Zacks Small-Cap Research

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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: New Publication Shows M-001 Incites Immune Protection Against Current and Future Influenza Strains…

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 $15/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 (01/20/17)	$4.60
Valuation	**$15.00**

OUTLOOK

On January 12, 2017, BiondVax Pharmaceuticals Ltd. (BVXV) announced the publication of an article in the journal *Vaccine* that reported plasma samples from elderly subjects who received M-001 in 2011 (as part of the BVX-005 clinical trial) showed significantly increased protective antibodies against the 2014/15 influenza strain (A/Swiss), which was not known to be in existence when M-001 was administered during the BVX-005 study.

The results highlight one of the unique attributes of M-001, which by targeting conserved sequences of the influenza virus, can offer broadly protective immunity against current and even future strains of the virus without the necessity for re-immunization.

SUMMARY DATA

52-Week High	**$5.25**
52-Week Low	**$3.25**
One-Year Return (%)	**25.00**
Beta	**0.00**
Average Daily Volume (sh)	**88,498**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$16**
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	**-10.1**
P/E using 2017 Estimate	**-124.3**

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)
2015	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2016	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2017					0.0 E
2018					0.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.01 A	-$0.02 A	$0.00 A	-$0.00 A	-$0.03 A
2016	-$0.00 A	-$0.01 A	-$0.00 A	-$0.01 E	-$0.02 E
2017					-$0.03 E
2018					-$0.03 E

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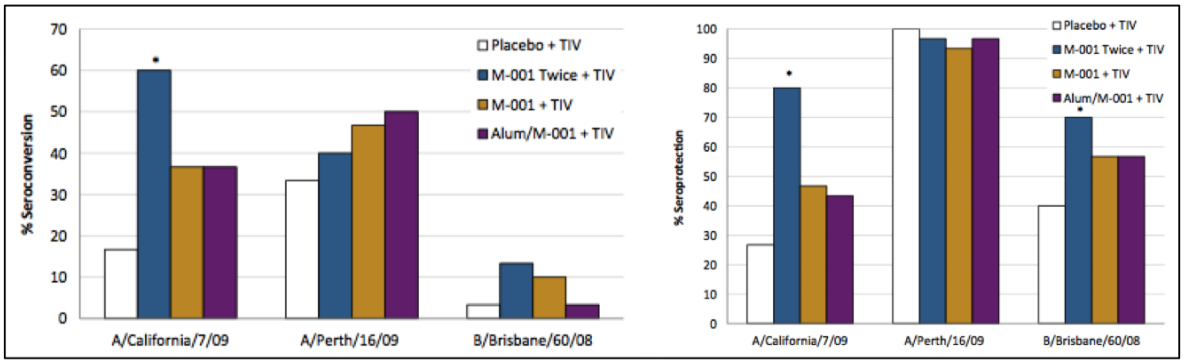
Publication Highlights Ability of M-001 to Incite Immunity to Present and Future Influenza Strains

On January 12, 2017, BiondVax Pharmaceuticals Ltd. (BVXV) announced the publication of an article in the journal *Vaccine* titled "Back to the future: Immunization with M-001 prior to trivalent influenza vaccine in 2011/12 enhanced protective immune responses against 2014/15 epidemic strain" (Lowell *et al*., 2017). In the article, BiondVax researchers reported plasma samples from people who received M-001 in 2011 (as part of the BVX-005 clinical trial in the elderly) showed significantly increased protective antibodies against the 2014/15 influenza strain (A/Swiss), which was not known to be in existence when M-001 was administered during the BVX-005 study. These results highlight the unique ability of M-001 to incite a protective immune response to not just currently circulating influenza strains, but to strains that may arise in the future due to the targeting of conserved regions of the influenza virus, in contrast to currently available influenza vaccines that target hypervariable regions of the influenza virus and must be re-formulated every year.

