

# BiondVax Pharmaceuticals

Company update

## New funds to support M-001's Phase III initiation

The €20m loan agreement with the European Investment Bank (EIB) is a game changing event for BiondVax, we believe. The agreement was signed on 19 June 2017 and over the next three years the company will be able to drawdown all the money presuming the development milestones related to the lead universal flu vaccine candidate M-001 are met. BiondVax now aims to initiate Phase III activities and also invest in a new manufacturing facility securing the supply of M-001 for the remaining development and commercial launch. We have revised our model to reflect the changes and value BiondVax at \$111m (NIS398m), up from \$77m (NIS278m).

| 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            | (15.2)      | (0.10)     | 0.0       | N/A     | N/A       |
| 12/18e   | 0.0            | (20.1)      | (0.12)     | 0.0       | N/A     | N/A       |

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

## External validation of BiondVax technology

BiondVax now plans to go ahead with the Phase III trial and will likely still seek to land a partnering deal while in Phase III. We view such a strategy favourably, as this could potentially create more value in the form of retaining a higher portion of the value of M-001 when negotiating with the partner. In addition to the fact that the funding provides financial visibility for the medium term, we also take it as an external validation of BiondVax's technology.

## Ramping up production expertise

In a separate development, BiondVax announced in March 2017 its plans to build a production facility, which will be partly financed by a government grant. BiondVax decided to invest in the production of its vaccine rather than just out-source, which will give it more control of the supply and create tangible asset. The expected capacity is up to tens of millions of doses per year, which should cover the requirement for Phase III trials and likely for commercial launch. The company has already started preparing plans, but specific timelines have not been announced.

## Valuation: Increased to \$111m (NIS398m)

Our valuation of BiondVax is increased to \$111m (NIS398m) or \$26.4/ADR (NIS2.4/share), from \$77m (NIS278m) or \$18.2/ADR (NIS1.7/share), including cash of \$9.6m (NIS34m) at end-Q117. We maintain our scenario that BiondVax will initiate Phase III trials next year in the pandemic primer indication and then will seek to expand into a seasonal primer for populations at risk. However, BiondVax remains open-minded about which indication it will target first. To reflect the fact that the company now has substantial funding to invest in late-stage development, we have changed the nature of the partnership deal in our model from simple out-licensing to a co-development partnership and increased BiondVax's share of the NPV, which was the main driver behind the increase in our valuation.

Pharma &amp; biotech

17 July 2017

**Price\*** **NIS0.69**
**Market cap** **NIS117m**

\*Priced as at 12 July 2017.

NIS3.57/US\$

NIS3.99/€

Net cash at end-Q117 \$9.6m (NIS34m)

Shares in issue 168.9m

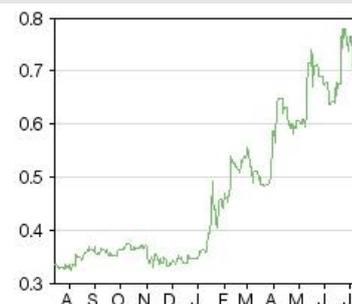
Free float 75%

Code BVXV

Primary exchange TASE

Secondary exchange NASDAQ

### Share price performance



| %           | 1m  | 3m   | 12m   |
|-------------|-----|------|-------|
| Abs         | 8.1 | 11.4 | 108.4 |
| Rel (local) | 6.3 | 7.7  | 101.3 |

52-week high/low NIS0.8 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 | Q317 |
|--|------|

|   |      |
|---|------|
| Start of enrolment in Phase II with NIH in the US | 2017 |
|---|------|

### Analysts

|               |                     |
|---------------|---------------------|
| Jonas Peculis | +44 (0)20 3077 5728 |
|---------------|---------------------|

|                    |                     |
|--------------------|---------------------|
| Juan Pedro Serrate | +44 (0)20 3681 2534 |
|--------------------|---------------------|

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)
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## Loan enables advancement into Phase III with M-001

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The EIB loan is interest-free; remuneration will vary depending on royalties from net sales of BiondVax M-001 once approved. BiondVax retains an option to repay the loan and repurchase the royalties at any time. The company can drawdown in three tranches within 12, 24 and 36 months, which will also depend on certain agreed milestones, eg manufacturing of first clinical batch for the Phase III clinical trials. The tranches are repayable five years after each drawdown. The funds from EIB cannot exceed 50% of the total financing requirement for the M-001 development and related activities. So, BiondVax will need to match the funding from EIB in each tranche, although this can come from a variety of sources and will not necessarily be dilutive to BiondVax equity holders; for example, it could be upfront and milestone payments from a potential partnership deal.

