

MabVax Therapeutics (MBVX - \$2.64)

Healthcare/Biotechnology

Maturing MVT-5873 Clinical Data Could Expand Opportunities

After a recent meeting with MBVX management, we walked away with increased confidence given the maturation of Phase I/IIa MVT-5873 in pancreatic ductal adenocarcinomas (PDACs) study has helped MBVX to identify more possibilities to advance the drug forward with potentially more upside.

Ticker: **MBVX**
Rating: **Buy**
Price Target: **\$18.00**

- Details.** MBVX reported encouraging preliminary results of MVT-5873 in difficult-to-treat advanced PDACs monotherapy dose finding study (Figure 1). The data showed 7/22 patients were stable at 4 cycles of treatment with 2 RECIST assessments, and 10/22 patients were stable at 2 cycles of treatments with 1 RECIST assessment. As such, we believe these initial results suggested MVT-5873 exhibited encouraging activities as a monotherapy. We believe this is promising and important as MVT-5873 needs to provide its own therapeutic effect when used in combination with Abraxane plus gemcitabine as a potential first-line pancreatic cancer therapy. In addition, MBVX is contemplating the use of MVT-5873 as a maintenance therapy after initial first-line chemotherapy to mitigate shortcomings of repeating chemotherapies, like 1) intolerable cumulative toxicity after multi-cycle of treatments; and 2) the lack of benefit by continuing treatment until progression of disease. The objective of maintenance therapy is to prolong disease control, of which is already achieved by first-line therapy. In addition, with the IND approved, MVT-1075 radioimmunotherapy Phase I trial could start in 1H17. The first part of the MVT-2163 PET imaging agent Phase I study progressed well and MBVX is planning to start an expansion cohort in newly diagnosed PDAC patients before surgery in mid-2017. Further, MBVX is actively exploring potential partnering opportunities to accelerate development and increase shareholder values.

- Implications.** We are encouraged by MVT-5873 demonstrating monotherapy activities in difficult-to-treat advanced PDACs and believe it bodes well for this drug, potentially to combine with chemotherapies as a first-line treatment. In addition, we view MVT-5873's activities could also potentially expand the utility of this drug as a relatively new and novel maintenance therapy. We also view the clinical progress of MVT-2163 PET imaging agent and potential advancement of MVT-1075 into Phase I trial could materially increase the value of the HuMab-5B1-based platform.

- Action.** We are reiterating our Buy rating and \$18 price target to reflect our view on highly encouraging developments of the broad HuMab-5B1-based platform. Valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.83	-0.82	-0.85	-0.83	-3.33	NM
FY-16E	-0.15A	-0.92A	-0.86A	-0.86	-3.71	NM
FY-15A	-6.25	-0.29	-0.20	-1.03	-13.44	NM
FY-14A	-	-	-	-	-9.51	NM

Yale Jen, Ph.D.

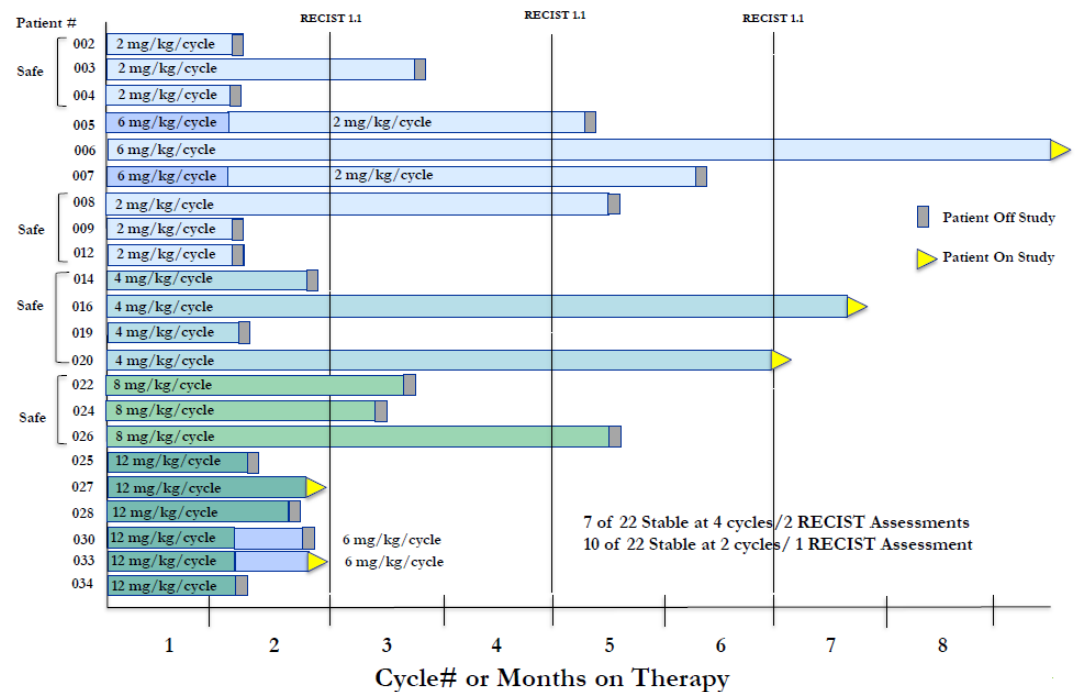
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Source: Laidlaw & Company estimates