Study BVX-005

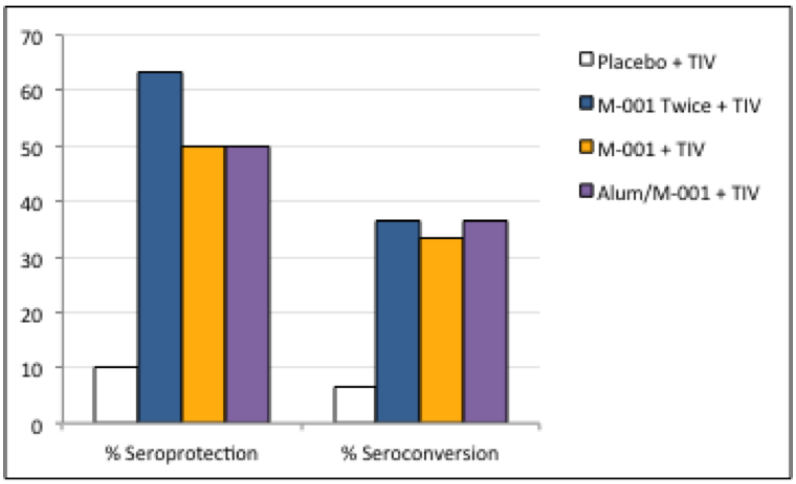
This was a two-center, randomized, placebo controlled study in a total of 120 elderly volunteers (age 65+) (Atsmon *et al*., 2014). The subjects were randomized 1:1:1:1 into four parallel groups to receive either 1) two sequential non-adjuvanted 0.5 mg M-001, or 2) a single non-adjuvanted 0.5 mg M-001, 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

2014/15 Strain Study

The new study reports the anti-HA antibody response in the sera of patients from study BVX-005 to the 2014/15 epidemic influenza strain A/Switzerland/9715293/2013(H3N2-like), a strain that was not known to be in circulation at the time of the BVX-005 study. The following chart shows the percentage of patients who achieved seroprotection (anti-HA titer ≥ 1:40 post immunization) and seroconversion (anti-HA titer ≥ 1:40 post immunization when pre-vaccine titer <10, or ≥ 4-fold increase in anti-HA titer if pre-vaccine titer ≥ 10). Each of the groups primed with M-001 showed average seroprotection levels of 50-63% against the 2014/15 strain as compared to a level of 10% for those in the control group only immunized with TIV but not primed with M-001. Approximately 1/3rd of all patients primed with M-001 achieved seroconversion compared to only 7% of placebo-primed patients. Each of the M-001-treated groups had a statistically significant increase in seroprotection/seroconversion compared to the placebo group.



Source: Lowell *et al*., 2016; Zacks SCR

These data add further support to the notion that M-001 is truly a 'universal' influenza vaccine, as it appears to not only elicit protection against currently circulating influenza strains, but can also provide protection against future strains that may arise. In addition, these data were obtained following immunization of elderly patients, a cohort known to be particularly susceptible to deleterious outcomes from influenza. The fact that M-001 is able to elicit a protective immune response to a non-circulating influenza strain in an at-risk population is highly encouraging and additional studies to verify this effect are clearly warranted.

Angels High Tech Investments Ltd. Acquires $2.8M in BiondVax Stock

On January 2, 2017, BiondVax announced that Angels High Tech Investments Ltd. had agreed to invest approximately $2.83 million in the company in exchange for 844,000 Nasdaq listed ADS. Following the transaction, Angels Investments will hold 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.

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 is ongoing in Europe (BVX-007) and one that will soon start admitting participants in the U.S. (BVX-008).

BVX-007: The BVX-007 trial is a Phase 2b clinical trial with 219 adults (age 18-60) who have completed the study. It is 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 results from this trial to be reported near the end of the first 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.

As a primer for both the seasonal vaccine in the elderly and a pandemic stockpile, we model for the current Phase 2 clinical trials to be completed by the first half of 2017. This will allow for an end-of-Phase 2 meeting with the FDA and initiation of a Phase 3 program in 2018, regulatory filings in 2020, and approval in 2021.

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 $41 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 $34 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 $36 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 of $15 million, we arrive at a net present value for the company of approximately $106 million. Dividing this by the company's fully diluted share count of 7.1 million ADSs leads to a valuation of approximately $15 per share.

