Zacks Small-Cap Research

June 2, 2017
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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Immunogenicity Results From Phase 2b Trial of M-001 Expected Soon…

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 $18/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 (06/02/17)	$7.28
Valuation	**$18.00**

OUTLOOK

BiondVax Pharmaceuticals,Ltd. is a biopharmaceutical company developing a universal influenza vaccine designed to protect individuals from all strains of influenza. Recently, the company announced positive preliminary safety results from the Phase 2b clinical trial of M-001, which was conducted in collaboration with the European UNISEC consortium. We anticipate immunogenicity results from the study by the end of the second quarter of 2017.

BiondVax recently announced financial results for the first quarter of 2017. The company exited the first quarter of 2017 with approximately $9.6 million in cash, cash equivalents, and marketable securities.

SUMMARY DATA

52-Week High	**$8.40**
52-Week Low	**$3.25**
One-Year Return (%)	**106.23**
Beta	**0.56**
Average Daily Volume (sh)	**30,554**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$32**
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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WHAT'S NEW

Financial Update

On May 30, 2017, BiondVax announced financial results for the first quarter of 2017. As expected, the company did not report any revenues during the quarter. The company reported a net loss of $3.2 million for the first quarter of 2017, which was comprised of $0.5 million in R&D expenses and $0.3 million in G&A expenses. Total cash burn for the first quarter of 2017 was approximately $0.65 million.

As of March 31, 2017, BiondVax had cash, cash equivalents, and marketable securities of $9.6 million. On January 2, 2017, BiondVax announced that Angels High Tech Investments Ltd., which is owned by Marius Nacht (co-founder of Check Point Software Technologies Ltd. [Nasdaq: CHKP]), had agreed to invest approximately $2.83 million in the company in exchange for 844,000 Nasdaq listed ADS. Following the transaction, Angels Investments holds 19.99% of all issued and outstanding shares of the company. An investment such as this is important as it shows a level of confidence in both M-001 and the BiondVax management team as well as providing the company with much needed capital to continue development of M-001 into Phase 3 clinical trials. Lastly, the added financial stability provided by the investment could make it easier for the company to pursue grants and other non-dilutive funding sources.

BiondVax Publishes Regulatory Approval Strategy for Universal Influenza Vaccines

On March 13, 2017, BiondVax Pharmaceuticals Ltd. (BVXV) announced the publication of an article written by BiondVax-affiliated authors titled, "Strategy for approving a universal flu vaccine" in the journal *Future Virology* (Ben-Yedidia et al., 2017). The authors discuss the strategy to get M-001 through the regulatory process by using a stepwise approach that first utilizes an existing regulatory marker before using newly defined markers.

Currently, the efficacy of all seasonal influenza vaccines is tested based on induction of hemagglutination inhibition (HAI) antibodies that target the outer variable regions of the viral hemagglutinin protein. Since M-001 is targeted against conserved regions of the influenza virus, it does not elicit HAI antibodies but instead induces a cellular response. Thus far, BiondVax has taken the conservative approach of using M-001 as a primer to be given ahead of the seasonal influenza vaccine. This has allowed the HAI antibody response to continue to be used to verify the efficacy of M-001. When given has a primer, M-001 enhances and broadens the HAI antibody response induced by the seasonal influenza vaccine.

One possible path forward that the company is considering is to conduct two Phase 3 clinical trials to support approval of M-001 as a primer vaccine. One Phase 3 study would likely focus on the use of M-001 as a primer for seasonal vaccination in the elderly, while another Phase 3 study would focus on the use of M-001 as a primer for pandemic immunization for approval to be stored in the national stockpile. According to the article by Ben-Yedidia *et al*., regulatory agencies have suggested 3,000 participants in the experimental group and 1,500 in the placebo group. Assuming a 10% drop out rate leads to a total of approximately 5,000 individuals in total for those studies.

The primer vaccine trials will continue to employ the serum HAI titer as an efficacy outcome, which will be measured on Day 0 and 42. Success will be measured as a seroconversion response of ≥10% to at least two of the trivalent influenza vaccine (TIV) strains and noninferiority to the third TIV strain. This outcome was accepted by the FDA for the Sanofi Fluzone High Dose vaccine marketing authorization.

If BiondVax were to seek approval as a primer vaccine in the elderly first, it would likely be followed up by Phase IV clinical trials being conducted with M-001 as an independent, stand alone influenza vaccine. These trials will need to include tens of thousands of participants with an efficacy endpoint of reduction of influenza illness rate and severity with M-001 compared to those immunized with the seasonal vaccine.

BiondVax is planning to apply for an FDA-accelerated approval pathway that could lead to approval based on a limited-size Phase 3 clinical trial, such as the planned trial in the elderly to test M-001 as a primer to the seasonal vaccine.

