

VBI Vaccines (VBIV - \$4.43)

More Details Regarding the Upcoming Sci-B-Vac Phase III Trial

This morning, VBIV hosted a conference call discussing details of the Sci-B-Vac Phase III trial as a potential 3rd-generation adult HBV vaccine after the recent positive responses from multiple regulatory agencies.

- Details.** The Phase III trial is comprised of two studies: PROTECT for safety and immunogenicity, and CONSTANT for lot-to-lot consistency. The two studies will be conducted concurrently. PROTECT is a double-blind, two-arm, randomized, 1,600-adult (≥ 18 year) controlled study. Subjects will be randomized 1:1 to receive a three-dose course of either Sci-B-Vac (10 μ g) or Engerix-B (20 μ g) as a control. Age group is one of the stratification criteria as patients < 44 -years-old account for 20% of the total enrolled patients, while patients ≥ 45 -years-old account for the remainder. Co-primary endpoints are: 1) non-inferiority of Sci-B-Vac induced seroprotection rate (SPR) four weeks after the 3rd vaccination in ≥ 18 -year-old adults; and 2) superiority of Sci-B-Vac induced SPR four weeks after the 3rd vaccination in ≥ 45 -year-old adults. The second superiority primary endpoint is not required for approval but is significant for the commercial outlook of the product. Secondary endpoints include speed to seroprotection and the overall safety and tolerability. CONSTANT is a double-blind, four-arm, randomized, 3,200-adult (ages 18-45) controlled study. Subjects will be randomized 1:1:1:1 for receiving either 10 μ g of Sci-B-Vac of Lot A, Lot B, Lot C, or 20 μ g of Engerix-B as a control. The primary endpoint is to demonstrate lot-to-lot consistency for immune response measured by geometric mean concentration (GMC) of antibodies across three independent, consecutive lots of Sci-B-Vac four weeks after the 3rd vaccination. Secondary endpoints include safety and efficacy of Sci-B-Vac vs. Engerix-B. The trial will be started in 2H17 at ~ 40 sites in the U.S., EU and Canada and could take ~ 15 months to complete. Topline results are expected in 1H19.
- Implications.** Based on prior positive clinical study results, we believe the announced trial design bodes well for an enhanced probability of success of the Phase III study. For example, in prior clinical trials, in ≥ 45 -year-old individuals, SPR was 96% for Sci-B-Vac vs. 78% for Engerix B ($p < 0.001$ with $n = 241$). In a younger age group, Sci-B-Vac exhibited a 97% SPR vs. 86% for Engerix B ($p < 0.003$ with $n = 254$).
- Action.** We are reiterating our Buy rating and target price of \$7. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. We believe VBIV shares remain undervalued given their differentiated and promising platform technology, several vaccines in development, and potentially positive multiple catalysts over the next 18 months.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.22A	-0.21	-0.23	-0.18	-0.85	N.A.
FY-16A	-0.06	-0.23	-0.21	-0.22	-0.77	N.A.
FY-15A	-0.27	-0.15	-1.07	-0.22	-2.07	N.A.
FY-14A	NA	NA	NA	NA	NA	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	VBIV
Rating:	Buy
Price Target:	\$7.00

Trading Data:

