Zacks Small-Cap Research

September 20, 2017
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Raises $10 Million to Help Support M-001 Pivotal P3 Program 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 $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 (09/20/17)	$7.17
Valuation	**$30.00**

OUTLOOK

BiondVax is currently in the planning stages for a global Phase 3 program for M-001 as a standalone universal influenza vaccine. Support for the program comes in part from the encouraging Phase 2b clinical trial results, the recent €20 million EIB funding, and the Israeli Ministry of Economy grant approval to support the construction of a manufacturing plant.

BiondVax recently announced a public offering of 1.67 million ADSs that raised gross proceeds of $10 million. In addition, the company is voluntarily delisting its common stock from the Tel Aviv Stock Exchange while remaining on the Nasdaq, a move intended to coincide with the company's upcoming international Phase 3 clinical program and potential global commercialization.

SUMMARY DATA

52-Week High	**$10.42**
52-Week Low	**$3.25**
One-Year Return (%)	**99.17**
Beta	**0.61**
Average Daily Volume (sh)	**65,958**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
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 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	-$0.02 A	-$0.00 E	-$0.01 E	-$0.03 E
2018					-$0.02 E
2019					-$0.03 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Update

On August 31, 2017, BiondVax announced financial results for the second quarter of 2017. As expected, the company did not report any revenues during the quarter. The company reported a net loss of $3.5 million for the second quarter of 2017, which was comprised of $0.6 million in R&D expenses and $0.2 million in G&A expenses. Total cash burn for the first quarter of 2017 was approximately $0.9 million.

As of June 30, 2017, BiondVax had cash, cash equivalents, and marketable securities of $10.5 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. The company has had a number of other recent positive financial developments as well, including:

- ✓ 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.

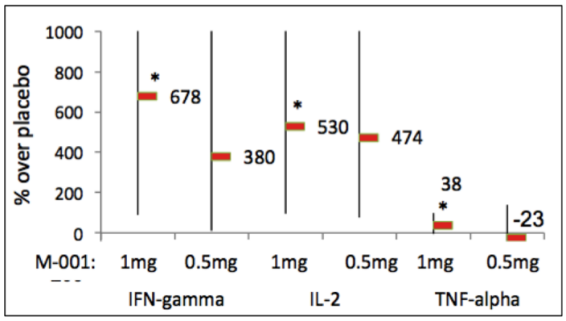
Lastly, the company announced that the Board of Directors has decided to voluntarily delist from the Tel Aviv Stock Exchange (TASE) and continue being listed only on the Nasdaq. In addition, the company will search for a new Chairman of the Board with relevant global experience as the company transitions to conducting international Phase 3 trials and potential global commercialization. The delisting process from TASE is expected to take place before the end of 2017.

Business Update

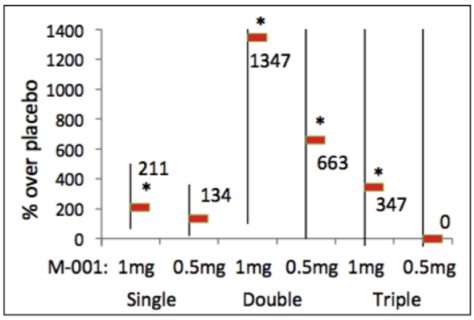
Positive Results from Phase 2b Trial of M-001

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 (as discussed in the Financial Update section) that has resulted in the company now considering moving M-001 directly into a pivotal Phase 3 trial as a standalone influenza vaccine.

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 into 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.

