

MabVax Therapeutics (MBVX - \$ 4.75)

MVT-5873 in PDAC Phase I/II Single Agent Study Dosed 13 Patients With Combo Trial to Start in 4Q16

This morning MBVX provided an update on the interim progress for its MVT-5873 in pancreatic adenocarcinoma (PDAC) monotherapy Phase I clinical trial.

- Details.** MBVX updated investors this morning of the continued progress of the two lead programs for treating pancreatic adenocarcinoma (PDAC). For MVT-5873, the dose-finding portion of Phase I/II monotherapy has enrolled 13 stage 3 and 4 metastatic treatment refractory PDAC patients with monitoring of CA19-9 levels both pre and post dosing. Additionally, MBVX indicated that MVT-5873 dose levels tested have already exceeded the highest dose levels to be used for the MVT-2163 (PET imaging) Phase I trial and also cleared the dose intended for the MVT-1075 (Lu¹⁷⁷ HuMab-5B1) Phase I trial. We anticipate more interim results (safety, tolerability and PK) from MVT-5873 Phase I/II single agent dose-finding portion in 4Q16 and the initiation of the MVT-5873/nab-paclitaxel combo study potentially also in 4Q16. As for the potential combo trial, we estimate the interim and top-line efficacy results (such as response rate based on RECIST 1.1, duration of response, presence of anti-5B1 antibodies and the level of circulating CA19-9) could be available in 1H17 and 2H17, respectively. MBVX indicated that the IND submission for MVT-1075 in PDAC is on track in 4Q16 with Phase I trial commencement likely to occur in 1H17. It will be a Phase I dose escalating study evaluating safety, response rate and response duration with interim results potentially in 2H17.
- Implications.** We view today's news encouragingly for demonstrating MBVX management's timely execution of clinical advancement of MVT-5873 and MVT-1075. Should the program advance as expected, MBVX could have two HuMab-5B1-based clinical programs with different mechanisms of action for potentially eradicating cancer cells ongoing in 2017. Further, we believe the outcomes from the combo Phase I/II trial could be the most critical for MBVX value given such a combination setup is likely to be the one for treating the difficult-to-treat pancreatic cancer.
- 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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (09/19/2016)	\$ 4.75
52-Week High (9/21/2015)	\$ 10.88
52-Week Low (2/16/2016)	\$ 3.03
Market Cap. (MM)	\$ 25
Shares Out. (MM)	5

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.15A	-0.92A	-0.84	-0.85	-3.70	NM
FY-15A	-6.25	-0.29	-0.20	-1.03	-13.44	NM
FY-14A	NA	NA	NA	NA	-9.51	NM
FY-13A	NA	NA	NA	NA	NA	NM

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
HuMab-5B1 (MVT-5873)	Pancreatic adenocarcinoma (PDAC)	Report interim results of Phase I study	4Q16	***
		Potentially start combination Phase I /II study	4Q16	***
		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 top-line results of the combination Phase I /II study	2H17	****
HuMab-5B1 RIT	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	1H17	***
HuMab-5B1 ADC	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	2018	***
HuMab-5B1 PET	Pancreatic adenocarcinoma (PDAC)	Potentially report Phase I study interim results	4Q16	****
		Potentially report Phase I study top-line results	Mid-2017	****
Sarcoma vaccine	Sarcoma	Potentially report Phase II study OS results	4Q16	***
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	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue												
Grants	304	1,267	148	-	-	-	148	1	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	1	1	1	1,500	3,383
Gross revenue											1,500	3,383
Research and development	3,503	9,597	1,701	1,596	1,676	1,709	6,682	8,218	9,780	11,638	14,082	16,476
General and administrative	5,204	9,795	2,652	1,929	1,948	1,987	8,517	9,709	10,680	11,641	12,573	13,453
Marketing and sales												
Total operating costs and expenses	8,707	19,392	4,352	3,525	3,624	3,697	15,199	17,928	20,460	23,279	26,655	29,929
Operating Incomes (losses)	(8,393)	(18,125)	(4,204)	(3,525)	(3,624)	(3,697)	(15,050)	(17,927)	(20,459)	(23,278)	(25,155)	(26,546)
Interest and other income (expense)	(0)	(0)	(200)	(263)	(200)	(400)	(1,063)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)
Change in fair value of warrant liability	475	20	-	0	0	-	0	0	0	0	0	0
Tax												
Net Income (Loss)	(7,918)	(18,105)	(4,405)	(3,788)	(3,824)	(4,097)	(16,114)	(19,527)	(22,059)	(24,878)	(26,755)	(28,146)
Deemed dividend on Series A-1 preferred-stock	(2,215)	(9,018)	-	0	0	-	0	0	0	0	0	0
Deemed dividend on Series A-1 warrant		(179)	-	0	0	-	0	0	0	0	0	0
Deemed dividend on Series B preferred stock		(8,656)	-	0	0	-	0	0	0	0	0	0
Accretion of preferred stock dividends	(445)	(93)	-	0	0	-	0	0	0	0	0	0
Net loss allocable to common stockholders	(10,578)	(36,051)	(4,405)	(3,788)	(3,824)	(4,097)	(16,114)	(19,527)	(22,059)	(24,878)	(26,755)	(28,146)
Basic and diluted net loss per share	(\$9.51)	(\$13.44)	(\$0.15)	(\$0.92)	(\$0.84)	(\$0.85)	(\$3.70)	(\$2.86)	(\$2.24)	(\$1.94)	(\$1.80)	(\$1.67)
Shares used to calculate the basic and diluted net loss per share	1,112	2,682	3,947	4,129	4,529	4,829	4,358	6,829	9,829	12,829	14,829	16,829
Margin Analysis (% of Sales/Revenue)												
Costs of goods										15%	15%	15%
R&D	1115%	757%	1149%	NA	NA	NA	4513%	821841%	977991%	1163809%	939%	487%
SG&A	1657%	773%	1791%	NA	NA	NA	5753%	970925%	1068018%	1164139%	838%	398%
Operating Income (loss)	-2671%	-1430%	-2840%	NA	NA	NA	-10166%	-1792666%	-2045908%	-2327848%	-1677%	-785%
Pretax	-2520%	-1429%	-2975%	NA	NA	NA	-10884%	-1952666%	-2205908%	-2487848%	-1784%	-832%
Tax Rate												
Net Income	-705%	-2845%	-2975%	NA	NA	NA	-10884%	-1952666%	-2205908%	-2487848%	-1784%	-832%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	303%	-38%	-100%	-100%	-100%	-88%	-99%	0%	0%	149904%	126%
R&D	NA	174%	-1%	-31%	-46%	-29%	-30%	23%	19%	19%	21%	17%
SG&A	NA	88%	170%	-54%	-15%	-14%	-13%	14%	10%	9%	8%	7%
Operating Income (Losses)	NA	116%	70%	-45%	-31%	-7%	-17%	19%	14%	14%	8%	6%
Pretax Income	NA	241%	-78%	-41%	-28%	3%	-55%	21%	13%	13%	8%	5%
Net Income	NA	241%	-78%	-41%	-28%	3%	-55%	21%	13%	13%	8%	5%
EPS	NA	41%	-98%	216%	322%	-18%	-72%	-23%	-22%	-14%	-7%	-7%

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

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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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	63.16%	28.95%	2.63%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.63%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.63%	0.00%	0.00%

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