EDISON

BiondVax Pharmaceuticals

Q217 results

Positive Phase IIb, preparing for pivotal Phase III

Pharma & biotech

Following the positive Phase IIb trial results with universal flu vaccine, M-001, BiondVax is now preparing to initiate a Phase III study, which will likely evaluate M-001 as a universal, standalone vaccine – another major strategic decision by BiondVax – as opposed to a stepwise approach to develop M-001 as a primer and then as a standalone vaccine. A universal, standalone flu vaccine indication is the most lucrative and the pivotal trial could start in 2018. We increase our valuation of BiondVax to $165m (NIS577m), $26.8/ADS (NIS2.34/share), from $111m previously.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/15	0.0	(10.2)	(0.10)	0.0	N/A	N/A
12/16	0.0	(9.2)	(0.07)	0.0	N/A	N/A
12/17e	0.0	(15.0)	(0.08)	0.0	N/A	N/A
12/18e	0.0	(19.7)	(0.08)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

M-001 as a universal, standalone vaccine

In July 2017, BiondVax announced results from the Phase IIb BVX-007 trial, which was one of the last two remaining trials before moving to Phase III. The results showed that both primary endpoints were met, with the safety profile confirmed. BiondVax now plans to move straight into a pivotal Phase III trial to evaluate M-001 as a universal, standalone flu vaccine initially targeting subjects aged 50 years or more. The company can initiate the trial standalone after it received substantial financial support from the EIB in the form of a €20m loan. This was further boosted by raising $10m gross during the recent share issue.

Q217 opex broadly in line with our expectations

BiondVax's Q217 operating expenses were largely in line with our expectations, with R&D costs at $578m (NIS2.0m) and G&A expenses at $163k (NIS569k). BiondVax reported cash of $10.5m (NIS36.6m) at end-Q217, while we estimate cash to be at $21.0m (NIS73.6m) at end-2017. Notably, our forecast includes the first drawdown of €6m from the European Investment Bank (EIB) loan. However, according to the agreement the first drawdown could be completed within a 12-month period since the agreement was signed in June 2017, so it may slip into 2018. Citing the need to focus on global markets BiondVax has also announced a couple of strategic decisions: delisting from the Tel Aviv Stock Exchange by end-2017, while maintaining the listing on NASDAQ and searching for a new chairman with relevant international experience to support Phase III studies of M-001.

Valuation: Increased to $165m (NIS577m)

We have increased our valuation of BiondVax to $165m (NIS577m) or $26.8/ADS (NIS2.34/share) from $111m (NIS398m) or $26.4/ADS (NIS2.4/share) due to increasing the probability of success from 60% to 70% following the positive Phase IIb trial results, including newly raised funds and rolling our model forward. For the time being, we continue to base our valuation on the pandemic primer and seasonal primer indications; however, we will revise our model once the Phase III trial design is confirmed.

8 October 2017

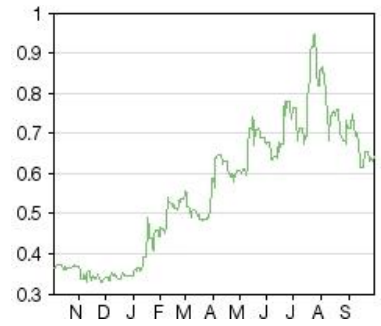
Price*	**NIS0.64**
Market cap	**NIS168m**

*Priced as at 29 September 2017.

NIS3.50/US$
NIS4.19/€

Net cash at end-Q217 + fundraise in September 2017	$20.5m (NIS71.8m)
Shares in issue	261.4m
Free float	75%
Code	BVXV
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(4.6)	(12.8)	76.9
Rel (local)	(8.1)	(13.6)	71.6

52-week high/low	NIS0.9	NIS0.3

Business description

BiondVax Pharmaceuticals is developing a potentially universal influenza vaccine and the lead candidate M-001 could be positioned as a primer for seasonal or pandemic vaccines or as a standalone influenza vaccine. So far M-001 has been tested in two Phase I/II and four Phase II trials and consistently demonstrated immunogenicity to multiple virus strains.