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

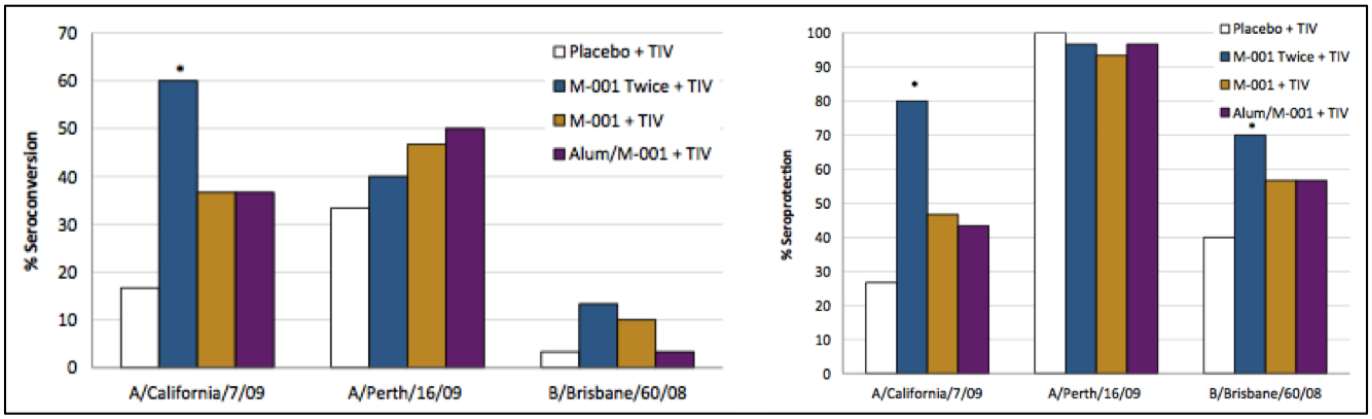
Prior to the Phase 2b study mentioned above, M-001 had been tested in 479 participants through five different clinical trials, with the details presented in the following chart. In each of the trials, the vaccine was shown to be safe and able to induce a robust immune response.

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

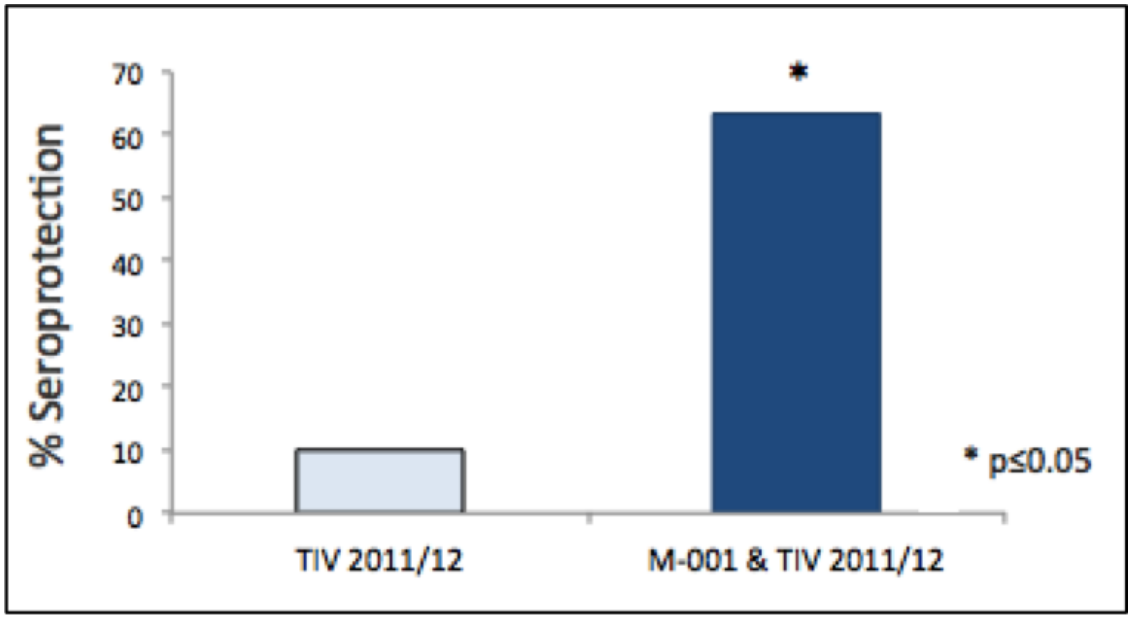
BVX-002 (Atsmon *et al*., 2012): This was a single-center, randomized, placebo controlled, single blind first-in-human study to examine the safety and immunological response to M-001 in healthy adults age 18-49. For safety purposes, three subjects were dosed once with 0.125 mg of M-001 and monitored 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 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 over the past few months 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 $30 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.

.