The new funds are available via Horizon 2020, the EU Research and Innovation Framework Programme for 2014-20, managed by the European Commission and the European Investment Bank Group. Over this period, the initiative will make available more than €24bn to support research and innovation products being developed by various sized companies investing in R&D. We believe that before the loan was agreed, BiondVax underwent a substantial due diligence process to demonstrate the potential of its universal flu vaccine's potential. We therefore take it as an external validation of BiondVax technology, which could also raise the company's profile when approaching potential partners.

Recently, BiondVax also provided an update about the ongoing Phase IIb trial with M-001, which is due to report final results. This was expected to happen before end-Q217, but the company mentioned that the announcement will be postponed somewhat, although it should come in shortly. The delay was a result of the number of parties involved in the European UNISEC Consortium, which is running and funding the trial.

## Valuation

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Our valuation of BiondVax is increased to \$111m (NIS398m) or \$26.4/ADR (NIS2.35/share), from \$77m (NIS278m) or \$18.2/ADR (NIS1.7/share). If we include c 111m outstanding options and warrants, the relative valuation on a fully diluted basis would be \$15.9/ADR (NIS1.42/share). We value BiondVax based on a risk-adjusted NPV analysis using a 12.5% discount rate and including cash of \$9.6m (NIS34m) at end-Q117. Exhibit 2 provides assumptions and our valuation of M-001 in each indication separately.

BiondVax indicated that it will start preparations for Phase III, which is still expected to be initiated next year. As previously, the company is open-minded as to which indication to choose for the upcoming trial and what would be the best trial design. Due to the novelty of BiondVax's vaccine technology, existing industry experience in vaccine development is not directly transferable to design late-stage trials with M-001. In our [initiation report](#) we assumed one scenario in which BiondVax would go for pandemic primer indication and then would expand into seasonal primer 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.

We also assumed that BiondVax would land a partnership deal ahead of the Phase III studies and would not invest in these clinical trials. To reflect the fact that BiondVax can now invest a substantial amount of additional money in M-001, we have changed the nature of the potential partnership deal from simple out-licensing to joint development with a partner that co-funds the late-stage studies. BiondVax's recently announced plan to build manufacturing facility was budgeted at c €5m

(NIS20m), of which 20% (€1m) will be funded by a government grant. We therefore assume that €16m of the EIB loan will go into M-001 development, while our assumption of the R&D cost needed for the whole Phase III in the epidemic primer indication is \$50m.

We now assume that both BiondVax and the partner will contribute the funds, which implies a likely higher rNPV share for BiondVax than our original assumption of 25%, as detailed in our initiation report. We have increased BiondVax's share to 35% for both indications, which was the main driver of the increase in our valuation. We keep other R&D assumptions unchanged as in our [initiation report](#), including the scenario that after the market launch the partner would be running the commercialisation.

| Exhibit 1: 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%                        | 61.1                  | 14.48         | 1.29             | 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 <a href="#">initiation report</a> . |
| M-001 as seasonal vaccine primer                          | 2027   | 1,380            | 122.9           | 60%                    | 30%                        | 40.6                  | 9.61          | 0.86             |  |
| Net cash (\$)   |        |                  | 9.6             | 100%                   |                            | 9.6                   | 2.27          | 0.20             |  |
| <b>Valuation (\$)</b>                                     |        |                  | <b>301.7</b>    |                        |                            | <b>111.3</b>          | <b>26.36</b>  |                  |  |
| <b>Valuation (NIS)</b>                                    |        |                  | <b>1,077.5</b>  |                        |                            | <b>397.5</b>          |               | <b>2.35</b>      |  |

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

## Financials

BiondVax is debt-free and reported end-Q117 cash and cash equivalents (cash, cash equivalents and short- and long-term marketable securities) of \$9.6m (NIS34m). The company booked operating expenses of \$817k (NIS3.0m) in Q117, while R&D expenditures were \$516k (NIS1.87m), broadly in line with our expectations. So far, BiondVax has been running 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.

