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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Positive Preclinical Results for Inhaled COVID-19 NanoAb…

Based on our probability adjusted DCF model that takes into account potential future revenues from the NanoAb platform, BVXV is valued at $57.00/ADS. This model is highly dependent upon clinical success of NanoAb candidates and will be adjusted accordingly based upon future clinical results.

Current Price (12/08/22)	$9.87
Valuation	**$57.00**

OUTLOOK

On November 30, 2022, BiondVax Pharmaceuticals Ltd. (BVXV) announced financial results for the third quarter of 2022 and provided a business update. The company recently announced positive preclinical results for its inhaled COVID-19 therapy. Using the industry-standard hamster model for COVID-19 therapeutics, results showed that hamsters treated with BiondVax's NanoAb therapy had significantly (*P*<0.001) less weight loss than hamsters treated with placebo. In addition, eight other parameters, including heart rate and social behaviors, indicated that the group treated with the inhaled NanoAb experienced a shorter and milder illness. We anticipate additional data from this study in the first quarter of 2023. Assuming continued success, we expect BiondVax to initiate a Phase 1/2a clinical trial of the anti-COVID NanoAb in the fourth quarter of 2023.

SUMMARY DATA

52-Week High	**$29.20**
52-Week Low	**$5.50**
One-Year Return (%)	**-42.92**
Beta	**2.43**
Average Daily Volume (sh)	**10,500**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$18**
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 2018 Estimate	**N/A**
P/E using 2019 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)
2021	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2022	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2023					0.0 E
2024					0.0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.00 A	-$0.01 A	-$0.01 A	$0.01 A	-$0.02 A
2022	-$0.01 A	-$0.00 A	-$0.01 A	-$0.01 E	-$0.03 E
2023					-$0.02 E
2024					-$0.02 E

WHAT'S NEW

Business Update

Positive Preclinical Results for Inhaled COVID-19 NanoAb

On November 29, 2022, BiondVax Pharmaceuticals Ltd. (BVXV) 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.

BiondVax's study consisted of a group treated with the anti-COVID-19 NanoAb, administered via inhalation beginning one day after being infected, and a second group of animals treated with saline as a placebo. The results showed that the group treated with the anti-COVID-19 NanoAb had an average weight loss of 3.80% compared to 12.01% for the control group ($P<0.001$). In addition to tracking weight loss, eight additional parameters were tracked, including heart rate and social behaviors, all of which supported the conclusion that the inhaled anti-COVID-19 NanoAb contributed to a milder and shorter illness.

The study will continue early next year testing additional dose levels of the inhaled NanoAb therapy as well as its use as a prophylactic treatment. The company will also be performing toxicology studies in rats and will examine toxicity following a longer exposure to the NanoAbs (8 days) and a two-week recovery period. The results of the efficacy study will guide the dose selection level for the first-in-human trial, which we anticipate initiating in the fourth quarter of 2023.

In June 2022, BiondVax announced Scientific Advice from the Paul Ehrlich Institute (PEI) that included support for conducting a combined Phase 1/2a first-in-human clinical trial that would include patients with confirmed COVID-19 infection in mild to moderate condition. PEI Scientific Advice is typically viewed as a key first step toward approval for a first-in-human clinical trial, and BiondVax will be aligning their development plans with the PEI's advice. This combined clinical trial would avoid the need to provide the standard of care (SOC) medicines prior to receiving BiondVax's inhaled NanoAb. Performing a combined Phase 1/2a trial without the need to provide SOC will also allow BiondVax to assess safety and efficacy in one, small-sized trial as opposed to two sequential trials (that would include a large phase 2 trial) to achieve a meaningful efficacy readout. In addition, the abovementioned trial strategy could potentially accelerate development timelines while saving money by not only circumventing the need to conduct two separate trials, but also by requiring a smaller number of participants thereby reducing patient recruitment timelines.