PROJECTED FINANCIALS

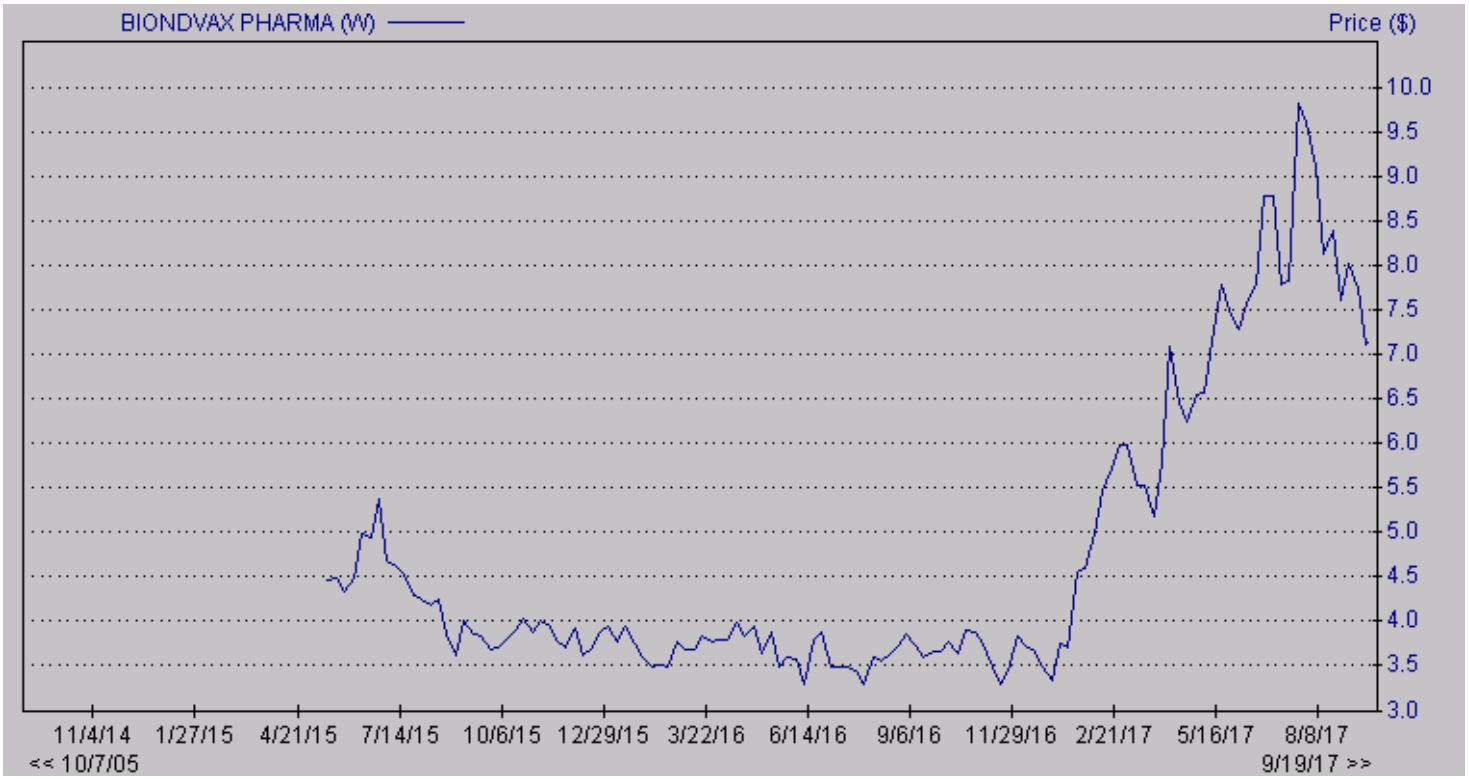
BiondVax Pharmaceuticals, Ltd.
Income Statement

BiondVax Therapeutics, Ltd.	2016 A	Q1 A	Q2 A	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	$0.6	$0.5	$0.6	$2.2	$5.0	$10.0
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)	($0.8)	($0.8)	($0.9)	($3.3)	($6.4)	($11.7)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$0.7	($2.4)	($2.7)	$0.0	$0.0	($5.1)	$0.0	$0.0
Pre-Tax Income	($2.4)	($3.2)	($3.5)	($0.8)	($0.9)	($8.4)	($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)**	**($0.8)**	**($0.9)**	**($8.4)**	**($6.4)**	**($11.7)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.02)**	**($0.02)**	**($0.02)**	**($0.00)**	**($0.01)**	**($0.05)**	**($0.03)**	**($0.05)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	135.1	162.5	169.2	170.0	170.0	167.9	200.0	220.0
Basic ADS Outstanding	3.4	4.1	4.2	4.3	4.3	4.2	5.0	5.5

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.