Next events

Further details about the Phase III trial	2018
Start of enrolment in Phase II with NIH in the US	2017

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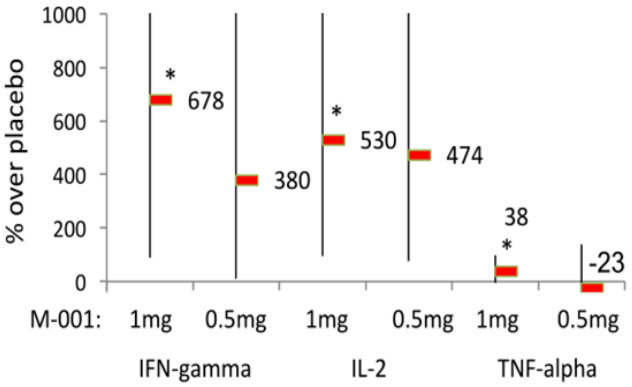
Phase IIb results allow move to Phase III

In July 2017, BiondVax announced the results from the Phase IIb BVX-007 trial, which reinforced the data from previous studies. Before BVX-007, M-001 had been tested in two Phase I/II and three Phase II trials involving 479 participants in total. M-001 elicited immunogenicity to multiple flu virus strains and activated both humoral and cellular immune responses (cell-mediated immunity), as opposed to the mainly strain-specific humoral arm stimulation elicited with conventional seasonal flu vaccines.

BVX-007 was one of two remaining studies before proceeding to Phase III. The trial was initiated in Hungary in September 2015 in collaboration with and financing from the UNISEC European Consortium. This was a randomised, double-blind, controlled trial that enrolled 219 adults into three arms: M-001 doses of 0.5mg and 1.0mg, and placebo. The total monitoring period was 180 days. The primary endpoints of **safety and CMI response** were both achieved:

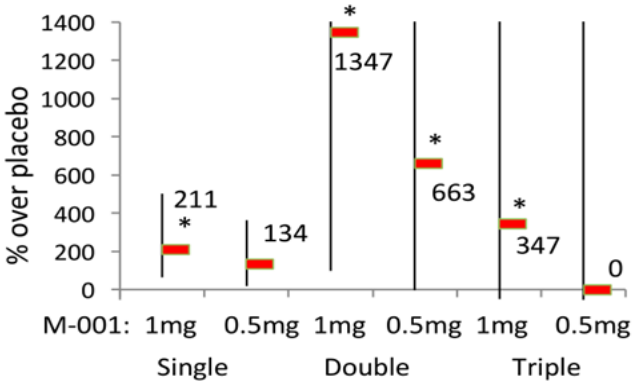
- **The safety** results had already been reported and confirmed by BiondVax.
- **Influenza-specific, cell-mediated immunity (CMI).** CMI was evaluated by measuring cytokine levels produced by T-cells (Th1 subset). Statistically significant elevated interferon (IFN)-gamma, interleukin (IL)-2 and tumor necrosis factor (TNF) beta levels were found in the 1.0mg dose group compared to the placebo group (Exhibit 1). BiondVax also found that responders to M-001 expressed multiple cytokines significantly more often than placebo (Exhibit 2). T-cells producing multiple cytokine levels have been shown to be functionally superior to single cytokine-producing cells.

Exhibit 1: Levels of anti-viral cytokines compared to placebo



Source: BiondVax

Exhibit 2: Number of cytokines expressed by responders



Source: BiondVax

Antibody (hemagglutination inhibition assay, HAI) response to avian H5N1 pandemic vaccination after M-001 or placebo administration was the secondary endpoint. Current influenza vaccines are derived from surface proteins of three or four inactivated virus strains and rely predominantly on triggering antibody responses to the hemagglutinin protein. The M-001 vaccine does not induce the production of these antibodies by itself, therefore in this trial M-001 was used as a primer to the avian H5N1 pandemic vaccine to test the synergy. Only limited information has been released so far with regard to this endpoint, but BiondVax stated that with one of the four H5N1 strains tested, a statistically significant HAI elevation was observed in participants who had received M-001. More detailed results should be published in a peer-reviewed article.

