Zacks Small-Cap Research

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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Positive Results From Phase 2b Trial of M-001; Ready to Move Into Pivotal P3 Trial as Standalone Universal Influenza Vaccine…

Based on our probability adjusted DCF model that takes into account potential future revenues from M-001 as a universal flu vaccine, BVXV is valued at $33/share. This model is highly dependent upon continued clinical success of M-001 and will be adjusted accordingly based upon future clinical results.

Current Price (08/01/17)	$9.52
Valuation	**$33.00**

OUTLOOK

On July 20, 2017, BiondVax Pharmaceuticals, Ltd. announced positive results from a Phase 2b clinical trial of M-001, the company's universal influenza vaccine. The study hit both of the primary endpoints in safety and influenza-specific cellular immune responses.

Based on the encouraging clinical trial results, the recent €20 million EIB funding, the Israeli Ministry of Economy grant approval, and following discussions with regulatory experts in both the E.U. and U.S., BiondVax may proceed directly to a pivotal Phase 3 clinical trial with a clinical efficacy outcome measuring reduction of influenza illness rate and severity. Based on the positive results and expedited timelines, we have increase our valuation to $33 per share.

SUMMARY DATA

52-Week High	**$10.42**
52-Week Low	**$3.25**
One-Year Return (%)	**187.61**
Beta	**0.57**
Average Daily Volume (sh)	**43,504**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2017	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2018					0.0 E
2019					0.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.00 A	-$0.01 A	$0.00 A	-$0.00 A	-$0.03 A
2017	-$0.02 A	-$0.00 E	-$0.00 E	-$0.01 E	-$0.03 E
2018					-$0.02 E
2019					-$0.03 E

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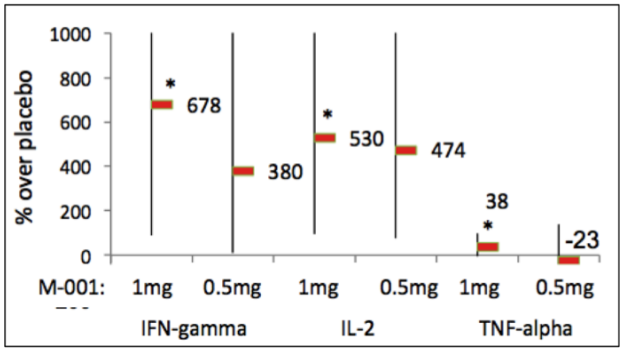
Business Update

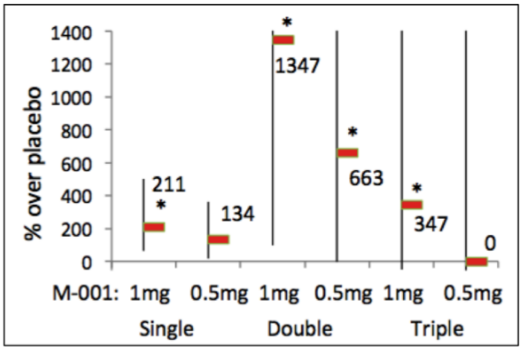
Positive Results from Phase 2b Trial of M-001

On July 20, 2017, BiondVax Pharmaceuticals, Ltd. announced results from the company's Phase 2b clinical trial of M-001, the universal influenza vaccine candidate. The trial, which was funded through a grant from the European Union and was conducted in conjunction with the European UNISEC Consortium, enrolled a total of 219 participants aged 18 to 60 years. Each participant received two injections of either 0.5 mg M-001, 1.0 mg M-001, or placebo prior to a partial dose of avian H5N1 pandemic vaccine.

The trial hit both primary endpoints for safety and immunological response. The company had previously reported positive preliminary safety results based on blinded data from the trial, and has since confirmed that treatment with M-001 was safe and well tolerated. To test for immunological response, T cell activation was measured in *in vitro* assays through the release of the cytokines interleukin (IL)-2, interferon (INF)-γ, and tumor necrosis factor (TNF)-α. The following figure on the left shows that statistically significant T cell activation was found in participants that received 1.0 mg M-001 when compared to the placebo group. The following figure on the right shows that the there was a significant increase in T cells that expressed two cytokines, which have been shown to be functionally superior to single-cytokine producing T cells (Kannanganat *et al*., 2007).



Source: BiondVax Pharmaceuticals Ltd.



Source: BiondVax Pharmaceuticals Ltd.

The study's secondary endpoint evaluated antibody response to avian H5N1 pandemic vaccination. In one of the four H5N1 strains tested there was a statistically significant increase in antibody response in those receiving M-001.

