

MabVax Therapeutics (MBVX - \$ 0.61)

1Q16: Uneventful Quarterly Financial Reporting with Several Programs Underway and Initial Data Potentially in 2H16

MBVX reported 1Q16 financial results yesterday with net loss of (\$4.4MM) or (\$0.15)/share. MBVX ended 1Q16 with cash of ~\$5.6MM.

- HuMab-5B1 in pancreatic adenocarcinoma (PDAC) Phase I/II study update.** MBVX indicated that patient enrollment of HuMab-5B1 in PDAC Phase I study is on track to report interim results in 3Q16 regarding the safety, tolerability and PK from the single agent dose-finding study. The trial will advance to a chemotherapy (gemcitabine and Abraxane) combination study afterward with interim and top-line efficacy results potentially available in 1H17 and 2H17, respectively. Patients of the monotherapy will expect to receive HuMab-5B1 IV infusion every two weeks in ascending doses until reaching maximum tolerated dose (MTD). Patients of the combination therapy study will receive SOC chemotherapy in combination with HuMab-5B1 IV infusion every two weeks of a few ascending doses to further determine MTD in a combination setting and assess the response rate (based on RECIST 1.1), duration of response, presence of anti-5B1 antibodies and the level of circulating CA19-9.
- HuMab-5B1 PET and RIT in PDAC updates.** For HuMab-5B1 PET, MBVX will start the Phase I study shortly with the first patient potentially examined in May. The study initially intends to image ~ 4-6 patients by mid-2016 and report interim results in 2H16. It is an open-label dose escalation trial starting by evaluating ⁸⁹Zr-HuMab-5B1 (hot) antibody in the first patient cohort, followed by the addition of increasing doses (17mg and 47mg/patient) of non-radioactive (cold) HuMab-5B1 to improve the PET image in the subsequent cohorts. The trial objectives are to identify the optimal conditions that could help to concentrate the hot antibody onto the proper tumor sites for sufficient duration to create the best image. MBVX is in the process of choosing the best isotope [Lutetium 177 (Lu¹⁷⁷) or Yttrium 139 (Y³⁹)] as payload for its HuMab-5B1- RIT program with a decision likely in mid-2016. Both isotopes are β-emitters. The Phase I study in PDAC could potentially start in 1H17.
- Action.** We are reiterating our Buy rating and \$2.50 price target to reflect our view that broad HuMab-5B1-based platform development is highly encouraging. Our valuation is based on our peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Healthcare/Biotechnology

Ticker: **MBVX**
Rating: **Buy**
Price Target: **\$ 2.50**

Trading Data:

Last Price (05/10/2016)	\$ 0.61
52-Week High (7/2/2015)	\$ 2.82
52-Week Low (2/16/2016)	\$ 0.41
Market Cap. (MM)	\$ 19
Shares Out. (MM)	31

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.15A	-0.15	-0.16	-0.17	-0.64	NM
FY-15A	-6.25	-0.29	-0.20	-0.14	-1.82	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	Pancreatic adenocarcinoma (PDAC)	Report interim results of Phase I study	2H16	***
		Potentially complete Phase I trial patient recruitment	YE16	***
		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 determine the isotope to be used for Phase I study	Mid-'16	***
		Potentially start Phase I study	1H17	***
HuMab-5B1 ADC	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	2H17	***
HuMab-5B1 PET	Pancreatic adenocarcinoma (PDAC)	Potentially start Phase I study	2Q16	***
		Potentially report Phase I study interim results	2H16	****
Sarcoma vaccine	Sarcoma	Potentially report Phase II study OS results	4Q16	***
Ovarian cancer vaccine	Ovarian cancer	Potentially report Phase II study PFS results at the ASCO	2Q16	***
		Potentially report Phase II study OS results	4Q16	***