In regards to demand for additional COVID-19 therapies, it is generally accepted that SARS-CoV-2 is going to become endemic and new strains of the virus are likely to continue to emerge. Coupled with the fact that booster vaccination rates are very low, we believe there will continue to be a demand for COVID-19 therapeutics. In support of this, Pfizer recently announced a collaboration with Clear Creek Bio for a next-generation COVID-19 antiviral treatment and potential combination therapies with Paxlovid. While financial details were not released, the collaboration included an upfront payment and the potential for milestone payments and royalties on product sales.

Financial Update

On November 30, 2022, BiondVax announced financial results for the third quarter of 2022. The company reports its financials in New Israel Shekels (NIS), which were translated to $US for that quarter using the exchange rate of 3.543 (NIS/$US), the rate as of September 30, 2022. As expected, the company did not report any revenues for the third quarter of 2022. R&D expenses for the third quarter of 2022 were NIS 3.9 million (approximately $1.1 million) compared to NIS 2.0 million for the third quarter of 2021. The increase was primarily due to the drug development activities related to the COVID-19 NanoAb program. G&A expenses for the third quarter of 2022 were NIS 3.3 million (approximately $1.0 million) compared to NIS 6.0 million for the third quarter of 2021. The decrease was primarily due to decreased salaries, lower share-based payments, decreased directors' fees, and lower professional services fees.

As of September 30, 2022, BiondVax had approximately NIS 29.4 million (approximately $8.3 million) in cash and cash equivalents. With a current burn rate of approximately $1 million per month, we estimate the company has sufficient capital to fund operations for the next 12 months. On November 25, 2022, BiondVax effected a ratio change of the company's ADSs from 1 ADS representing 40 ordinary shares to 1 ADS representing 400 ordinary shares, which had the same effect as a reverse split of 1 new ADS for every 10 old ADSs. We estimate the company currently has approximately 1.9 million ADSs outstanding (of which approximately 21% is owned by a single long-term shareholder) and, when factoring in options and restricted stock units, a fully diluted ADS count of approximately 2.0 million.

Conclusion

We're excited to see initial positive preclinical results for the company's inhaled anti-COVID-19 NanoAb candidate and we look forward to additional results from that trial in the first quarter of 2023. The company remains on track to initiate the first-in-human trial for the inhaled anti-COVID-19 NanoAb in the fourth quarter of 2023, and we look forward to updates regarding trial design as it gets closer to initiating. In addition to the COVID-19 program, BiondVax will be advancing a NanoAb targeting IL-17 with a likely indication of psoriasis, however that is still subject to change. We have accounted for the ratio change of the company's ADSs and have increased our estimate for the number of shares necessary for raising additional capital. Our valuation now stands at $57.00 per share.

PROJECTED FINANCIALS

BiondVax Therapeutics, Ltd.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Covid-19 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	$3.3	$1.2	$1.9	$4.0	$1.5	$8.5	$7.0	$10.0
General & Administrative	$7.9	$1.5	$1.2	$3.5	$2.3	$8.4	$9.0	$10.0
Other Expenses	$0	$0	$0	($3)	$0	$0	$0	$0
Operating Income	($11.2)	($2.6)	($3.1)	($4.3)	($3.8)	($16.9)	($16.0)	($20.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($1.7)	($0.4)	($0.6)	($0.9)	($0.4)	($2.3)	($1.6)	($1.6)
Pre-Tax Income	($12.9)	($3.0)	($3.7)	($5.2)	($4.2)	($19.2)	($17.6)	($21.6)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($12.9)**	**($3.0)**	**($3.7)**	**($5.2)**	**($4.2)**	**($19.2)**	**($17.6)**	**($21.6)**
Net Margin		-	-	-	-			
Reported EPS	**($0.02)**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.02)**	**($0.02)**
Basic Shares Outstanding	564.6	570.1	745.8	746.3	750.0	703.1	850.0	950.0
Basic ADS Outstanding	1.4	1.4	1.9	1.9	1.9	1.8	2.1	2.4

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

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