

# Bionomics

Earnings update

## PTSD programme on track for results in Q3

The fiscal year 2018, which ended in June, was a major transition for Bionomics as it realigned itself to focus on disorders of the central nervous system. This strategy hinges on the company's lead asset BNC210, a negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor, which has a potentially novel anxiolytic mechanism of action. The drug is in Phase IIb for post-traumatic stress disorder (PTSD) (with a readout expected in this quarter) and Phase IIa for agitation in the elderly.

| Year end | Revenue (A\$m) | PBT* (A\$m) | EPS* (A\$) | DPS (A\$) | P/E (x) | Yield (%) |
|----------|----------------|-------------|------------|-----------|---------|-----------|
| 06/17    | 18.6           | (4.4)       | (0.01)     | 0.00      | N/A     | N/A       |
| 06/18    | 4.0            | (24.4)      | (0.05)     | 0.00      | N/A     | N/A       |
| 06/19e   | 17.9           | (19.3)      | (0.04)     | 0.00      | N/A     | N/A       |
| 06/20e   | 4.3            | (32.5)      | (0.06)     | 0.00      | N/A     | N/A       |

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

## PTSD treatment complete, results coming

The company previously announced it completed treatment for its Phase IIb study of BNC210 in patients with PTSD in July 2018. The study enrolled 193 patients across three doses compared to placebo over 12 weeks. The primary endpoint of the study will be the CAPS-5 rating, which is the approvable endpoint for the disorder, but will also have readouts for common comorbidities such as depression and anxiety. The company has confirmed that data should be available in late Q3 CY2018.

## Agitation study ongoing

The company has also confirmed that data should be available for its Phase IIa study of BNC210 in Q1 CY2019 for agitation in the elderly. The randomised, double-blind, placebo-controlled study is enrolling 40 patients from hospital wards across Australia. Agitation is a common symptom of patients with dementia and there is a significant need for non-sedating treatments for the condition.

## Potential licensing: Legacy assets and Merck collab.

A part of the shift towards a focus exclusively on diseases of the central nervous system, the company has made the strategic decision to divest its legacy oncology assets: BNC101 for colorectal cancer, and BN105 for chronic lymphocytic leukaemia and melanoma. Bionomics also has an ongoing collaboration with Merck for the development of a drug to treat cognitive dysfunction, which has US\$465m in future milestones attached. Phase I is expected to complete in H2 CY18.

## Valuation: Increased to A\$562m or A\$1.16 per share

We have increased our valuation to A\$562m or A\$1.16 per basic share from A\$491m or A\$1.02 per basic share. This is driven by advancing our NPVs and exchange rate effects (A\$/US\$1.37 vs 1.25 before) and is offset by lower net cash. The company ended FY18 with A\$24.9m in gross cash (A\$3.5m net), and we expect it to require an additional A\$40m to reach profitability in 2022.

### Pharma & biotech

24 August 2018

**Price** **A\$0.48**
**Market cap** **A\$232m**

A\$1.37/US\$

Net cash (A\$m) at 30 June 2018 3.5

Shares in issue 482.4m

Free float 84.03%

Code BNO

Primary exchange ASX

Secondary exchange OTCQX

### Share price performance



% 1m 3m 12m

Abs 0.0 (16.5) (4.0)

Rel (local) (0.6) (19.4) (12.6)

52-week high/low A\$0.63 A\$0.35

### Business description

Bionomics is a clinical-stage pharmaceutical company with two small molecule discovery platforms: ionX for ion channel targets and MultiCore chemistry for rapid candidate identification. The company is testing BNC210 in Phase IIb for post-traumatic stress disorder and Phase IIa for agitation. It also has a programme licensed to Merck in Phase I for royalties and up to US\$465m in future milestones.

### Next events

PTSD Phase II results Late Q318

Merck collaboration Phase I complete H218

Agitation Phase I results Q119

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## Programme updates

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Bionomics recently presented its fiscal year 2018 results and provided an update on its operations. The company's core focus is the development of its drug BNC210, which is in Phase II clinical trials for PTSD and agitation. In the company update, it reiterated that results from these studies will be available at the end of calendar Q318 and calendar Q119 respectively. BNC210 is a negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor and there is preliminary evidence that the drug may provide anxiolytic effects. Most importantly, the drug has a novel mechanism of action that may avoid the adverse effect profile typical of other anxiolytics in the GABA agonist class, such as benzodiazepines, which include sedation, cognitive impairment and loss of co-ordination. We expect the readout for the PTSD study to be highly informative for the prospects of this molecule in this and other indications. The Phase IIb study was initiated in June 2016 and completion of enrolment (at 193 patients) was announced in April 2018. Subsequently it was announced that treatment of these patients was completed in July 2018. Three doses of BNC210 (150mg, 300mg, 600mg) are being compared against placebo over 12 weeks of twice-daily treatment. The primary endpoint of the study is improvement in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), the approvable endpoint for PTSD.

