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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Developing anti-IL-17 NanoAb…

Based on our probability adjusted DCF model that takes into account potential future revenues from the NanoAb platform, BVXV is valued at $8.00/ADS. This model is highly dependent upon clinical success of NanoAb candidates and will be adjusted accordingly based upon future clinical results.

Current Price (05/30/23)	$1.82
Valuation	**$8.00**

OUTLOOK

On April 17, 2023, BiondVax Pharmaceuticals Ltd. (BVXV) announced financial results for 2022 and provided a business update. The company intends to exercise its option to obtain an exclusive license at pre-agreed financial terms to anti-IL-17 VHH antibodies (NanoAbs) as a potential treatment for psoriasis. IL-17 is a validated target for treating psoriasis, with four FDA-approved anti-IL-17 antibodies that generated approximately $5.7 billion in 2022 revenues (EvaluatePharma), and NanoAbs demonstrate multiple biobetter advantages over these current treatments. Proof-of-concept data from an *in vitro* study of anti-IL-17 NanoAbs may be available by the end of the year. BiondVax is continuing to evaluate its options regarding a Phase 1/2a clinical trial of its inhaled COVID-19 NanoAb, which demonstrated highly promising results in a recent preclinical in vivo proof-of-concept study.

The company is now offering its cGMP manufacturing capabilities to interested parties for CDMO services. This may optimize use of BiondVax's assets and generate revenues, while enabling the Company to prioritize its NanoAb pipeline development.

SUMMARY DATA

52-Week High	**$13.50**
52-Week Low	**$1.76**
One-Year Return (%)	**-86.00**
Beta	**2.47**
Average Daily Volume (sh)	**9,206**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2023	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.01 A	-$0.00 A	-$0.00 A	$0.01 A	-$0.01 A
2023	-$0.00 A	-$0.00 E	-$0.00 E	-$0.00 E	-$0.01 E
2024					-$0.00 E
2025					-$0.00 E

WHAT'S NEW

Business Update

Developing Anti-IL-17 NanoAb

BiondVax Pharmaceuticals Ltd. (BVXV) is a biopharmaceutical company that is focused on developing, manufacturing, and commercializing innovative immunotherapeutic products primarily for the treatment of infectious and autoimmune diseases. In March 2022, the company signed a five-year research collaboration agreement with the Max Planck Society and the University Medical Center Göttingen that covers the discovery, selection, and characterization of VHH antibodies, also known as nanobodies and NanoAbs, for up to nine molecular targets for the treatment of disease indications with large underserved needs and attractive commercial opportunities such as psoriasis, psoriatic arthritis, asthma, and wet macular degeneration.

BiondVax recently announced that it intends to exercise an option to obtain an exclusive license at pre-agreed financial terms to NanoAbs targeting immune system cytokines such as IL-17 as a potential treatment for psoriasis. IL-17 is a validated target for treating psoriasis and follows the company's strategy to position the NanoAb as a "biobetter" that utilizes prior discoveries by others to mitigate risk while offering potential advantages over existing therapeutics. These advantages of NanoAbs include:

- Size and physical stability: NanoAbs are approximately 1/10th the size of regular antibodies, which may allow for delivery through more convenient routes of administration (e.g., intra-dermal, nasal, inhalation, etc.) that are not possible for regular antibodies.
- Ultra-high thermo-stability: NanoAbs retain biological activity even at high temperatures. This leads to an extended shelf life and reduces the need for cold chain shipping and storage.
- Extremely high binding affinity with effective neutralization: The company's COVID-19 NanoAb has demonstrated affinity and neutralization at doses that are approximately 100 to 1000 times lower than the publicly reported doses of other anti-COVID-19 antibodies. This level of affinity should be achievable against other targets as well.
- High specificity and short half-life: NanoAbs exhibit very high specificity, meaning there is a very low likelihood of binding to unintended targets, which should lead to fewer side effects. In addition, the short half-life of NanoAbs means they are quickly degraded or excreted from the body, thus also limiting the potential for adverse effects.

IL-17's Role in Psoriasis

The IL-17 family contains six members (including IL17-A, IL-17F, and IL-17A/F complex) that are involved in the inflammatory response and microbial defense (Martin *et al*., 2013). IL-17A appears to be the primary driver of psoriasis, however other members of the IL-17 family (most notably IL-17F) also play a role. While it was once thought that IL-17A was primarily produced by T helper 17 (Th17) cells (in fact, psoriasis patients have increased numbers of Th17 cells in their blood and affected skin), there is increasing evidence for IL-17A also being produced by mast cells, $\delta\gamma$ T cells, $\alpha\beta$ T cells, and innate lymphoid cells (Keijsers *et al*., 2014).

IL-23 stimulates the differentiation, activation, proliferation, and survival of Th17 cells (Puig, 2017). IL-23 injection produces a "psoriasis-like" disease in wild-type mice, but not in *IL17* knockout mice, or in mice pre-treated with anti-IL-17A antibodies (Rizzo *et al*., 2011). These and other results showed that IL-23 lies upstream of IL-17 and that IL-17 is the cytokine that directly affects tissue. Excess IL-17 production has a wide range of effects on the skin and joints through promotion of inflammation, coagulation, and bone/joint damage (Zenobia *et al*., 2015).

Given the central role of the IL-23/IL-17 signaling axis in psoriasis, a number of therapeutics have been developed that target those cytokines (see table below). Each of the anti-IL-17 antibodies target IL-17A, although bimekizumab also targets IL-17F and brodalumab targets the IL-17A receptor. They are all also full-length antibodies delivered systemically, thus a potentially differentiating factor for an anti-IL-17 NanoAb could be its direct application to psoriasis plaques, since it may be safer and more convenient for patients.