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- Maintenance therapy in pancreatic cancer treatment is a new and novel approach.** Maintenance therapy for managing pancreatic cancer is a novel concept but has already generated encouraging results from a Phase II study (PACT-12) evaluating Sutent (sunitinib) in patients of stabilized disease after 6 months of first-line chemotherapy¹. Although Sutent alone did not demonstrate to be an effective 2nd-line pancreatic cancer treatment, it demonstrated a significant improvement in progression free survival in 6 month (PFS-6) of 22% vs. 3.6% of the control (primary endpoint). Median PFS was 3.2 months vs. 2 months (p<0.01). Stable disease was achieved in 62% vs. 21% patients (P=0.02). The two-year OS was 23% vs. 7%. Overall, roughly similar percentage of patients (81% vs. 86%) subsequently need to take 2nd-line treatment. In our opinion, although maintenance therapy with Sutent is far from curative, this treatment modality could potentially provide a more tolerable treatment for improving OS and PFS in some patients.

Figure 1: Interim clinical results of MVT-5873 single agent dose-finding Phase I study



Source: Company presentation

¹ Reni, M., et. Al., Europ. J of Cancer (2013) 49:3609-3615

Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
MVT-5873	Pancreatic adenocarcinoma (PDAC)	Report top-line results of the single agent Phase I /II study	1H17	***
		Report interim results of the combination Phase I /II study	1H17	****
		Report results of the combination Phase I /II study	2H17	****
MVT-1075	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	1H17	***
		Potentially report early Phase I data	2H17	***
HuMab-5B1 ADC	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	2018	***
MVT-2163	Pancreatic adenocarcinoma (PDAC)	Potentially report Phase I study top-line results	Mid-2017	****
		Potentially report early Phase I data	2H17	***
		Potential partnership for further development	2017	****
Sarcoma vaccine	Sarcoma	Potentially report Phase II study OS results	2017	***
Ovarian cancer vaccine	Ovarian cancer	Potentially report Phase II study OS results	1H17	***

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company estimates and company presentation.

Major risks

Clinical study failure could have a major impact on MBVX share value. Despite promising pre-clinical results of the company's lead products, HuMab-5B1 and HuMab-5B1-PET, it remains too early to predict the longer term safety and efficacy from the upcoming clinical studies. Given that clinical validation has not been established, it would be critical for these studies to demonstrate efficacy and a positive safety profile in order to increase the assets and shareholder value. Negative results of Phase I and future clinical studies could have a materially negative impact on the shareholder value; especially since the company has a very diverse-limited pipeline profile.

Yet-to-be-validated vaccinated patient derived monoclonal antibody (Mab) screening platform could remain uncertain. Although monoclonal antibodies have been established as a validated cancer treatment modality; currently there is no Mab derived from vaccinated patients that has been approved or is in a late clinical development stage to demonstrate efficacy. As such, clinical risks for monoclonal antibody based cancer therapy derived from successfully vaccinated patients are higher than similar products generated from other more proven development platforms.

Product may not be approved or reach anticipated sales. Although MBVX's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and the possible changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect MBVX shareholder value.

Additional financings could dilute shareholder value. Although the company currently has ~\$10MM (pro forma) cash after its recent financing, MBVX most likely would need more financial resources going forward if they want to expand and further develop their pipeline. Should the future operational expenses, especially from R&D, increase significantly, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Limited trading liquidity limits shareholder options. Given that MBVX shares only entered the public market recently; daily trading volume and name recognition are relatively modest. As such, shareholders wanting to increase or reduce their positions more substantially in a volatile stock market may face constraints.