Company Turns Attention to Pivotal Phase 3 Trial

BiondVax's strategy for commercializing M-001 had previously centered on attaining approval for M-001 as a stockpiled vaccine to be used in the case of a pandemic outbreak and a primer for the seasonal influenza vaccine before initiating a Phase 3 trial of M-001 as a standalone influenza vaccine. However, BiondVax has had a number of significant positive developments in the past few months that has resulted in the company now considering moving M-001 directly into a pivotal Phase 3 trial as a standalone influenza vaccine. Recently the company has:

- Announced that the Israeli Ministry of Economy and Industry approved a grant to cover 20% of a NIS 20 million budget for the construction of a manufacturing facility for M-001. The facility will be used to produce sufficient quantities of vaccine for Phase 3 clinical trials and commercialization.

- Announced it entered into a $22 million (€20 million) financing agreement with the European Investment Bank (EIB) to fund.

- Consulted with regulatory experts in both the E.U. and U.S. to determine the most efficient path to market.

The general outline for the Phase 3 trial is shown below. The company is planning to enroll approximately 7500 patients and will focus on patients over the age of 50. The primary outcome of the trial will be safety and clinical efficacy of M-001, defined as a reduction in illness rate and severity. The company is hoping to be able to initiate the trial in Fall 2018. A U.S. based contract manufacturing organization (CMO) will likely produce the first batch of

M-001 for use in the first cohort of patients, while BiondVax will produce the subsequent batches in the new manufacturing facility. Following dosing, patients will be followed through the next two influenza seasons, with interim results likely after both seasons. Following patients past the third influenza season may be necessary depending upon the severity of the circulating influenza strains for each season (which will dictate the overall illness rate). Investors should be aware that this is only a preliminary outline of the potential study design and the details may change, however the general outline of the trial shouldn't.

Proposed Trial Design	Season 1			Season 2	Season 3 (optional)
	Day 1	Day 21	Day 180	Follow up	Follow up
Experimental	1mg M-001	1mg M-001	Safety, Culture, and PCR on any ILI (flu season)	Culture and PCR on any ILI (flu season)	Culture and PCR on any ILI (flu season)
Control	Placebo	Placebo			

Source: BiondVax Pharmaceuticals Ltd.

Conclusion and Valuation

BiondVax has had a nice run of positive news over the last several months that culminated with the positive results from the Phase 2b trial. We are pleased to see that the company is planning to next move into a pivotal Phase 3 clinical trial for M-001 as a standalone influenza vaccine as there is ample evidence of efficacy and safety in the clinical studies up to this point.

We have made a number of adjustments to our model based on the recent news that includes increasing the probability of approval for M-001 to 50% and BiondVax selling M-001 in the U.S. while partnering for sales overseas. We continue to include the stockpiling of M-001 as a pandemic influenza vaccine. The critical workforce in the U.S. is approximately 15% of the population (20 million people), and 1/3rd of the stockpile is replaced annually (given a shelf-life of three years). At $12 per dose that represents a $240 million annual opportunity. We apply an 18% discount rate and a 50% probability of approval to arrive at a net present value for M-001 as a primer for a pandemic vaccine of $86 million.

As a stand-alone universal vaccine, we model for M-001 to have peak market share of 25% in the U.S., which leads to peak revenues of approximately $750 million, and peak revenues of approximately $300 million overseas. We believe peak revenue forecasts for >$1 billion are justified based upon the clear advantages that M-001 has over the seasonal influenza vaccines, particularly in regard to efficacy with limitation brought about by whichever influenza strain happens to be circulating. With an 18% discount rate and a 50% probability of approval, we value M-001 as a standalone vaccine at approximately $160 million.

Combining the net present value for M-001 as a stockpiled and standalone vaccine along with the company's current cash position and expected operating burn of leads to a valuation of $33 per share. The stock has had a good run in 2017 thus far, however we believe there is still considerable upside left for investors today.