We believe the plan as set forth in the article by Ben-Yedidia *et al*. for gaining regulatory approval for M-001 is a sound one. The plan is likely to prove successful as the company already has a large amount of data showing the ability of M-001 to induce a greater immune response in patients when used as a primer compared to those who are

only given the seasonal influenza vaccine. In addition, it allows regulatory agencies the opportunity to get comfortable with a new type of influenza vaccine through its use as a primer, and to collect an abundance of real-world efficacy and safety data before considering it as a stand alone vaccine.

BiondVax Approved for Grant to Help Construct Manufacturing Facility

On March 30, 2017, BiondVax Pharmaceuticals Ltd. (BVXV) announced that the Israeli Ministry of Economy and Industry approved a grant to cover 20% of the NIS 20 million budget for 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. BiondVax is planning to construct a mid-sized facility in Jerusalem that could potentially one day produce tens of millions of doses of M-001.

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.

The company is planning to seek regulatory approval through a two-part strategy:

1. As a "Universal Primer" to be used before any hemagglutinin-based flu vaccine. BiondVax targets two indications for its universal primer: i) seasonal primer for influenza vaccine in the elderly, and ii) pandemic primer for national stockpile.
2. As a stand-alone independent "universal" vaccine against influenza.

Many infectious diseases have been eradicated over the past century, for example polio and smallpox, thanks to vaccination. In order to eradicate an infectious disease, a community (or herd) immunity must be achieved. Three conditions are required to achieve community immunity:

1. An effective vaccine,
2. Broad coverage and unchanging vaccine formulation, and
3. Enough people to be vaccinated.

With a universal flu vaccine such as BiondVax's M-001, it appears theoretically possible, for the first time in history, to achieve the goal of influenza eradication. In support of this, the company was recently invited to attend the "Eighth WHO meeting on the development of influenza vaccines that induce broadly protective and long-lasting immune responses". The Global Vaccine Action Plan (GVAP) has a goal for at least one universal influenza vaccine to be on the market by 2020, and the World Health Organization (WHO) is supporting this initiative through constant interaction with leading experts in the field through events such as the one BiondVax will be attending. M-001 is a leading contender to be the first universal influenza vaccine due to its safety profile and strong immunogenicity along with currently being in Phase 2b clinical trials.

M-001 Composition

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. As discussed above, 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.

M-001 Clinical Trial Results

Thus far, M-001 has 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. Due to the fact that M-001 does not target the variable region of HA, the HAI assay (which is utilized to test the effectiveness of currently available seasonal influenza vaccines) cannot be employed as a surrogate endpoint for determining vaccine efficacy when M-001 is administered on its own. Thus, the company has developed additional immunological assays to determine immunogenicity. In addition, in its first stage in bringing M-001 to market, the company is pursuing a "prime-boost" strategy, where M-001 is given prior to immunization with the traditional seasonal influenza vaccine, in which case the HAI assay can be utilized to compare immunogenicity to currently available influenza vaccines. The trials completed thus far are presented below.

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

Final Phase 2 Clinical Trials for M-001

BiondVax has initiated two Phase 2 clinical trials that will involve a total of 372 participants; one that has completed in Europe (BVX-007) and one that will soon start admitting participants in the U.S. (BVX-008).

BVX-007: The BVX-007 trial was a Phase 2b clinical trial with 219 adults (age 18-60) who have completed the study. It was designed to evaluate the safety and immunogenicity of M-001 when used as a primer to the H5N1 avian influenza vaccine. The H5N1 avian influenza vaccine was given once, at a sub-optimal dose, in order to test whether M-001 can enhance its immunogenicity.

On November 29, 2016, Biondvax Pharmaceuticals, Ltd. (BVXV) announced positive preliminary safety results from the BVX-007 trial. Since the data is still blinded, the distribution of adverse events amongst the total of 219 participants who completed the study in the control and experimental groups is unknown. However, only three moderate adverse events were considered to be possibly or probably related to treatment and no treatment-related serious adverse events were reported.

If successful, this trial could show the dose sparing potential of M-001, which in the case of a pandemic situation could allow for the available doses of pandemic vaccine to be administered to more subjects. The trial is being funded through a grant from the European Union and is being conducted in conjunction with the European UNISEC Consortium. We anticipate immunogenicity results from this trial will be reported near the end of the second quarter of 2017.

BVX-008: This will be a Phase 2 clinical trial being conducted by the NIAID, which is part of the NIH. The double blind, multicenter, randomized, placebo controlled trial is expected to enroll 150 adults (18-45) and will examine the use of M-001 as a primer vaccine to be given several weeks before the H7N9 avian pandemic vaccine. The primary outcome will be safety and tolerability with secondary endpoints examining humoral and cellular immune responses. We anticipate this trial will begin in the next few months with results available in 2017.

Valuation Methodology

We value BiondVax using a probability adjusted discounted cash flow model that takes into account potential revenues from the sale of M-001 as 1) a seasonal primer for influenza vaccine in the elderly; 2) a pandemic primer for a national stockpile; and 3) a stand-alone independent universal influenza vaccine. At this point, we are assuming that the company will enter into one or more partnerships with larger pharmaceutical companies that will result in BiondVax receiving royalties (we model 15% for all indications) on the sale of M-001.