Phase III trial with M-001 as standalone vaccine likely next

As we discussed before, BiondVax was considering several approaches to bring the M-001 vaccine to market. M-001 as a pandemic primer for national stockpile or as a seasonal primer for the at-risk

population were seen as faster routes to market, while a standalone, universal vaccine indication was the ultimate goal. Following the recent €20m funding from the EIB and consultations with European and American regulatory experts, BiondVax announced that it is working on plans to initiate a pivotal Phase III trial, which would test M-001 as a standalone flu vaccine.

Regulatory authorities currently evaluate seasonal vaccines based on HA antibodies, which correlate with protection, ie seasonal vaccine manufacturers do not need to conduct robust, large-scale clinical trials every year. Since the M-001 vaccine does not induce the production of these antibodies, BiondVax plans to evaluate the clinical efficacy of vaccination with M-001 by measuring the reduction in flu illness rate and severity, a robust primary endpoint. The clinical trial design (Exhibit 3) is yet to be confirmed, but BiondVax's preliminary plans are to recruit around 7,500 participants and will target 50+ year olds. M-001 will be administered twice intramuscularly. At least one season will be allowed for follow-ups, with interim reports likely after each season. The trial could start in 2018.

Exhibit 3: Potential Phase III trial with M-001 design

Trial	Season 1			Season 2	Season 3 (optional)
	Day 1	Day 21	Day 180 follow-up	Follow-up	Follow-up
Intervention	1mg M-001	1mg M-001	Safety, PCR and culture testing if influenza like illness is observed in subjects		
Control	Placebo	Placebo			

Source: BiondVax

Valuation

Our valuation of BiondVax is increased to $165m (NIS577m) or $26.8/ADS (NIS2.34/share) from $111m (NIS398m) or $26.4/ADS (NIS2.35/share). We note that there are c 100m out-of-the money options and warrants outstanding. We value BiondVax based on a risk-adjusted NPV analysis using a 12.5% discount rate and including net cash of $20.0m (NIS70.0m), which includes cash at end-Q217 and the recent fund-raise. On 18 September 2017, BiondVax closed a private placement with gross proceeds of $10m by issuing in total c 1.7m ADSs or 37% of the total outstanding prior to the issue and priced with a 21% discount to the prior day's close (each ADS represents 40 shares listed on TASE). BiondVax indicated that besides the support from the existing shareholders, new US-based healthcare investors also came on board.

In our initiation report, we assumed a scenario in which BiondVax would develop M-001 in a stepwise manner, with pandemic primer and seasonal primer for at-risk populations being the first indications, and then expanding to universal, standalone influenza indication, which is the ultimate goal, but also the most R&D-intensive. With the new funds from the EIB and the recent share issue, BiondVax is able to initiate and partly fund the large Phase III on its own. For the time being, we make no significant changes in our valuation approach, but we will revise our model accordingly once Phase III details are confirmed. We adjusted the technology probability of success from 60% to 70%, which is the only change in our model. While the company will consider different funding sources to complete the Phase III trial, we maintain our previous approach and assume a partnering deal where each party will co-fund the Phase III trial, as described in our last report.

Exhibit 4: Sum-of-the parts summary of BiondVax valuation

Product	Launch	Peak sales ($m)	Full rNPV ($m)	Technology probability	Licensing deal probability	BiondVax's rNPV ($m)	rNPV/ ADS ($)	rNPV/ share (NIS)	Comments
M-001 as pandemic vaccine primer	2023	670	249.3	70%	30%	87.4	14.18	1.24	Full rNPV reflects the valuation as if BiondVax develops and markets M-001 by itself assuming all associated costs. The licensing deal was modelled on the basis of full rNPV split at 35% (BiondVax):65% (partner). See our initiation report.
M-001 as seasonal vaccine primer	2027	1,380	169.5	70%	30%	57.6	9.35	0.82	
Net cash ($)			20.0	100%		20.0	3.25	0.28	
Valuation ($)			**438.7**			**165.0**	**26.77**		
Valuation (NIS)			**1,535.6**			**577.3**		**2.34**	

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations.