**** / ***** 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	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue												
Grants	304	1,267	148	221	-	-	369	1	1	1	0	0
Product revenue	10	0	0		-	-	0	0	0	0	1,500	3,383
Total revenues	314	1,267	148	221	0	0	369	1	1	1	1,500	3,383
Gross revenue											1,500	3,383
Research and development	3,503	9,597	1,701	1,905	2,000	2,040	7,645	9,403	11,190	13,316	16,112	18,851
General and administrative	5,204	9,795	2,652	2,678	2,705	2,759	10,795	12,306	13,536	14,755	15,935	17,050
Marketing and sales												
Total operating costs and expenses	8,707	19,392	4,352	4,583	4,705	4,799	18,439	21,709	24,726	28,070	32,047	35,901
Operating Incomes (losses)	(8,393)	(18,125)	(4,204)	(4,362)	(4,705)	(4,799)	(18,071)	(21,708)	(24,725)	(28,069)	(30,547)	(32,518)
Interest and other income (expense)	(0)	(0)	(200)	(200)	(200)	(400)	(1,000)	(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
Tax												
Net Income (Loss)	(7,918)	(18,105)	(4,405)	(4,562)	(4,905)	(5,199)	(19,071)	(23,308)	(26,325)	(29,669)	(32,147)	(34,118)
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)	(4,562)	(4,905)	(5,199)	(19,071)	(23,308)	(26,325)	(29,669)	(32,147)	(34,118)
Basic and diluted net loss per share	(\$9.51)	(\$1.82)	(\$0.15)	(\$0.15)	(\$0.16)	(\$0.17)	(\$0.64)	(\$0.66)	(\$0.65)	(\$0.65)	(\$0.64)	(\$0.62)
Shares used to calculate the basic and diluted net loss per share	1,112.5	19,845	29,208	29,608	30,008	30,308	29,783	35,308	40,308	45,308	50,308	55,308
Margin Analysis (% of Sales/Revenue)												
Costs of goods										15%	15%	15%
R&D	1115%	757%	1149%	863%	NA	NA	2074%	940296%	1118953%	1331554%	1074%	557%
SG&A	1657%	773%	1791%	1214%	NA	NA	2928%	1230581%	1353639%	1475467%	1062%	504%
Operating Income (loss)	-2671%	-1430%	-2840%	-1977%	NA	NA	-4902%	-2170778%	-2472492%	-2806921%	-2036%	-961%
Pretax	-2520%	-1429%	-2975%	-2068%	NA	NA	-5173%	-2330778%	-2632492%	-2966921%	-2143%	-1008%
Tax Rate												
Net Income	-705%	-2845%	-2975%	-2068%	NA	NA	-5173%	-2330778%	-2632492%	-2966921%	-2143%	-1008%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	303%	-38%	61%	-100%	-100%	-71%	-100%	0%	0%	149904%	126%
R&D	NA	174%	-1%	-18%	-36%	-16%	-20%	23%	19%	19%	21%	17%
SG&A	NA	88%	170%	-36%	18%	19%	10%	14%	10%	9%	8%	7%
Operating Income (Losses)	NA	116%	70%	-32%	-11%	21%	0%	20%	14%	14%	9%	6%
Pretax Income	NA	241%	-78%	-29%	-7%	31%	-47%	22%	13%	13%	8%	6%
Net Income	NA	241%	-78%	-29%	-7%	31%	-47%	22%	13%	13%	8%	6%
EPS	NA	-81%	-98%	-47%	-18%	23%	-65%	3%	-1%	0%	-2%	-3%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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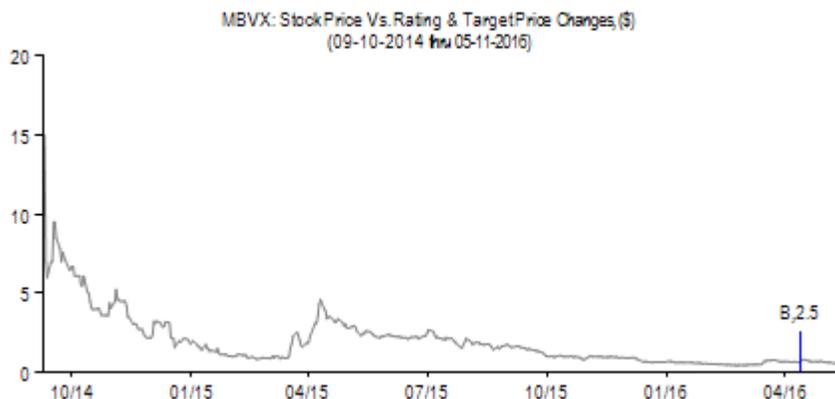
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Rating and Price Target Change History



Date	Rating	Closing Price (\$)
04/13/2016	Buy (B)	0.70

Date	Target Price (\$)	Closing Price, (\$)
04/13/2016	2.50	0.70

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
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Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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