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BiondVax Pharmaceuticals, Ltd. (BVXV-NASDAQ)

BVXV: Results for Preclinical Inhalation Proof-of-Concept Study in COVID-19 Expected by End of This Year…

Based on our probability adjusted DCF model that takes into account potential future revenues from the NanoAb platform, BVXV is valued at $12.00/ADS. This model is highly dependent upon clinical success of NanoAb candidates and will be adjusted accordingly based upon future clinical results.

Current Price (09/22/22)	$0.96
Valuation	**$12.00**

OUTLOOK

On August 25, 2022, BiondVax Pharmaceuticals Ltd. (BVXV) announced financial results for the second quarter of 2022 and provided a business update. The COVID-19 NanoAb program is proceeding on schedule, with an inhalation proof-of-concept study with the anti-SARS-CoV-2 NanoAb in COVID-19 infected animals expected to begin by the end of 2022. Based on European advice the company will initiate a first-in-human Phase 1/2a clinical trial in patients, thereby compressing clinical development timelines. BiondVax also recently announced that researchers at Max Planck Institute have successfully isolated NanoAbs targeting IL-17 and other cytokines, which could potentially be used to treat diseases such as psoriasis, psoriatic arthritis, asthma, and macular degeneration. BiondVax has an exclusive option for an exclusive license to develop and commercialize those drug candidates.

SUMMARY DATA

52-Week High	**$2.92**
52-Week Low	**$0.96**
One-Year Return (%)	**-59.34**
Beta	**2.33**
Average Daily Volume (sh)	**29,642**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$11**
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	**Below Avg.**
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 E	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 E	-$0.01 E	-$0.02 E
2023					-$0.02 E
2024					-$0.02 E

WHAT'S NEW

Business Update

NanoAb Program Advancing on Schedule

BiondVax Pharmaceuticals Ltd. (BVXV) is developing alpaca-derived nanosized antibodies (NanoAbs), with an initial program focused on anti-SARS-CoV-2 NanoAbs. The company signed definitive agreements with the Max Plank Institute for Multidisciplinary Sciences and the University Medical Center Göttingen, Germany, for the creation of a NanoAb pipeline in which BiondVax will have an exclusive option for an exclusive worldwide license to advance NanoAbs for the treatment of diseases such as psoriasis, psoriatic arthritis, asthma, and macular degeneration. On September 20, 2022, BiondVax announced it has decided to focus further development on NanoAbs targeting IL-17A, IL-17F, and IL-17A/F (for the potential treatment of psoriasis and psoriatic arthritis) as well as NanoAbs targeting IL-13 and TSLP (for the potential treatment of asthma).

The lead NanoAb program, targeting SARS-CoV-2, is advancing on schedule. BiondVax has manufactured a pilot quantity of the lead NanoAb in-house, and has sent that material for preclinical inhalation device evaluation and selection of an inhaler for human use. We expect an inhalation proof-of-concept efficacy study to initiate in October 2022 for the anti-SARS-CoV-2 NanoAbs in animals infected with COVID-19. The Syrian hamster model will be utilized for those studies. Outcome measures will include weight loss, viral titer, and safety parameters during five treatment days. Preliminary data from that study should be available by the end of this year. 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.

BiondVax has multiple anti-SARS-CoV-2 NanoAbs that were generated and initially characterized by the Max Planck Institute. All of these NanoAbs showed high affinity to and strong neutralization of most SARS-CoV-2 variants of concern (VoCs), including Omicron BA.1 and BA.2. Testing of these NanoAbs for neutralization capabilities against the currently circulating variants BA.2.75 and BA.5 is ongoing

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 who are not in at-risk groups 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 the smaller number of required participants would allow shorter patient recruitment timelines. We look forward to additional updates from the company as it continues work toward getting an anti-SARS-CoV-2 NanoAb into clinical trials in 2023.

Financial Update

On August 10, 2022, BiondVax announced formal approval from the European Investment Bank (EIB) for new terms of its outstanding €24 million loan. The new terms include: 1) an extension of the maturity date to December 2027; 2) interest on the loan will only begin to accrue starting January 1, 2022 at an annual rate of 7%. The interest payments will be deferred until the new maturity date and will be added to the principal balance at the end of each year during the loan period; 3) $900,000 was paid by BiondVax shortly after execution of the amended terms of the loan, which was applied to reduce the outstanding loan. In the future, 10% of all capital raises until maturity will be used to repay the loan principal; 4) once BiondVax's commercial sales exceed €5 million, 3% of the company's topline revenue will be paid to the EIB as royalties until the EIB receives the higher of a) a total of 2.8 times the original €24 million principle, or b) 20% IRR on the principal calculated from January 1, 2022.