PROJECTED FINANCIALS

BiondVax Pharmaceuticals, Ltd.
Income Statement

BiondVax Therapeutics, Ltd.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 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	$0.4	$0.6	$0.5	$2.1	$2.8	$3.3
General & Administrative	$0.9	$0.2	$0.3	$0.3	$0.3	$1.0	$1.3	$1.4
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.9)	($0.8)	($0.6)	($0.9)	($0.8)	($3.1)	($4.1)	($4.7)
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	$0.3	$0.3	($0.0)	$0.3	$0.1	$0.6	($0.2)	($0.2)
Pre-Tax Income	($2.6)	($0.5)	($0.7)	($0.6)	($0.7)	($2.5)	($4.3)	($4.9)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($2.6)**	**($0.47)**	**($0.67)**	**($0.62)**	**($0.7)**	**($2.5)**	**($4.3)**	**($4.9)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($0.02)**	**($0.00)**	**($0.00)**	**($0.00)**	**($0.01)**	**($0.02)**	**($0.03)**	**($0.03)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	105.5	135.1	135.1	135.1	135.1	135.1	140.0	150.0
Basic ADS Outstanding	2.6	3.4	3.4	3.4	3.4	3.4	3.5	3.8

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

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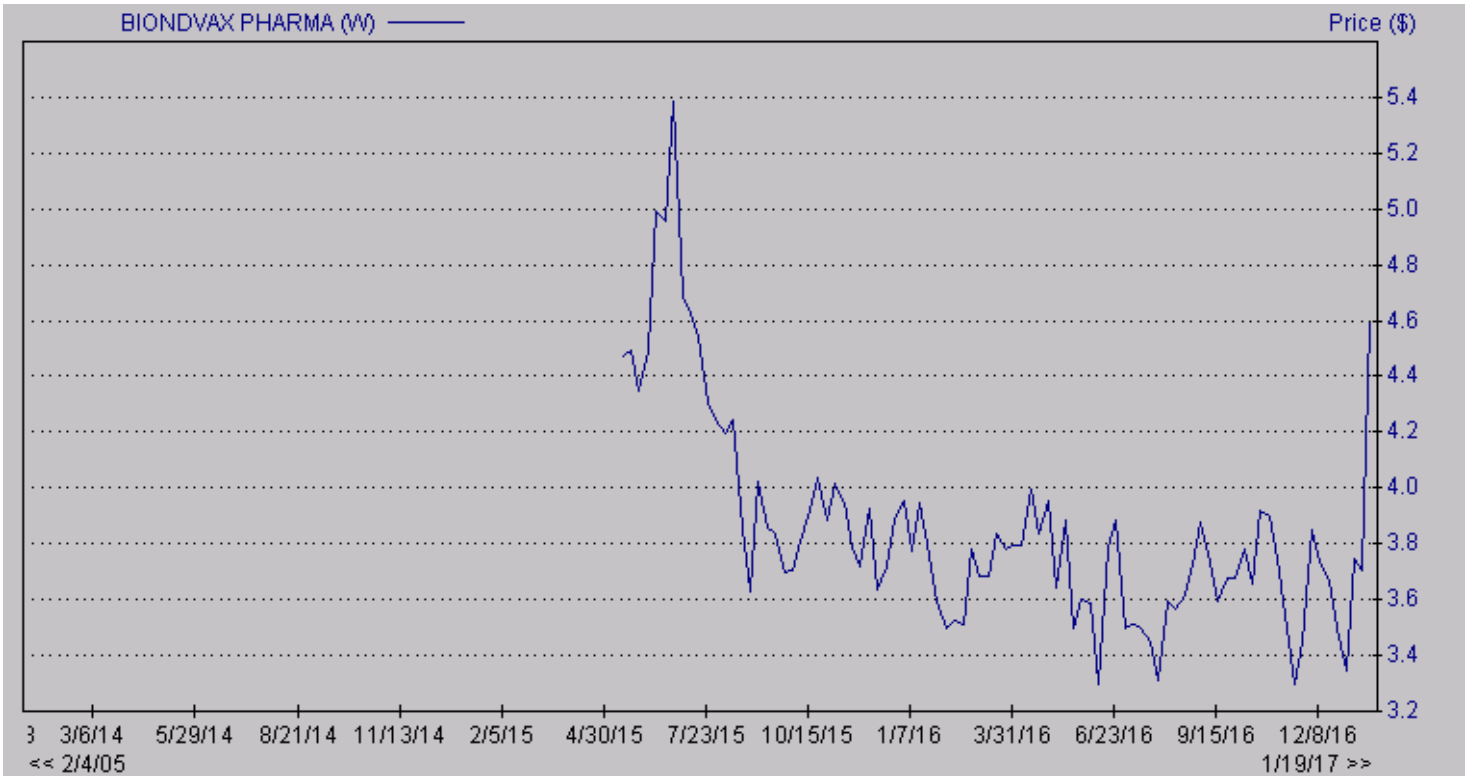
HISTORICAL STOCK PRICE



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