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Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

July 27, 2017

VBI Vaccines (VBIV - $4.64)

Healthcare/Biotechnology

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

FDA Released Briefing Document for VRBPAC Meeting of Dynavax's Heplisav-B

Yesterday, the FDA released the brief document of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting for reviewing Dynavax's Heplisav-B approval. The meeting will be held on this Friday (07/28). (https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandotherbiologics/vaccinesandrelatedbiologicalproductsadvisorycommittee/ucm568492.pdf).

- **Details.** One of interesting elements of the briefing document is the discussion and assessment of cardiovascular AEs (including myocardial infarction or MI), which were not well known to the public before. Seven questions were posted and responses from three cardiology consultants were presented. The data showed in the HBV-23 study, an imbalance of MI events (14 Heplisav, 1 Engerix-B) and cardiovascular death (3 Heplisav, 1 Engerix-B). The data also suggested that the MI event of the Engerix-B comparator arm of the study might be lower than that of the real-world experience. Overall, all three consultants seemed to agree that the endpoints used for assessing CV risks are appropriate. A mixed conclusion regarding the assessment of the cardiovascular risk associated with Heplisav. One believed there is not likely to have a reliable safety signal problem; while the other two indicated having certain level of concerns.
- **Implications.** Overall, we view the briefing document and potential outcome from the upcoming VRBPAC meeting for Heplisav-B as mixed and with some uncertainties. Although Heplisav-B has shown efficacy, it would be very interesting to see the interactions and responses at the 07/28 meeting regarding the newly learned CV AEs and ultimately, the FDA approval decision later. We reiterate our opinion that VBIV's Sci-B-Vac remains a potentially safer 3rd generation HBV vaccine given its real-world experience of over 300,000 individual exposures and approvals in 15 countries. Prior Sci-B-Vac Phase II studies also demonstrated promising efficacy. VBIV recently announced the study design of the Sci-B-Vac Phase III (CONSTANT) trial (n=3,200); and we anticipate the trial to start in 2H17 with topline results expected in 1H19.
- **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.

Trading Data:

Last Price (7/26/2017)	$4.64
52–Week High (3/14/2017)	$6.60
52–Week Low (11/3/2016)	$2.75
Market Cap. (MM)	$185
Shares Out. (MM)	40.1

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

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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 reportt 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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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	232.3	433.1	671.5
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)	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.	N.A.	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%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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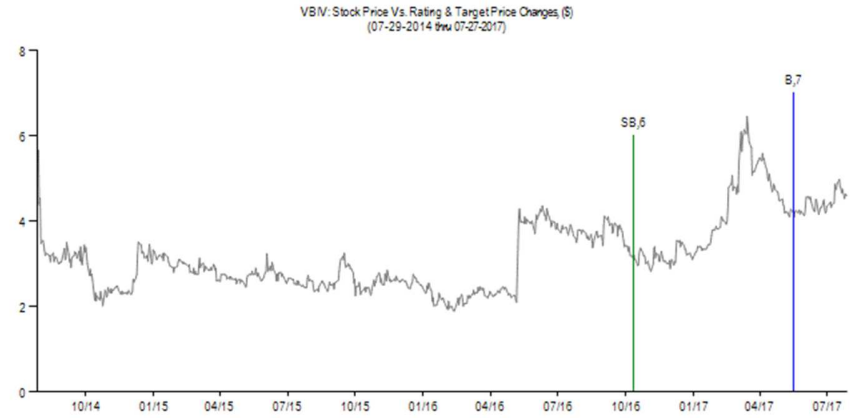
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
10/11/2...	Strong Buy (SB)	3.13
05/16/2...	Buy (B)	4.17

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
10/11/2...	6.00	3.13
05/16/2...	7.00	4.17

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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Buy (B)	Expected to outperform the sector average over 12 months.	63.04%	30.43%	2.17%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Yale Jen, Ph.D.
yjen@laidlawltd.com

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NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com