In May 2018, the company initiated a Phase IIa clinical programme to investigate BNC210 for the treatment of agitation in the elderly. Agitation is a common symptom associated with dementia, affecting 13% to 24% of these patients.<sup>1</sup> The Phase IIa study will be randomised, double-blind and placebo controlled. In total, 40 patients from geriatric hospital wards in Australia will be enrolled and monitored over a five-day treatment and a two-day follow-up period. The company confirmed in its earnings update that data from the study should be available in Q1 CY19.

In the past fiscal year, the company made the strategic decision to shift its focus to exclusively diseases of the central nervous system, which put BNC210 in the spotlight. Historically, however, the company has developed drugs for other indications and it has two legacy assets BNC101 for colorectal cancer (CRC) and BNC105 for chronic lymphocytic leukaemia and melanoma. The company has completed the Phase I clinical study of BNC101. Detailed safety data from the trial have not been released, but the company previously stated at an interim update that no safety issues were observed, and it provided an update in a poster presentation at the AACR 2018 meeting that no biomarkers of gut toxicity were observed. We expect to update our valuation following the release of any additional data. The company has stated its intention to out-license both BNC101 and BNC105, which remains an ongoing strategic goal.

Finally, the company has an ongoing collaboration with Merck, which is developing a drug licensed from Bionomics in Phase I. Few details of the collaboration or the drug have been released, although it has been confirmed that it is a candidate for the treatment of cognitive dysfunction. The company has already received US\$30m in milestones with the potential for US\$465m more.

## Valuation

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We have increased our valuation to A\$562m or A\$1.16 per basic share from A\$491m or A\$1.02 per basic share. This change is driven by advancing our NPVs to the most recent period and exchange rate effects and is offset by lower net cash. On a constant currency basis (at previous A\$1.25/US\$ forex), our valuation would be A\$514m. The fundamentals of our model remain unchanged. The

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<sup>1</sup> Steinberg M, et al. (2008) Point and 5-year period prevalence of neuropsychiatric symptoms in dementia: the Cache County Study. *Int J Geriatr Psychiatry* 23, 170-177.

upcoming readout from the PTSD Phase II study will be a major inflection point in our valuation, depending on its outcome.

| Exhibit 1: Valuation of Bionomics      |  |                  |             |                   |                |             |
|--|--|------------------|-------------|-------------------|----------------|-------------|
| Program                                | Market                                       | Prob. of success | Launch year | Peak sales (A\$m) | Margin/Royalty | rNPV (A\$m) |
| BNC210                                 | PTSD   | 30%              | 2022        | 1004.3            | 54%            | 410.2       |
| BNC210                                 | Agitation                                    | 20%              | 2023        | 283.9             | 52%            | 55.4        |
| BNC101                                 | CRC  | 10%              | 2025        | 1209.3            | 55%            | 94.9        |
| Merck collaboration milestones         | Alzheimer's associated cognitive dysfunction | 10%              | 2025        | 1995.8            | 5%             | 18.8        |
| CRO business                           |  |                  |             | 5.4               | 4%             | 1.1         |
| Unallocated costs                      |  |                  |             |                   |                | -21.5       |
| Total                                  |  |                  |             |                   |                | 558.9       |
| Net cash and equivalents (FY18) (A\$m) |  |                  |             |                   |                | 3.5         |
| Total firm value (A\$m)                |  |                  |             |                   |                | 562.4       |
| Total shares (m)                       |  |                  |             |                   |                | 482.8       |
| Value per share (A\$)                  |  |                  |             |                   |                | 1.16        |
| Dilutive warrants and options (m)      |  |                  |             |                   |                | 51.51       |
| Total diluted shares                   |  |                  |             |                   |                | 534.3       |
| Value per diluted share (A\$)          |  |                  |             |                   |                | 1.11        |

