking forward to data from Part 2 of the Phase 1 study where MVT-5873 will be administered in combination with standard of care chemotherapy. Preliminary data from that part of the study should be available later in 2017. The initial PET scans with MVT-2163 can clearly highlight metastatic lesions starting one day after dosing and could offer physicians a new option when considering the best treatment approach in newly diagnosed patients.

One of the most important aspects of the data accumulated for both MVT-5873 and MVT-2163 could be the read through that is available for MVT-1075. As discussed above, preclinical results showed that treatment with MVT-1075 resulted in tumor regression, thus alluding to the potential for increased activity compared to MVT-5873. Now that we know HuMab-5B1 can effectively bind to tumors in patients, it stands to reason that MVT-1075 will also be able to effectively saturate tumor cells and **may** lead to tumor cell killing, which is a very exciting possibility.

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.

We continue to be very positive about MabVax and the prospects for its development pipeline. Our probability adjusted discounted cash flow model leads to a valuation of $15, and we believe that as more investors begin to see the potential for the company's pipeline the share price should align much closer with our valuation.

PROJECTED FINANCIALS

MabVax Therapeutics, Inc.
Income Statement

MabVax Therapeutics, Inc.	2015 A	Q1 A	Q2 A	Q3 A	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	$2.4	$2.4	$9.4	$11.0	$13.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($18.1)	($4.204)	($3.525)	($4.092)	($4.1)	($15.9)	($27.0)	($35.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.2)	($0.3)	($0.3)	($0.0)	($0.7)	($0.1)	($0.1)
Pre-Tax Income	($18.1)	($4.4)	($3.8)	($4.4)	($4.1)	($16.7)	($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)**	**($4.4)**	**($4.1)**	**($16.7)**	**($27.1)**	**($35.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($13.44)**	**($1.12)**	**($0.92)**	**($0.86)**	**($0.69)**	**($3.49)**	**($3.01)**	**($2.93)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.682	3.947	4.129	5.041	6.000	4.779	9.000	12.000

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

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