In our financial forecasts we now reflect the new loan, plans to go ahead with the manufacturing facility and the initiation of the first trial. We assume that BiondVax will drawdown €6m in each of 2017 and 2018 (according to the agreement, the first two drawdowns are between €4-6m), while the last drawdown will include the rest. As mentioned before, we assume €16m will be spent on R&D, while €4m will be invested in the construction of the manufacturing plant. Although no timelines were provided, BiondVax appears to have a firm intention to proceed with the works. Therefore we add capex of €0.5m, €2.25m and €2.25m in 2017, 2018 and 2019, respectively, and a grant of €1m in the P&L in 2018.

**Exhibit 2: Financial summary**

|  | NIS000s | 2013     | 2014     | 2015     | 2016     | 2017e    | 2018e    |
|--|---------|----------|----------|----------|----------|----------|----------|
| Year end 31 December                         |         | IFRS     | IFRS     | IFRS     | IFRS     | IFRS     | IFRS     |
| <b>PROFIT &amp; LOSS</b>                     |         |          |          |          |          |          |          |
| 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)  | (10,714) | (18,750) |
| EBITDA                                       |         | (6,932)  | (7,465)  | (10,675) | (11,279) | (14,721) | (18,964) |
| Operating Profit (before amort. and except.) |         | (7,627)  | (8,142)  | (11,303) | (11,900) | (15,436) | (20,190) |
| 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) | (15,436) | (20,190) |
| Net Interest                                 |         | (395)    | 378      | 1,104    | 2,716    | 265      | 140      |
| Profit Before Tax (norm)                     |         | (8,022)  | (7,764)  | (10,199) | (9,184)  | (15,171) | (20,050) |
| Profit Before Tax (reported)                 |         | (8,036)  | (7,764)  | (10,199) | (9,184)  | (15,171) | (20,050) |
| Tax  |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Profit After Tax (norm)                      |         | (8,022)  | (7,764)  | (10,199) | (9,184)  | (15,171) | (20,050) |
| Profit After Tax (reported)                  |         | (8,036)  | (7,764)  | (10,199) | (9,184)  | (15,171) | (20,050) |
| 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)   | (0.10)   | (0.12)   |
| EPS - normalised and fully diluted (NIS)     |         | (0.17)   | (0.14)   | (0.10)   | (0.07)   | (0.10)   | (0.12)   |
| EPS - (reported) (NIS)                       |         | (0.17)   | (0.14)   | (0.10)   | (0.07)   | (0.10)   | (0.12)   |
| 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      |
| <b>BALANCE SHEET</b>                         |         |          |          |          |          |          |          |
| Fixed Assets                                 |         | 5,458    | 5,753    | 4,379    | 3,971    | 5,252    | 10,956   |
| Intangible Assets                            |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Tangible Assets                              |         | 3,285    | 2,638    | 2,044    | 1,443    | 2,724    | 10,478   |
| Investments                                  |         | 2,173    | 3,115    | 2,335    | 2,528    | 2,528    | 478      |
| Current Assets                               |         | 20,365   | 12,709   | 36,928   | 26,139   | 46,729   | 46,894   |
| 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   | 35,849   | 45,633   |
| Other  |         | 2,013    | 2,016    | 2,016    | 9,619    | 9,619    | 0        |
| Current Liabilities                          |         | (1,782)  | (1,813)  | (1,699)  | (1,375)  | (2,316)  | (3,034)  |
| Creditors                                    |         | (1,782)  | (1,813)  | (1,699)  | (1,375)  | (2,316)  | (3,034)  |
| 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   | 25,649   | 6,859    |
| <b>CASH FLOW</b>                             |         |          |          |          |          |          |          |
| Operating Cash Flow                          |         | (4,338)  | (7,624)  | (10,262) | (9,688)  | (12,965) | (16,985) |
| Net Interest                                 |         | 133      | 52       | (5)      | 35       | 265      | 140      |
| Tax  |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Capex  |         | (196)    | (30)     | (34)     | 0        | (1,996)  | (8,980)  |
| 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) | (3,796)  | (14,156) |
| Opening net debt/(cash)                      |         | (11,029) | (17,863) | (9,612)  | (33,470) | (15,705) | (11,909) |
| 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) | (11,909) | 2,247    |

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

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