On August 25, 2022, BiondVax announced financial results for the second quarter of 2022. The company reports its financials in New Israel Shekels (NIS), which were translated to $US for that quarter using the exchange rate of 3.5 (NIS/$US), the rate as of June 30, 2022. As expected, the company did not report any revenues for the second quarter of 2022. R&D expenses for the second quarter of 2022 were NIS 6.5 million (approximately $1.85 million)

compared to NIS 1.9 million for the second quarter of 2021. The increase was primarily due to the new NanoAb program. G&A expenses for the second quarter of 2022 were NIS 4.3 million (approximately $1.2 million) compared to NIS 7.0 million for the second quarter of 2021. The decrease was primarily due to decreased salaries along with lower share-based payments.

As of June 30, 2022, BiondVax had approximately NIS 39.5 million (approximately $11.3 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. As of June 30, 2022, BiondVax had approximately 18.6 million ADS 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 20.3 million.

Valuation and Conclusion

We value BiondVax based on the potential for the company's SARS-CoV-2 NanoAb candidate as well as the NanoAb pipeline that the company will be developing. Investors should be aware that a valuation assigned to a therapeutic for a pandemic virus is fraught with uncertainty and will likely need to be adjusted many times both as the therapeutic is developed and the trajectory of the pandemic unfolds. Thus, what we present below is how we view the current situation and as events change our analysis is likely to change along with them.

At this juncture, we see the most likely outcome for an effective SARS-CoV-2 treatment being a U.S. government procurement contract such that the therapy can be administered in a judicious and fair manner. We anticipate BiondVax obtaining proof-of-concept data for the SARS-CoV-2 NanoAb in 2022 and obtaining initial clinical trial results in 2023. Our estimate for approval is currently 2025, at which time we model for a $350 million contract. We assign a 4x multiple, a 15% probability of approval, and a 20% discount rate, which leads to a net present value for the SARS-CoV-2 NanoAb of $122 million.

For the NanoAb pipeline, we assign a valuation of $150 million. This is derived from estimating peak sales ten years from now for the candidates in psoriasis, psoriatic arthritis, asthma, and macular degeneration of $1.5 billion, $750 million, $1.5 billion, and $1 billion, respectively, applying a 4x multiple to peak sales, a 5% probability of approval, and a 20% discount rate. These values are going to change as the NanoAb pipeline matures, but we believe this is a fair valuation estimate as of today.

Combining the net present value for the SARS-CoV-2 NanoAb candidate, the NanoAb pipeline, and the company's current cash position leads to a valuation of approximately $283 million. BiondVax currently has a fully diluted share count of approximately 20 million ADSs and we add 4 million ADSs for future dilution as the company will need to raise additional funds to acquire clinical proof-of-concept data for the SARS-CoV-2 asset. This leads to a current valuation of $12 per ADS and we note that there is still room for upside to that valuation as the NanoAb pipeline develops.

PROJECTED FINANCIALS

BiondVax Therapeutics, Ltd.	2021 A	Q1 A	Q2 A	Q3 E	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	$1.4	$1.5	$5.9	$7.0	$10.0
General & Administrative	$7.9	$1.5	$1.2	$2.2	$2.3	$7.2	$9.0	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($11.2)	($2.6)	($3.1)	($3.6)	($3.8)	($13.1)	($16.0)	($20.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($1.7)	($0.4)	($0.6)	($0.4)	($0.4)	($1.8)	($1.6)	($1.6)
Pre-Tax Income	($12.9)	($3.0)	($3.7)	($4.0)	($4.2)	($14.8)	($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)**	**($4.0)**	**($4.2)**	**($14.8)**	**($17.6)**	**($21.6)**
Net Margin		-	-	-	-			
Reported EPS	**($0.02)**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.02)**
Basic Shares Outstanding	564.6	570.1	745.8	750.0	750.0	704.0	850.0	950.0
Basic ADS Outstanding	14.1	14.3	18.6	18.8	18.8	17.6	21.3	23.8

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

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