Figure 1: Income Statement

MabVax Therapeutics – Income Statement												
(\$ '000)	2014	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue												
Grants	304	1,267	148	-	-	0	148	0	1	1	0	0
Product revenue	10	0	0	-	-	0	0	0	0	0	1,500	3,383
Total revenues	314	1,267	148	0	0	0	148	0	1	1	1,500	3,383
Gross revenue											1,500	3,383
Research and development	3,503	9,597	1,701	1,596	1,671	1,705	6,672	8,023	9,547	11,361	13,747	16,084
General and administrative	5,204	9,795	2,652	1,929	2,421	2,469	9,470	10,276	11,304	12,321	13,307	14,239
Marketing and sales												
Total operating costs and expenses	8,707	19,392	4,352	3,525	4,092	4,174	16,143	18,299	20,851	23,683	27,054	30,323
Operating Incomes (losses)	(8,393)	(18,125)	(4,204)	(3,525)	(4,092)	(4,174)	(15,995)	(18,299)	(20,850)	(23,682)	(25,554)	(26,939)
Interest and other income (expense)	(0)	(0)	(200)	(263)	(266)	(400)	(1,129)	(1,160)	(1,160)	(1,160)	(1,160)	(1,160)
Change in fair value of warrant liability	475	20	-	-	-	0	0	0	0	0	0	0
Tax												
Net Income (Loss)	(7,918)	(18,105)	(4,405)	(3,788)	(4,358)	(4,574)	(17,124)	(19,459)	(22,010)	(24,842)	(26,714)	(28,099)
Deemed dividend on Series A-1 preferred-stock	(2,215)	(9,018)	-	-	-	0	0	0	0	0	0	0
Deemed dividend on Series A-1 warrant		(179)	-	-	-	0	0	0	0	0	0	0
Deemed dividend on Series B preferred stock		(8,656)	-	-	-	0	0	0	0	0	0	0
Accretion of preferred stock dividends	(445)	(93)	-	-	-	0	0	0	0	0	0	0
Net loss allocable to common stockholders	(10,578)	(36,051)	(4,405)	(3,788)	(4,358)	(4,574)	(17,124)	(19,459)	(22,010)	(24,842)	(26,714)	(28,099)
Basic and diluted net loss per share	(\$9.51)	(\$13.44)	(\$0.15)	(\$0.92)	(\$0.86)	(\$0.86)	(\$3.71)	(\$3.33)	(\$2.49)	(\$2.10)	(\$1.93)	(\$1.77)
Shares used to calculate the basic and diluted net loss per share	1,112	2,682	3,947	4,129	5,041	5,341	4,615	5,841	8,841	11,841	13,841	15,841
Margin Analysis (% of Sales/Revenue)												
Costs of goods										15%	15%	15%
R&D	1115%	757%	1149%	NA	NA	NA	4507%	NA	954710%	1136105%	916%	475%
SG&A	1657%	773%	1791%	NA	NA	NA	6397%	NA	1130410%	1232147%	887%	421%
Operating Income (loss)	-2671%	-1430%	-2840%	NA	NA	NA	-10803%	NA	-2085020%	-2368152%	-1704%	-796%
Pretax	-2520%	-1429%	-2975%	NA	NA	NA	-11566%	NA	-2201020%	-2484152%	-1781%	-831%
Tax Rate												
Net Income	-705%	-2845%	-2975%	NA	NA	NA	-11566%	NA	-2201020%	-2484152%	-1781%	-831%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	303%	-38%	-100%	-100%	-100%	-88%	-100%	NA	0%	149904%	126%
R&D	NA	174%	-1%	-31%	-47%	-30%	-30%	20%	19%	19%	21%	17%
SG&A	NA	88%	170%	-54%	6%	6%	-3%	9%	10%	9%	8%	7%
Operating Income (Losses)	NA	116%	70%	-45%	-23%	5%	-12%	14%	14%	14%	8%	5%
Pretax Income	NA	241%	-78%	-41%	-17%	15%	-53%	14%	13%	13%	8%	5%
Net Income	NA	241%	-78%	-41%	-17%	15%	-53%	14%	13%	13%	8%	5%
EPS	NA	41%	-98%	216%	332%	-17%	-72%	-10%	-25%	-16%	-8%	-8%
Yale Jen, Ph.D. 212-953-4978												

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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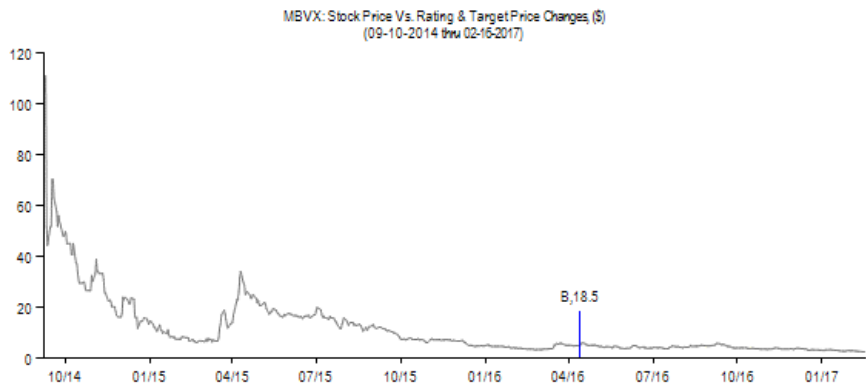
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/13/2016	Buy (B)	5.18

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/13/2016	18.50**	5.18

** Split Adjusted

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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