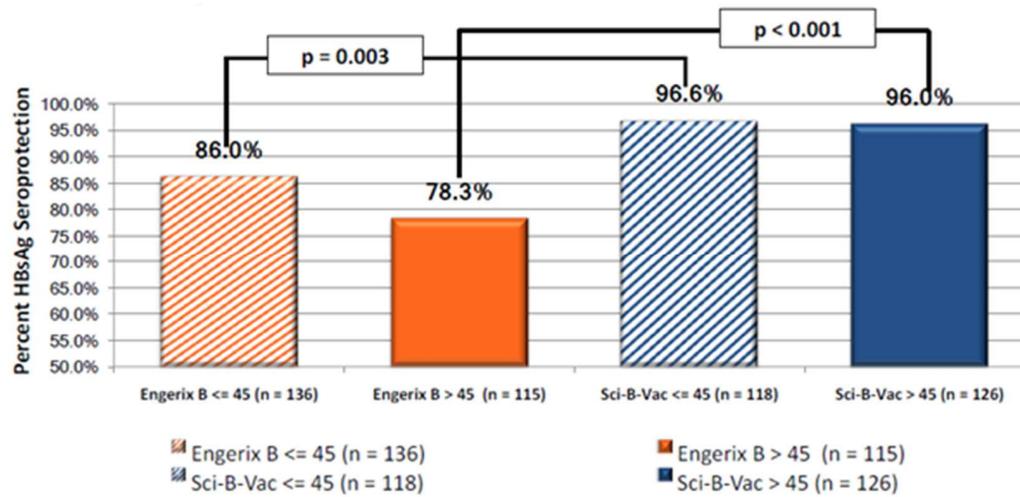
Last Price (7/11/2017)	\$4.43
52-Week High (3/14/2017)	\$6.60
52-Week Low (11/3/2016)	\$2.75
Market Cap. (MM)	\$195
Shares Out. (MM)	40.1

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Figure 1: Prior clinical trials showed materially better SPR in older adults of Sci-B-Vac vs. Engerix-B



Source: Company report

Anticipated milestones in 2017 and beyond

Program	Indication	Event	Timing	Importance
Sci-B-Vac	Hepatitis B vaccine	FDA's AdComm (VRBPAC) meeting of HEPLISAV-B	28-Jul-17	****
		FDA's PDUFA decision of HEPLISAV-B	Aug. 10, 2017	****
		Potentially start a Phase III study	2H17	****
VBI-1501A	Congenital CMV vaccine	Phase I Interim results	Mid-17	****
		Phase I top-line results	2018	****
VBI-1901	GBM	Complete GMP manufacturing	1H17	***
		Start Phase I trial	2H17	***
		Potentially report Phase I study results	2H18/2019	****

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

Source: Laidlaw & Company and company presentation

Major Risks

Clinical study failure could have a major impact on VBIV share value. Despite promising clinical and pre-clinical results of the company's product candidates, it remains too early to predict the long-term safety and efficacy outcomes from the ongoing and upcoming clinical studies. Given that clinical validation has not been fully established in some pipeline products, it would be critical for the current and future studies to demonstrate efficacy and an acceptable safety profile after a longer follow-up, higher dosage and in broader patient population in order to increase the assets and shareholder value. Negative results of ongoing and future clinical studies could have a materially negative impact on the shareholder value.

Product may not be approved or reach anticipated sales. Although VBIV'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 various reasons, like narrow-scoped product label, physician consensus for prescribing the drug, treatment paradigm changes, entrance of or superior marketing capabilities of competitors, and the possible changes in pricing flexibility that could potentially have a negative impact on payer reimbursement. Further, a below expectation revenue outlook could also negatively affect VBIV shareholder value.

The possibility of insufficient IP protection of pipeline products could create uncertainty. There is a risk that third parties or competitors may challenge VBIV's patents if insufficient protection. VBIV's family of patents and patent applications that covers eVLP technology for use in human vaccines under its license agreement with UPMC could become expired in the U.S. by 2022 and in other countries by 2021. Since eVLP technology is very significant to VBIV's pipeline development, expiration may open up competitive eVLP-like products by others. However, we believe VBIV might have additional issued or pending patents to potentially negate such concern. Otherwise, competitions of like-minded products could negatively affect VBIV share value.

Additional financings could dilute shareholder value. Although the company currently sufficient cash and financial resource to advance development forward, VBIV would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can continuously explore un-dilutive financial sources successfully. Should the future operational expenses significantly increase, especially in the areas of R&D and SG&A, failed 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.