Product	Generic Name	Target	2022 Revenues ($millions)
Cosentyx	secukinumab	IL-17A	3,572
Taltz	ixekizumab	IL-17A	1,867
Siliq	brodalumab	IL-17RA	185
Bimzelx	bimekizumab	IL-17A/IL-17F	37

Source: EvaluatePharma; Zacks Small Cap Research

BiondVax has announced that it intends to exercise the option to obtain an exclusive worldwide license at pre-agreed financial terms to anti-IL-17 NanoAbs. The company will begin work on scaling up in-house manufacturing of these NanoAbs and conduct initial *in vitro* proof-of-concept studies to select a lead candidate. A preclinical trial testing the anti-IL-17 NanoAb as a therapy for psoriasis may also occur later this year or early next year.

COVID-19 NanoAb Serves as Proof-of-Concept for Platform

BiondVax previously announced positive results from a preclinical *in vivo* proof-of-concept study of its inhaled anti-COVID-19 NanoAb therapy. The study utilized the Syrian hamster model of SARS-CoV-2 infection. This model recapitulates a number of features seen in human infections, including respiratory distress, lethargy, weight loss, and pulmonary lesions (Braxton *et al*., 2021). It has been used to test the effectiveness of multiple prophylactic and therapeutic SARS-CoV-2 agents, including the therapeutic monoclonal antibody cocktail REGN-COV2, which was approved by the FDA.

Results showed that hamsters infected with SARS-CoV-2 and then treated with an inhaled anti-COVID-19 NanoAb developed significantly less severe illness and faster recovery compared to infected hamsters treated with inhaled placebo. In addition, animals treated with the inhaled anti-COVID-19 NanoAb had less than 30 times lung viral titer compared to those treated with inhaled placebo. Also, prophylactic inhalation 3 hours *prior* to infection virtually protected against illness in contrast to the placebo group who experienced significant illness.

These results are very encouraging, both in terms of developing a potential therapeutic for COVID-19 but also has a proof-of-concept for the NanoAb platform. BiondVax is currently evaluating plans to commence a Phase 1/2a clinical trial while it monitors the evolution of SARS-CoV-2 and variants of concern (VoCs) around the world. There has been a major shift in predominant VoCs and were this pace of evolution to continue it may be difficult to utilize the results of the Phase 1/2a trial in a subsequent pivotal trial were the VoCs to be different from the ones circulating during the Phase 1/2a trial. At this point, the company is likely to focus on additional NanoAbs while continuing to monitor the evolution of the COVID-19 virus.

Financial Update

On May 15, 2023, BiondVax announced financial results for the first quarter of 2023. The company began filing as a U.S. domestic issuer in 2023, thus it is now reporting in U.S. GAAP whereas previously financial results were reported under IFRS GAAP. As expected, the company did not report any revenues in the first quarter of 2023. R&D expenses in the first quarter of 2023 were $2.0 million compared to $1.2 million for the first quarter of 2022. The increase was primarily due to the initiation of R&D activities for the NanoAb platform. G&A expenses for the first quarter of 2023 were $1.2 million compared to $1.4 million in the first quarter of 2022.

As of March 31, 2023, BiondVax had cash and cash equivalents of $10.9 million and we estimate the company has sufficient funds through the first quarter of 2024. As of March 31, 2023, the company had approximately 3.3 million ADSs outstanding and, when factoring in options, restricted stock units, and warrants, a fully diluted ADS count of approximately 6.2 million.

To optimize use of BiondVax's assets and generate revenues, while enabling the company to prioritize its NanoAb pipeline development, BiondVax is offering its cGMP manufacturing assets to interested parties, including aseptic fill and finish suite, laboratories, and experienced professionals for CDMO services.

Conclusion

We believe the shift to focusing on the anti-IL-17 NanoAb is a good decision as the continual evolution of SARS-CoV-2 could lead to an unclear clinical pathway for that program. Encouragingly, the COVID-19 program did serve as an excellent proof-of-concept for the NanoAb platform, and we are fully confident that similar positive results can be obtained for other NanoAbs. We look forward to updates on the IL-17 program as the company prepares for initial *in vitro* testing later this year and the potential for preclinical studies. We have removed the COVID-19 program from our model and have accounted for an additional financing, which has resulted in a valuation of $8.00.

PROJECTED FINANCIALS

BiondVax Therapeutics, Ltd.	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
IL-17 NanoAb	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
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	$5.8	$2.0	$1.4	$1.6	$1.7	$6.7	$6.2	$7.0
General & Administrative	$5.3	$1.2	$1.3	$1.4	$1.5	$5.4	$5.7	$5.9
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($11.1)	($3.2)	($2.7)	($3.0)	($3.2)	($12.1)	($11.9)	($12.9)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$5.3	($0.3)	$0.0	$0.0	$0.0	($0.3)	$0.0	$0.0
Pre-Tax Income	($5.8)	($3.5)	($2.7)	($3.0)	($3.2)	($12.4)	($11.9)	($12.9)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($5.8)**	**($3.5)**	**($2.7)**	**($3.0)**	**($3.2)**	**($12.4)**	**($11.9)**	**($12.9)**
Net Margin		-	-	-	-			
Reported EPS	**($0.01)**	**($0.00)**	**($0.00)**	**($0.00)**	**($0.00)**	**($0.01)**	**($0.00)**	**($0.00)**
Basic Shares Outstanding	754.1	1295.3	1320.0	2500.0	2500.0	1903.8	4000.0	5000.0
Basic ADS Outstanding	1.9	3.2	3.3	6.3	6.3	4.8	10.0	12.5

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

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