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PROJECTED FINANCIALS

BiondVax Pharmaceuticals, Ltd.
Income Statement

BiondVax Therapeutics, Ltd.	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
M-001 (Elderly Primer)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-			
M-001 (Pandemic Primer)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-			
M-001 (Universal Vaccine)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-			
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-			
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-			
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-			
Research & Development	$2.0	$0.5	$0.5	$0.5	$0.6	$2.1	$3.5	$4.0
General & Administrative	$1.1	$0.3	$0.2	$0.3	$0.3	$1.1	$1.4	$1.7
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($3.1)	($0.8)	($0.7)	($0.8)	($0.9)	($3.2)	($4.9)	($5.7)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$0.7	($2.4)	$0.0	$0.0	$0.0	($2.4)	$0.0	$0.0
Pre-Tax Income	($2.4)	($3.2)	($0.6)	($0.8)	($0.9)	($5.6)	($4.9)	($5.7)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($2.4)**	**($3.2)**	**($0.6)**	**($0.8)**	**($0.9)**	**($5.6)**	**($4.9)**	**($5.7)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.02)**	**($0.02)**	**($0.00)**	**($0.00)**	**($0.01)**	**($0.03)**	**($0.02)**	**($0.03)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	135.1	162.5	170.0	170.0	170.0	168.1	200.0	220.0
Basic ADS Outstanding	3.4	4.1	4.3	4.3	4.3	4.2	5.0	5.5

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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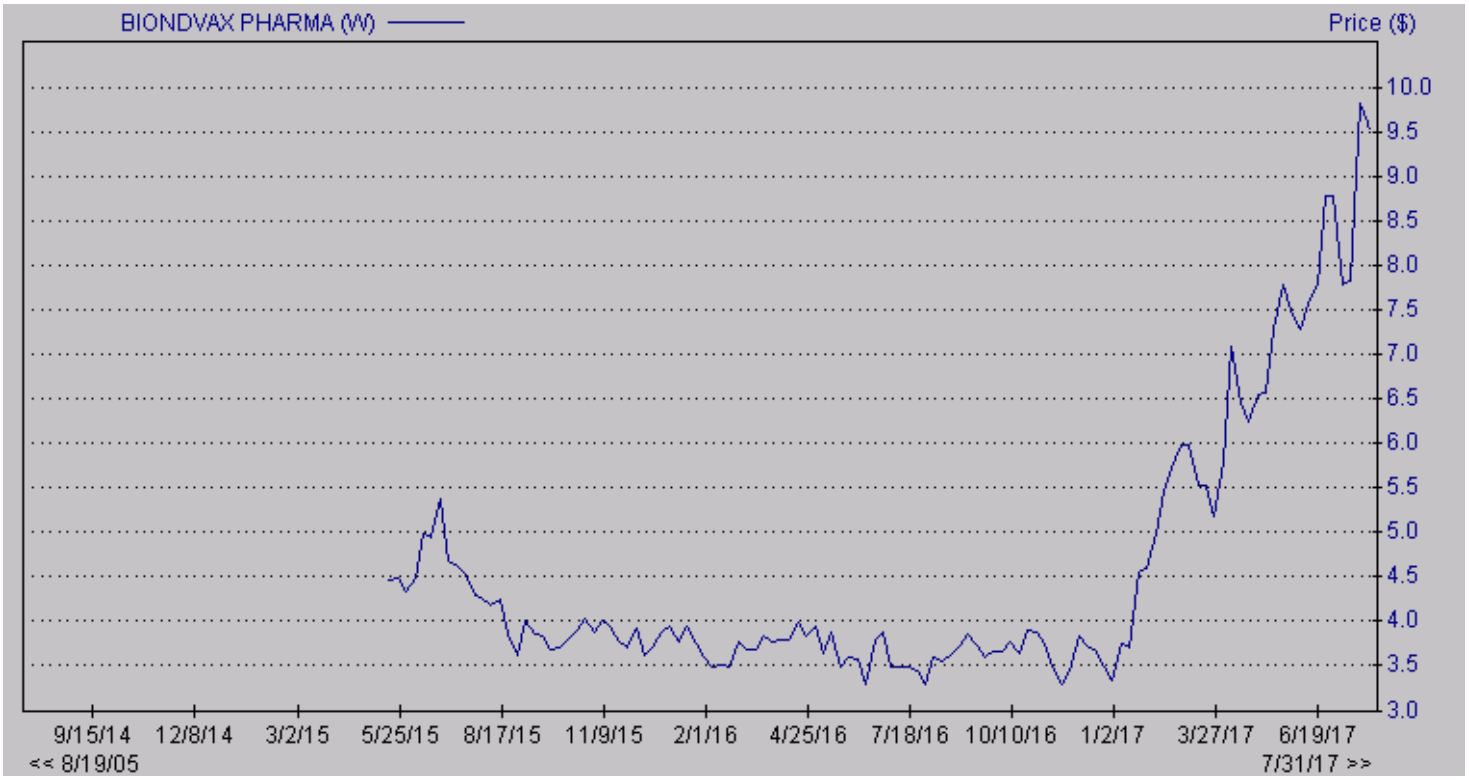
HISTORICAL STOCK PRICE



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