Figure 1: Income Statement

VBI Vaccines – Income Statement																
(\$ MM)	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Revenues																
VBI-1901														83.0	207.1	372.3
VBI-1501A															27.0	55.6
Sci-B-Vac											30.7	62.8	103.8	149.3	198.9	243.5
Product revenues	0.2	0.3	0.13	0.00	0.00	0.00	0.1	0.1	0.1	0.1	30.7	62.8	103.8	149.3	198.9	243.5
Services revenues	0.2	0.3	0.00	0.06	0.06	0.06	0.2	1.0	1.3	1.6	1.6	1.6	1.6	1.6	1.6	1.6
Services revenues - related parties	0.1	0.1	0.00	0.00	0.00	0.00	-	-	-	-	-	-	-	-	-	-
Total Revenue	1.0	0.5	0.1	0.1	0.1	0.1	0.3	1.1	1.4	1.7	32.3	64.4	105.4	233.9	434.7	673.1
Cost of revenue	3.75	3.67	1.28	1.30	0.23	0.23	3.04	2.80	2.26	3.17	5.2	10.3	16.9	37.9	68.4	104.6
Research and Development	14.1	10.0	4.7	4.7	5.2	5.4	20.0	31.0	35.0	35.7	36.5	37.9	39.8	31.9	26.1	27.2
General, administrative and selling	6.8	11.8	3.0	3.1	3.1	3.1	12.4	13.0	13.9	14.6	15.3	16.1	16.9	17.7	18.6	19.4
Marketing and sales											35.0	37.5	40.1	54.1	59.5	63.7
Total operating expenses	24.7	25.4	9.0	9.1	8.5	8.8	35.4	46.8	51.2	53.5	92.0	101.8	113.7	141.6	172.7	214.8
Operating Income (loss)	(23.8)	(24.9)	(8.8)	(9.1)	(8.5)	(8.7)	(35.1)	(45.7)	(49.8)	(51.8)	(59.7)	(37.4)	(8.3)	92.3	262.0	458.2
Interest expense, net	(1.1)	(0.3)	(0.7)	(0.2)	(0.2)	(0.2)	(1.2)	(1.4)	(1.7)	(1.5)	(1.4)	(1.4)	(1.4)	(1.4)	(1.4)	(1.4)
Foreign exchange gain (loss)	(1.5)	0.2	0.5	0.7	(0.5)	0.8	1.4	1.2	1.1	0.8	1.0	1.0	1.0	1.0	1.0	1.0
Incomes (losses) before income taxes	(26.3)	(25.0)	(9.1)	(8.6)	(9.1)	(8.1)	(34.9)	(45.9)	(50.4)	(52.4)	(60.1)	(37.8)	(8.7)	91.9	261.6	457.8
Income tax	0.1	1.8	0.4	0.0	0.0	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0	31.2	88.9	155.7
Net Incomes (Losses)	(26.2)	(23.2)	(8.6)	(8.6)	(9.1)	(8.1)	(35.3)	(45.9)	(50.4)	(52.4)	(60.1)	(37.8)	(8.7)	60.6	172.6	302.2
Other comprehensive income (loss) - currency translation adjustment	(2.2)	(2.2)	0.13	0.60	0.60	0.60	1.9	1.9	2.0	(1.6)	2.0	2.0	2.0	2.0	2.0	2.0
Total Comprehensive Incomes (Losses)	(26.2)	(25.4)	(8.51)	(7.99)	(8.52)	(7.49)	(\$33.4)	(\$44.0)	(\$48.4)	(\$54.0)	(\$58.1)	(\$35.8)	(\$6.7)	\$62.6	\$174.6	\$304.2
Net Earnings (Losses) Per Share—Basic	(2.07)	(0.77)	(0.22)	(0.21)	(0.23)	(0.18)	(\$0.85)	(\$1.01)	(\$0.98)	(\$0.97)	(\$1.05)	(\$0.62)	(\$0.14)	\$0.93	\$2.63	\$4.58
Net Earnings (Losses) Per Share—Diluted	(2.07)	(0.77)	(0.22)	(0.21)	(0.23)	(0.18)	(\$0.85)	(\$1.01)	(\$0.98)	(\$0.97)	(\$1.05)	(\$0.62)	(\$0.14)	\$0.93	\$2.63	\$4.58
Shares outstanding—basic	12.6	30.0	40.0	40.1	40.1	45.1	41.3	45.3	51.3	54.3	57.3	61.3	64.3	65.3	65.6	65.9
