Zacks Small-Cap Research

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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Planning Continues for M-001 Phase 3 Program …

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 $30/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 (12/12/17)	$5.30
Valuation	**$30.00**

OUTLOOK

BiondVax Pharmaceuticals,Ltd. is a biopharmaceutical company developing a universal influenza vaccine (M-001) designed to protect individuals from all strains of influenza. The company is currently in the planning stages for a global Phase 3 program for M-001 as a standalone universal influenza vaccine. The first Phase 3 trial is expected to take place in Europe and should begin before the 2018/2019 influenza season.

BiondVax also recently signed an agreement with the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) to conduct a Phase 2 clinical trial to examine the cell mediated immunity induced by M-001, as well as M-001's ability to enhance the immunogenicity of the current seasonal influenza vaccine. This trial is expected to start following the 2017/2018 influenza season.

SUMMARY DATA

52-Week High	**$10.42**
52-Week Low	**$3.35**
One-Year Return (%)	**41.58**
Beta	**0.33**
Average Daily Volume (sh)	**11,188**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$35**
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 A	0.0 A	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	-$0.02 A	$0.00 A	-$0.01 E	-$0.04 E
2018					-$0.03 E
2019					-$0.05 E

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Business Update

Planning Continues for Phase 3 Program

BiondVax's strategy for commercializing M-001 involves testing it in a pivotal Phase 3 program as a standalone influenza vaccine to assess its clinical efficacy. The first Phase 3 trial will be conducted in Europe and the company has already initiated discussions with the European Medicines Agency (EMA) regarding the trial design. We anticipate the EMA providing feedback soon. The trial is being conducted in Eastern Europe since there are not recommendations in some of those countries to get the yearly influenza vaccine, thus making it much easier to enroll sufficient numbers of subjects who have not been previously immunized with the yearly influenza vaccine. In addition, the company is working to align the Phase 3 plan with FDA requirements. Lastly, BiondVax is nearing selection of a Contract Research Organization (CRO) to conduct the trial.

The general outline for the Phase 3 trial is shown below. The company is planning to enroll approximately 7700 patients and will focus on patients over the age of 50. Approximately half of those subjects will be enrolled prior to the first influenza season. The trial is designed such that a certain overall rate of influenza infection is required for the trial to be properly powered. Thus, unblinding of the data following the first influenza season will be dictated by the overall rate of infection (i.e., how severe of an influenza season it is). If it is a mild influenza season, then additional subjects will likely need to be enrolled in Season 2 and the subjects from Season 1 will be followed as well. This process will continue until a sufficient number of influenza infections occur in the entire cohort, potentially into Season 3. Subjects from Season 1 will be followed up regardless of when the study is unblinded to determine long-term effectiveness of M-001.

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 before the start of the 2018/2019 influenza season. 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. 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. We will provide additional updates to the trial design as they become known.

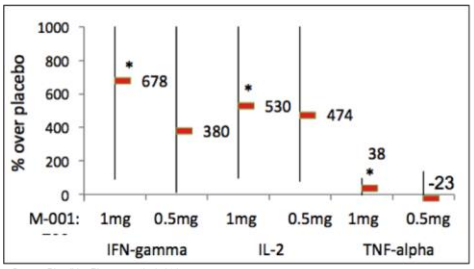
Proposed Trial Design	Season 1			Season 2	Season 3 (optional)
	Day 1	Day 21	Day 180	Follow up	Follow up
Experimental	1mg M-001	1mg M-001	Safety, Culture, and PCR on any ILI (flu season)	Culture and PCR on any ILI (flu season)	Culture and PCR on any ILI (flu season)
Control	Placebo	Placebo			

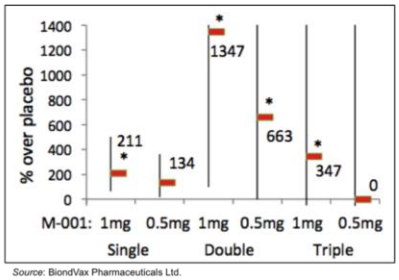
Source: BiondVax Pharmaceuticals Ltd.

Positive Results from Phase 2b Trial of M-001

Earlier this year, BiondVax 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 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).





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.

NIH to Conduct Phase 2 Trial of M-001

On November 20, 2017, BiondVax Pharmaceuticals, Ltd. (BVXV) announced the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) will conduct a Phase 2 clinical trial of M-001. The study is designed to evaluate the cell mediated immunity induced by M-001 as well as its ability to enhance the immunogenicity of the current seasonal influenza vaccine. The study will enroll 120 adults age 18-45 who will receive either M-001 or placebo followed later by a currently marketed trivalent seasonal influenza vaccine. The study is taking place at four medical institutions in the U.S. and will begin in the second quarter of 2018 after the end of the 2017/2018 influenza season.