Exhibit 5: Financial summary

NIS'000s	2013	2014	2015	2016	2017e	2018e
December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	0	0	0	0	0	0
Cost of Sales	0	0	0	0	0	0
Gross Profit	0	0	0	0	0	0
Research and development	(5,451)	(5,492)	(7,906)	(7,794)	(10,500)	(18,375)
EBITDA	(6,932)	(7,465)	(10,675)	(11,279)	(14,503)	(18,563)
Operating Profit (before amort. and except.)	(7,627)	(8,142)	(11,303)	(11,900)	(15,222)	(19,815)
Intangible Amortisation	(14)	0	0	0	0	0
Exceptionals	0	0	0	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(7,641)	(8,142)	(11,303)	(11,900)	(15,222)	(19,815)
Net Interest	(395)	378	1,104	2,716	265	140
Profit Before Tax (norm)	(8,022)	(7,764)	(10,199)	(9,184)	(14,957)	(19,675)
Profit Before Tax (reported)	(8,036)	(7,764)	(10,199)	(9,184)	(14,957)	(19,675)
Tax	0	0	0	0	0	0
Profit After Tax (norm)	(8,022)	(7,764)	(10,199)	(9,184)	(14,957)	(19,675)
Profit After Tax (reported)	(8,036)	(7,764)	(10,199)	(9,184)	(14,957)	(19,675)
Average Number of Shares Outstanding (m)	47.9	54.3	105.5	135.1	198.2	261.4
EPS - normalised (NIS)	(0.17)	(0.14)	(0.10)	(0.07)	(0.08)	(0.08)
EPS - normalised and fully diluted (NIS)	(0.17)	(0.14)	(0.10)	(0.07)	(0.08)	(0.08)
EPS - (reported) (NIS)	(0.17)	(0.14)	(0.10)	(0.07)	(0.08)	(0.08)
Dividend per share (NIS)	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	5,458	5,753	4,379	3,971	5,335	11,403
Intangible Assets	0	0	0	0	0	0
Tangible Assets	3,285	2,638	2,044	1,443	2,807	10,925
Investments	2,173	3,115	2,335	2,528	2,528	478
Current Assets	20,365	12,709	36,928	26,139	80,092	80,251
Stocks	0	0	0	0	0	0
Debtors	489	1,081	1,442	815	1,262	1,262
Cash	17,863	9,612	33,470	15,705	73,563	78,990
Other*	2,013	2,016	2,016	9,619	5,267	0
Current Liabilities	(1,782)	(1,813)	(1,699)	(1,375)	(2,297)	(2,999)
Creditors	(1,782)	(1,813)	(1,699)	(1,375)	(2,297)	(2,999)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(55)	(62)	(69)	(76)	(24,016)	(47,956)
Long term borrowings	0	0	0	0	(23,940)	(47,880)
Other long term liabilities	(55)	(62)	(69)	(76)	(76)	(76)
Net Assets	23,986	16,587	39,539	28,659	59,113	40,699
CASH FLOW						
Operating Cash Flow	(4,338)	(7,624)	(10,262)	(9,688)	(12,766)	(16,600)
Net Interest	133	52	(5)	35	265	140
Tax	0	0	0	0	0	0
Capex	(196)	(30)	(34)	0	(2,083)	(9,371)
Acquisitions/disposals	0	0	0	0	0	0
Financing	9,248	(782)	33,753	0	44,150	0
Other	1,987	133	406	(8,112)	4,352	7,317
Dividends	0	0	0	0	0	0
Net Cash Flow	6,834	(8,251)	23,858	(17,765)	33,918	(18,514)
Opening net debt/(cash)	(11,029)	(17,863)	(9,612)	(33,470)	(15,705)	(49,623)
HP finance leases initiated	0	0	0	0	0	0
Other	0	0	0	0	0	0
Closing net debt/(cash)	(17,863)	(9,612)	(33,470)	(15,705)	(49,623)	(31,110)

Source: Edison Investment Research, BiondVax accounts. Note: *Other = other liquid cash resources.

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