EDISON

BiondVax Pharmaceuticals

FY16 results update

Phase IIb with universal flu vaccine readout close

Pharma & biotech

BiondVax's FY16 business update reiterated that the company and its partners are on track to deliver full results from the ongoing Phase IIb trial with multimeric vaccine candidate M-001 by end Q217. According to plans, the US National Institutes of Health (NIH) will initiate the last Phase II study with M-001 in 2017, which will pave the way for partnering and the Phase III programme. Currently BiondVax is a leader in the development of a universal influenza vaccine. Our valuation is increased to NIS278m ($77m); on a per share basis it is down slightly to NIS1.7/share ($18.2/ADR) after the recent fund-raising.

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	(12.4)	(0.08)	0.0	N/A	N/A
12/18e	0.0	(13.2)	(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.

Financials: Keeping the operations lean

BiondVax has reported end-FY16 cash and cash equivalents (cash, cash equivalents and short- and long-term marketable securities) of NIS27.4m ($7.1m), before announcing a private placement of net NIS10.9m ($2.8m) in January 2017. FY16 R&D expenditures were NIS7.8m ($2.0m), in line with our expected NIS7.9m ($2.1m), while MG&A costs were somewhat higher than our estimate of NIS3.4m ($0.9m) but, in our opinion, still reasonable at NIS4.1m ($1.1m). According to our model, cash reach is beyond 2019 assuming a similar level of activities. Therefore, Phase III studies are achievable with current cash, but will require additional funding which, according to BiondVax, could come from non-dilutive sources.

All eyes on BVX-007 Phase IIb trial with M-001

The Phase IIb trial (BVX-007) is currently in focus. It is run in partnership with the UNISEC European consortium and is a sixth clinical trial, bringing the total number of subjects vaccinated with M-001 to c 700. The last patient in the BVX-007 trial was treated in September 2016 and the preliminary safety/tolerability results released in November 2016 echoed supportive results from the previous five trials. According to BiondVax, final results are expected by the end of Q217.

Valuation: Upped to NIS278m ($77m)

Our valuation of BiondVax is increased to NIS278m ($77m) or NIS1.7/share ($18.2/ADR), from NIS269m ($71m) or NIS2.0/share ($21.0/ADR) due to rolling our model forward and higher cash; on a per share basis the valuation is lower due to the share issue in January. Shareholders of BiondVax enjoyed a significant rally over the past few months; however, our valuation implies potential for more upside. This should be supported by the upcoming data readout from the Phase IIb trial, the initiation of the last Phase II trial in the US by NIH and any indications from BiondVax on discussions about partnering progress for late-stage development of M-001.

15 May 2017

Price	**NIS0.71**
Market cap	**NIS120m**
*Priced at 12 May 2017	
	NIS3.62/US$
Est. net cash at end-April 2017 (incl. fund-raise in January 2017)	NIS34m ($9m)
Shares in issue (does not include 111m outstanding options and warrants); ADR/shares 1:40	168.9m
Free float	75%
Code	BVXV
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	15.0	35.5	108.2
Rel (local)	11.0	31.6	96.1
52-week high/low	NIS0.7		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 three Phase II trials and consistently demonstrated immunogenicity to multiple virus strains.

Next events

Results from Phase IIb with UNISEC in Europe	Q217
Start of enrolment in Phase II with NIH in the US	2017

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Final Phase IIb data any time now

The Phase IIb trial BVX-007 was initiated in Hungary in September 2015 in collaboration with and financing from the UNISEC European consortium. Apart from demonstrating safety and immunogenicity of BiondVax's universal flu vaccine M-001, the study aims to show (details in Exhibit 1):

- the use of M-001 for better pandemic preparedness, where it can be stockpiled and used immediately on any pandemic outbreak instead of waiting six months for the pandemic-specific vaccine to reach the market; and
- the dose sparing potential of M-001 when given prior to a suboptimal avian (H5N1) vaccine dose. This would be highly desirable in a pandemic when existing stockpiles of vaccine may be low.