Financial Update

On November 28, 2017, BiondVax announced financial results for the third quarter of 2017. As expected, the company did not report any revenues during the quarter. The company reported net income of $0.4 million for the third quarter of 2017, which was comprised of $0.3 million in R&D expenses, $0.6 million in G&A expenses, and a non-cash gain of $1.3 million from the revaluation of options. Total cash burn for the third quarter of 2017 was approximately $0.8 million.

As of September 30, 2017, BiondVax had cash, cash equivalents, and marketable securities of approximately $22.1 million. On September 19, 2017, the company announced the closing of a public offering of 1.5 million American Depository Shares (ADS) for $6.00 per ADS. The underwriters exercised their over-allotment option in full to purchase an additional 166,667 ADS, thus the total public offering was approximately 1.67 million ADS for gross proceeds of $10 million. Additional positive financial developments in 2017 include:

- ✓ In June 2017, BiondVax Pharmaceuticals, Ltd. announced it entered into a $22 million (€20 million) loan agreement with the European Investment Bank (EIB). The non-dilutive financing agreement is structured as a 0% fixed interest rate loan. The funds will be made available in three tranches, up to 12, 24, and 36 months following the date of the agreement. Amounts between €4-6 million will be disbursed in tranches 1 and 2, with the remainder of the funds available in tranche 3.

- ✓ In August 2017, BiondVax announced that the Israel Innovation Authority (IIA), which was formerly known as the Office of the Chief Scientist, agreed to fund up to 40% of an approximately $750,000 budget toward ongoing development of M-001. Thus far, the IIA has granted over $6 million in non-dilutive funding to BiondVax to support the development of M-001.

- ✓ In March 2017, BiondVax 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. In July 2017, the company announced an agreement to lease 1800 m^2 in the Jerusalem BioPark. Planning and design of the facility has begun and BiondVax will begin lease payments in October 2018 following construction of the facility. We note that Teva Pharmaceuticals (TEVA), the world's leading generic drug manufacturer, also has a facility in the same area.

Lastly, the company announced that the Board of Directors has decided to voluntarily delist from the Tel Aviv Stock Exchange (TASE) and continue being listed only on the Nasdaq. In addition, the company will search for a new Chairman of the Board with relevant global experience as the company transitions to conducting international Phase 3 trials and potential global commercialization. The delisting process from TASE will take place Jan. 22,

2018. The company currently has approximately 6.5 million ADS's outstanding and when factoring in options and warrants a fully diluted ADS count of 8.7 million.

Background on M-001

BiondVax is developing the M-001 vaccine, a synthetic peptide-based protein that targets both existing and future seasonal and pandemic strains of the influenza virus. The vaccine targets conserved regions of Type A and B influenza viruses such that M-001 could be considered a "universal" influenza vaccine, capable of offering immunological protection against all strains of the influenza virus.

M-001 is composed of nine peptides that are believed to be common to most known influenza strains in existence, in part because these peptides seem to be critical for the virus' ability to infect a host cell. They are derived from hemagglutinin (HA), matrix 1 (M1) and nucleoprotein (NP) viral proteins and are arranged as triplicates into a single recombinant protein easily manufactured in bacteria. HA is an antigenic glycoprotein found on the surface of influenza viruses and is also the main constituent for a number of seasonal influenza vaccines. However, the peptides from HA in M-001 are derived from the inner parts of the protein where little to no variability between strains exists. M1 is a matrix protein that forms a layer under the patches of the viral cell membrane that contain HA, NA, and M2 proteins, and is responsible for mediating the encapsulation of RNA-nucleoprotein complexes into the membrane envelope (Sha *et al*., 1997). NP is a structural protein that encapsidates the viral RNA inside the virus. The sequence of each of the peptides is shown below, along with the order in which the peptides are arranged in the full-length recombinant protein.

Peptide	Amino Acids Sequence
Hemagglutinin (HA) epitope 1	PKYVKQNTLKLAT
Hemagglutinin (HA) epitope 2	SKAYSNCYPYDVPDYASL
Hemagglutinin (HA) epitope 3	WLTGKNGLYP
Hemagglutinin (HA) epitope 4	WTGVTQN
Hemagglutinin (HA) epitope 5	PAKLLKERGFFGAIAGFLE
Nucleoprotein (NP) epitope 6	FWRGENGRKTRSAYERMCNILKGK
Nucleoprotein (NP) epitope 7	SAAFEDLRVLSFIRGY
Nucleoprotein (NP) epitope 8	ELRSRYWAIRTRSG
Matrix (M) epitope 9	SLLTEVETYVP

(HA epitope 1) - (HA epitope 2) - (M1 epitope 9) - (HA epitope 3) - (HA epitope 4) - (NP epitope 6) - (HA epitope 5) - (NP epitope 7) - (NP epitope 8).