Shares outstanding—diluted	12.6	30.0	40.0	40.1	40.1	45.1	41.3	45.3	51.3	54.3	57.3	61.3	64.3	65.3	65.6	65.9
Margin Analysis (% of Revenue)																
COGS	393%	670%	1004%	2168%	383%	383%	989%	255%	158%	184%	17%	17%	17%	17%	17%	17%
R&D	1479%	1819%	3665%	7912%	8624%	9055%	6517%	2827%	2456%	2070%	113%	59%	38%	14%	6%	4%
SG&A	716%	2146%	2398%	5126%	5177%	5229%	4027%	1183%	973%	845%	47%	25%	16%	8%	4%	3%
M&S											108%	58%	38%	23%	14%	9%
Operating Income (loss)	-2488%	-4535%	-6966%	-15105%	-14084%	-14567%	-11434%	-4166%	-3488%	-2998%	-185%	-58%	-8%	39%	60%	68%
Pretax	-2756%	-4559%	-7141%	-14322%	-15201%	-13484%	-11359%	-4188%	-3532%	-3037%	-186%	-59%	-8%	39%	60%	68%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%
Net Income	-2743%	-4642%	-6702%	-13322%	-14201%	-12484%	-10872%	-4015%	-3392%	-3127%	-180%	-56%	-6%	27%	40%	45%
Financial Indicator Growth Analysis (Y/Y)																
Product/Product royalties	-79%	8%	N.A.	N.A.	-100%	N.A.	-53%	0%	0%	0%	24083%	104%	65%	124%	86%	55%
Total Revenue	#REF!	-43%	N.A.	20%	-48%	-84%	-44%	257%	30%	21%	1771%	99%	64%	122%	86%	55%
Research and development	418%	-29%	1732%	124%	53%	29%	101%	55%	13%	2%	2%	4%	5%	-20%	-18%	4%
General and administrative	979%	72%	54%	-2%	-1%	-10%	5%	5%	7%	5%	5%	5%	5%	5%	5%	4%
Sales and marketing	N.A.	N.A.	N.A.	N.A.	N.A.	7%	7%	35%	10%	7%						
Operating incomes	467%	5%	239%	53%	7%	4%	41%	30%	9%	4%	15%	-37%	-78%	-1212%	184%	75%
Pretax Income	288%	-5%	705%	33%	22%	-19%	40%	32%	10%	4%	15%	-37%	-77%	-1152%	185%	75%
Net Income	463%	-3%	368%	32%	7%	-22%	31%	32%	10%	12%	8%	-38%	-81%	-1031%	179%	74%
EPS - Basic	-57%	-63%	262%	-8%	10%	-18%	11%	19%	-3%	-2%	9%	-41%	-78%	-784%	183%	74%
EPS - Diluted	-57%	-63%	262%	-8%	10%	-18%	11%	19%	-3%	-2%	9%	-41%	-78%	-784%	183%	74%
Shares outstanding—basic	#REF!	138%	112%	45%	11%	20%	38%	10%	13%	6%	6%	7%	5%	2%	0%	0%
Shares outstanding—diluted	#REF!	138%	112%	45%	11%	20%	38%	10%	13%	6%	6%	7%	5%	2%	0%	0%

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

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3 Year Rating Change History

Date	Rating	Closing Price (\$)
10/11/2016	Strong Buy (SB)	3.13
05/16/2017	Buy (B)	4.17

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
10/11/2016	6.00	3.13
05/16/2017	7.00	4.17

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	64.44%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	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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