In September 2015, BiondVax announced a collaboration with the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to commence the BVX-008 trial in 180 adults in the US, which will be fully funded by the NIH. BVX-008 will also assess M-001's ability to serve as a pandemic primer to H7N9 avian pandemic vaccine. According to the latest update, the trial should be initiated in 2017. This study is expected to be the last Phase II trial before moving into Phase III. More details about BiondVax's existing clinical data and ongoing trials are summarised in our initiation report.

Exhibit 1: M-001 final Phase II clinical trials

Trial	Aim	Design	Size (n)	Status	Results expected
Phase IIb BVX-007 (with UNISEC European consortium)	M-001 as primer to pandemic influenza H5N1 (dose-sparing potential)	A randomised, double-blind, controlled trial. Primary endpoint – safety and CMI response; secondary – HAI response to strain in the pandemic vaccine and non-pandemic strains, the association between CMI marker and humoral immune response. Three arms with doses of 0.5mg and 1.0mg of M-001 and placebo; suboptimal dose of adjuvanted 3mcg of H5N1 pandemic vaccine after M-001. Total monitoring for 180 days.	219 adults (18-60 years)	Last participant out in September 2016. Preliminary safety announced November 2016	Q217
Phase II BVX-008 (collaboration with NIH)	M-001 as primer to pandemic influenza A/H7N9	A randomised, double-blind, controlled trial. Primary endpoint – safety; secondary – immunogenicity.	180 adults (18-60 years)	Start in 2017	2018

Source: BiondVax. Note: CMI – cell mediated immunity assays, a method to assess vaccine's effect; HAI – hemagglutination inhibition.

Financials

BiondVax is debt-free and reported end-FY16 cash and cash equivalents (cash, cash equivalents and short- and long-term marketable securities) of NIS27.4m ($7.1m). In January 2017, BiondVax raised NIS10.9m ($2.8m) in a private placement, issuing c 33.8m new shares, around 25% of the number of shares that existed before the issue. The institutional investor Angels High Tech Investments is owned by Marius Nacht, who is a co-founder and chairman of NASDAQ-listed Check Point Software Technologies, a large Israeli multinational provider of software and hardware products for IT security. BiondVax reported FY16 R&D expenditures of NIS7.8m ($2.0m), in line with our expected NIS7.9m ($2.1m), while MG&A costs were NIS4.1m ($1.1m), somewhat higher than our estimate of NIS3.4m ($0.9m). BiondVax is able to run its operations in a cost-effective way because its partners UNISEC in Europe and NIH in the US are funding the majority of the costs associated with the Phase II studies. BiondVax indicated that the cash burn is around $250k per month, implying current net cash position of around NIS34m ($9m) which, according to our model, supports operations beyond 2019 assuming a similar level of activities. Therefore, the transition to Phase III studies is reachable with current cash, but the initiation of the late-stage trials will likely be

with a partner on board, although the company has indicated that it will explore all options for Phase III funding.

In March 2017, BiondVax announced that the Israel Investment Center, affiliated with Israel's Ministry of Economy and Industry, approved a grant representing 20% of a NIS20m budget needed to build a mid-size vaccine factory in Jerusalem. The factory will have a capacity of up to tens of millions of doses of M-001. While no particular timelines or financing sources of the remaining part of the budget were revealed, this represents welcome non-dilutive committed funds to BiondVax.

Valuation

Our valuation of BiondVax is increased to NIS278m ($77m) or NIS1.7/share ($18.2/ADR) from NIS269m ($71m) or NIS2.0/share ($21.0/ADR). While on absolute basis our valuation has increased due to rolling our model forward and a higher cash position, it has decreased on a per share basis due to the share issue in January 2016. If we include c 111m outstanding options and warrants, the relative valuation on a fully diluted basis would be NIS1.0/share ($11.0/ADR).

We value BiondVax based on a risk-adjusted NPV analysis using a 12.5% discount rate and including estimated cash of NIS34m ($9m) at end-April 2017. Exhibit 2 provides assumptions and our valuation of M-011 in each indication separately. We have included two of the three indications envisioned by BiondVax, namely a primer for pandemic vaccines and a primer for seasonal vaccination for populations at risk. M-001 as a standalone universal influenza vaccine is the ultimate goal for the company; however, it is the most R&D-intensive route as well, so for the time being we do not include it in our valuation. The company has indicated that the priming direction is likely the fastest way to the market and that both indications (pandemic and seasonal vaccine primer) have the same priority, with the final development plan to be discussed with a future partner. We use a risk-adjusted NPV method to value each indication separately and all our assumptions remain unchanged, as discussed in our initiation report.