Source: Atsmon *et al*., 2012

The peptides were selected based upon their ability to elicit either a B- or T-cell immune response and each of them has the ability to bind to a wide array of human leukocyte antigen (HLA) proteins (both Class I and Class II), which are responsible for presenting peptides to the immune system. Some may question the use of peptides from proteins located inside the virus, however there is a strong rationale for their use. It has long been known that a mild influenza infection in animals provides protection against a subsequent, more severe challenge with a virus harboring different HA and NA (Yetter *et al*., 1980). This effect appears to be mediated by both CD4+ and CD8+ T-cells that recognize conserved regions on viral proteins (Furuya *et al*., 2010). The CD4+ T-cells that are specific for conserved internal viral antigens also potentiate antibody responses to the HA of subsequently encountered viruses (Scherle *et al*., 1986). The end result is that immunizing with conserved internal viral antigens results in an increased immunological response to infection following subsequent exposure to influenza viruses.

Previous Clinical Trial Results

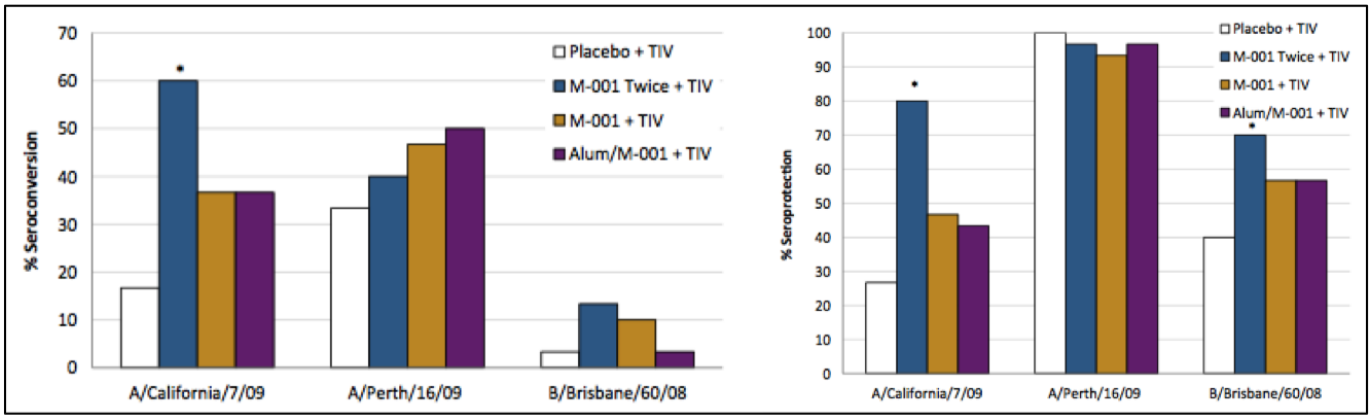
Prior to the Phase 2b study mentioned above, M-001 had been tested in 479 participants through five different clinical trials, with the details presented in the following chart. In each of the trials, the vaccine was shown to be safe and able to induce a robust immune response.

Study	ClinicalTrials.gov Identifier	Phase	Year	# Pts	Ages
BVX-002	NCT00877448	1/2	2009	63	18-49
BVX-003	NCT01010737	1/2	2010	60	55-75
BVX-004	NCT01146119	2	2011	200	18-49
BVX-005	NCT01419925	2	2012	120	65+
BVX-006	NCT02293317	2	2015	36	50-65