In the U.S., there were approximately 135 million doses of the influenza vaccine administered last year with approximately 20% of those administered to the elderly. Assuming a 33% penetration rate which will use M-001 as part of prime-boost vaccine, then at approximately $20 per dose (based on a midpoint between the Fluzone HD geared to the elderly price of $28 and the standard Fluzone price of $8 per dose) it is a potential $200 million opportunity just in the U.S. We believe the rest of the world represents a potential $300 million peak 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 seasonal vaccination in the elderly of $49 million.

Another market is the pandemic primer for national stockpile. 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 another $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 $40 million.

As a stand-along universal vaccine, we anticipate Phase 3 trials initiating in 2019 with a regulatory filing in 2021 and approval in 2022. By that time we model for approximately 140 million doses of the influenza vaccine being administered in the U.S., and with a peak market share of 25%, we model for peak revenues of over $700 million. We apply an 18% discount rate and a 33% probability of approval to arrive at a net present value for M-001 as a stand-along universal vaccine of $43 million.

Combining the net present value for each of the company's development programs along with the company's current cash total and expected operating burn leads to a valuation of approximately $18 per share.

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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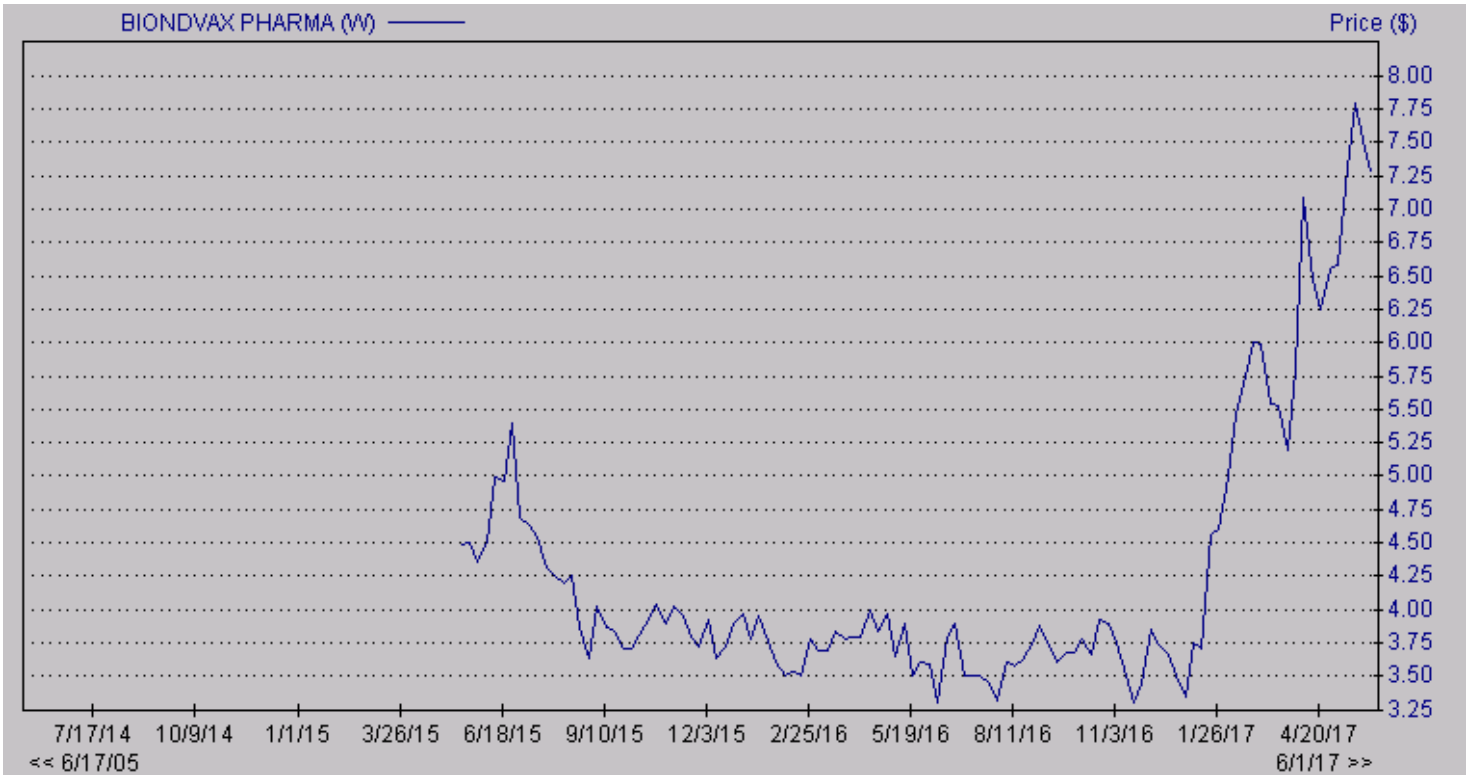
HISTORICAL STOCK PRICE



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