Exhibit 2: Sum-of-the parts summary of BiondVax valuation

Product	Launch	Peak sales ($m)	Full rNPV ($m)	Technology probability	Licensing deal probability	BiondVax's rNPV ($m)	rNPV/ADR ($)	rNPV/share (NIS)	Comments
M-001 as pandemic vaccine primer	2023	670	169.2	60%	30%	40.3	9.54	0.86	Full rNPV reflects the valuation as if BiondVax develops and markets M-001 standalone assuming all associated costs. The licensing deal was modelled on the basis of full rNPV split at 25% (BiondVax):75% (partner). See previous report.
M-001 as seasonal vaccine primer	2027	1,380	122.9	60%	30%	27.3	6.46	0.58	
Net cash ($)			9.4	100%		9.4	2.23	0.22	
Valuation ($)			**301.5**			**77.0**	**18.23**		
Valuation (NIS)			**1,090.7**			**278.4**		**1.65**	

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

Exhibit 3: Financial summary

NIS000s	2013	2014	2015	2016	2017e	2018e
Year end 31 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)	(7,906)	(7,906)
EBITDA	(6,932)	(7,465)	(10,675)	(11,279)	(12,006)	(12,714)
Operating Profit (before amort. and except.)	(7,627)	(8,142)	(11,303)	(11,900)	(12,628)	(13,336)
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)	(12,628)	(13,336)
Net Interest	(395)	378	1,104	2,716	265	140
Profit Before Tax (norm)	(8,022)	(7,764)	(10,199)	(9,184)	(12,363)	(13,196)
Profit Before Tax (reported)	(8,036)	(7,764)	(10,199)	(9,184)	(12,363)	(13,196)
Tax	0	0	0	0	0	0
Profit After Tax (norm)	(8,022)	(7,764)	(10,199)	(9,184)	(12,363)	(13,196)
Profit After Tax (reported)	(8,036)	(7,764)	(10,199)	(9,184)	(12,363)	(13,196)
Average Number of Shares Outstanding (m)	47.9	54.3	105.5	135.1	152.0	168.9
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	3,349	677
Intangible Assets	0	0	0	0	0	0
Tangible Assets	3,285	2,638	2,044	1,443	821	199
Investments	2,173	3,115	2,335	2,528	2,528	478
Current Assets	20,365	12,709	36,928	26,139	27,263	18,062
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	16,383	16,800
Other	2,013	2,016	2,016	9,619	9,619	0
Current Liabilities	(1,782)	(1,813)	(1,699)	(1,375)	(2,080)	(2,141)
Creditors	(1,782)	(1,813)	(1,699)	(1,375)	(2,080)	(2,141)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(55)	(62)	(69)	(76)	(76)	(76)
Long term borrowings	0	0	0	0	0	0
Other long term liabilities	(55)	(62)	(69)	(76)	(76)	(76)
Net Assets	23,986	16,587	39,539	28,659	28,457	16,522
CASH FLOW						
Operating Cash Flow	(4,338)	(7,624)	(10,262)	(9,688)	(10,487)	(11,391)
Net Interest	133	52	(5)	35	265	140
Tax	0	0	0	0	0	0
Capex	(196)	(30)	(34)	0	0	0
Acquisitions/disposals	0	0	0	0	0	0
Financing	9,248	(782)	33,753	0	10,900	0
Other	1,987	133	406	(8,112)	0	11,669
Dividends	0	0	0	0	0	0
Net Cash Flow	6,834	(8,251)	23,858	(17,765)	678	418
Opening net debt/(cash)	(11,029)	(17,863)	(9,612)	(33,470)	(15,705)	(16,383)
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)	(16,383)	(16,800)

Source: Edison Investment Research, BiondVax accounts. Note: Liquid cash resources = cash, cash equivalents and short- and long-term marketable investments.

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