Source: BiondVax Pharmaceuticals Ltd. / Zacks SCR

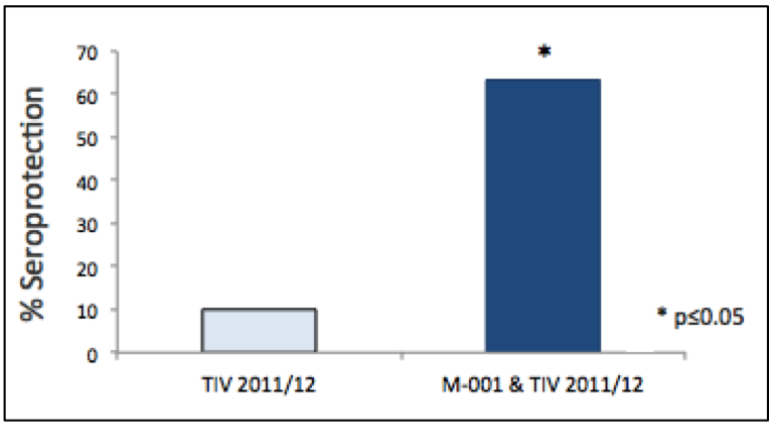
BVX-002 (Atsmon *et al*., 2012): This was a single-center, randomized, placebo controlled, single blind first-in-human study to examine the safety and immunological response to M-001 in healthy adults age 18-49. For safety purposes, three subjects were dosed once with 0.125 mg of M-001 and monitored for 7-9 days before the rest of the patients were administered the planned doses. There were four dosing cohorts, and within each cohort subjects were randomized in a 2:1 fashion to receive either 0.25 mg or 0.5 mg M-001 (n=10) or placebo (n=5), with or without adjuvant. The results showed that M-001 was well tolerated with only mild and moderate adverse events (AEs), with no significant difference between vaccine and placebo recipients for AEs. A robust humoral (antibodies to M-001) and cellular (PBMC proliferation to viral peptides) immune response was noted for participants immunized with M-001, and while there were greater humoral responses in patients immunized with M-001 plus adjuvant, there did not appear to be a difference in cellular response between subjects dosed with adjuvant and those without.

BVX-005 (Atsmon *et al*., 2014): This was a two-center, randomized, placebo controlled study in a total of 120 elderly volunteers (age 65+). The subjects were randomized 1:1:1:1 into four parallel groups to receive either 1) two sequential non-adjuvanted 0.5 mg M-001, or 2) a single non-adjuvanted 0.5 mg M-001, or 3) a single adjuvanted IM injection of 0.5 mg M-001, or 4) one placebo injection. All participants subsequently received the seasonal trivalent influenza vaccine (TIV) three weeks following the last M-001 or placebo injection. The primary outcome measures were safety, tolerability, and tolerance of M-001 with secondary outcomes being humoral and cellular immune responses. The results showed that priming with M-001 enhanced seroconversion towards all three strains in that season's influenza vaccine (denoted on the y-axis in the figure below). The following figure shows the percentage of patients that tested positive for seroconversion (defined as a mean fold increase in anti-HA antibody levels of ≥ four-fold from levels detected in sera collected on day 0, and reaching a level of ≥1:40 post-immunization) and seroprotection (defined as the number of participants per cohort expressing anti-HA antibody levels of ≥1:40 post-immunization). Addition of an adjuvant did not appear to offer any additional immunostimulatory effect.



Source: Atsmon *et al*., 2014

In 2015, a new 'Swiss' epidemic influenza strain (H3N2: A/Switzerland/9715293/13) emerged that did not exist in 2011, which was when the BVX-005 trial took place and the participants in the trial were immunized with M-001. Blood serum samples from the participants in the BVX-005 trial were exposed to the 'Swiss' influenza strain, with results showing that greater than 60% of the M-001 vaccinated group had seroprotection against this new Swiss strain, compared to only 10% of those immunized with just the seasonal vaccine. This suggests that M-001 may offer a broader, long-lasting immune response not just to strains currently in existence, but to future strains that do not even exist yet!



Source: BiondVax Pharmaceuticals, Ltd.

Conclusion and Valuation

BiondVax continues to steadily execute on its business plan and we look forward to learning additional details about the pivotal Phase 3 program. While not required to move M-001 into the Phase 3 program, the Phase 2 trial being conducted by the NIH will provide additional scientific insight into M-001's mechanism of action as well as providing additional safety data in another cohort of subjects.

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 without any limitations 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.

Our model also includes 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.

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 $30 per share.

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PROJECTED FINANCIALS

BiondVax Pharmaceuticals, Ltd.
Income Statement

BiondVax Therapeutics, Ltd.	2016 A	Q1 A	Q2 A	Q3 A	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	$0.6	$0.3	$0.6	$2.0	$5.0	$10.0
General & Administrative	$1.1	$0.3	$0.2	$0.6	$0.3	$1.4	$1.4	$1.7
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($3.1)	($0.8)	($0.8)	($0.9)	($0.9)	($3.4)	($6.4)	($11.7)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$0.7	($2.4)	($2.7)	$1.3	$0.0	($3.8)	$0.0	$0.0
Pre-Tax Income	($2.4)	($3.2)	($3.5)	$0.4	($0.9)	($7.2)	($6.4)	($11.7)
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)**	**($3.5)**	**$0.4**	**($0.9)**	**($7.2)**	**($6.4)**	**($11.7)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.02)**	**($0.02)**	**($0.02)**	**$0.00**	**($0.00)**	**($0.04)**	**($0.02)**	**($0.04)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	135.1	162.5	169.2	191.5	260.0	195.8	280.0	300.0
Basic ADS Outstanding	3.4	4.1	4.2	4.8	6.5	4.9	7.0	7.5

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

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