Source: Bionomics reports, Edison Investment Research

## Financials

The company reported a loss of A\$24.6m in its fiscal year ending 30 June 2018. The majority of this loss is attributable to the company's ongoing development programmes, with an R&D expenditure of A\$25.2m. The company did report some revenue from its CRO business (A\$3.8m), although this value has been steadily declining (A\$5.3m in 2017). The majority of the remainder of the company's income was from R&D incentives and grants (A\$8.2m). Operational cash burn for the year was A\$20.5m, which came in slightly higher than our expectations (A\$17.5m), due to a mix of reasons (operational spend, exchange rate effects, financing costs, etc). Adjusting our future burn rate on this basis, we expect the company to require A\$40m in additional capital to reach profitability in 2022, which is an increase from our previous estimate of A\$35m. The company ended FY18 with A\$24.9m in gross cash, which we expect to be able to support the company through the upcoming clinical results for PTSD and agitation. The company has A\$21.4m in outstanding debt, predominantly associated with the company's bank loan facility (at 9%).

**Exhibit 1: Financial summary**

|  | \$'000 | 2017     | 2018     | 2019e    | 2020e    |
|--|--------|----------|----------|----------|----------|
| 30-June  |        | IFRS     | IFRS     | IFRS     | IFRS     |
| <b>INCOME STATEMENT</b>                        |        |          |          |          |          |
| Revenue  |        | 18,606   | 3,954    | 17,896   | 4,280    |
| Cost of Sales                                  |        | 0        | 0        | 0        | 0        |
| Gross Profit                                   |        | 18,606   | 3,954    | 17,896   | 4,280    |
| EBITDA   |        | (3,214)  | (22,539) | (17,696) | (28,396) |
| Normalised operating profit                    |        | (3,671)  | (22,947) | (18,104) | (28,805) |
| Amortisation of acquired intangibles           |        | (1,286)  | (1,259)  | (1,259)  | (1,259)  |
| Exceptionals                                   |        | 0        | (20)     | 0        | 0        |
| Share-based payments                           |        | (504)    | (537)    | (537)    | (537)    |
| Reported operating profit                      |        | (5,461)  | (24,764) | (19,901) | (30,601) |
| Net Interest                                   |        | (766)    | (1,483)  | (1,204)  | (3,741)  |
| Joint ventures & associates (post tax)         |        | 0        | 0        | 0        | 0        |
| Exceptionals                                   |        | 0        | 0        | 0        | 0        |
| Profit Before Tax (norm)                       |        | (4,437)  | (24,430) | (19,309) | (32,546) |
| Profit Before Tax (reported)                   |        | (6,227)  | (26,247) | (21,105) | (34,343) |
| Reported tax                                   |        | (523)    | 1,161    | 891      | 1,451    |
| Profit After Tax (norm)                        |        | (4,810)  | (23,349) | (18,493) | (31,171) |
| Profit After Tax (reported)                    |        | (6,750)  | (25,086) | (20,214) | (32,892) |
| Minority interests                             |        | 0        | 0        | 0        | 0        |
| Other comprehensive income                     |        | (114)    | 502      | 0        | 0        |
| Net income (normalised)                        |        | (4,924)  | (22,847) | (18,493) | (31,170) |
| Net income (reported)                          |        | (6,864)  | (24,583) | (20,214) | (32,892) |
| Basic average number of shares outstanding (m) |        | 481      | 482      | 506      | 532      |
| EPS - basic normalised (c)                     |        | (1.00)   | (4.84)   | (3.65)   | (5.86)   |
| EPS - diluted normalised (c)                   |        | (0.98)   | (4.74)   | (3.58)   | (5.75)   |
| EPS - basic reported (c)                       |        | (1.40)   | (5.20)   | (3.99)   | (6.19)   |
| Dividend (c)                                   |        | 0.00     | 0.00     | 0.00     | 0.00     |
| <b>BALANCE SHEET</b>                           |        |          |          |          |          |
| Fixed Assets                                   |        | 29,597   | 29,146   | 27,965   | 26,785   |
| Intangible Assets                              |        | 26,595   | 26,017   | 24,758   | 23,499   |
| Tangible Assets                                |        | 2,618    | 2,744    | 2,823    | 2,902    |
| Investments & other                            |        | 384      | 384      | 384      | 384      |
| Current Assets                                 |        | 54,478   | 35,920   | 17,266   | 24,957   |
| Stocks   |        | 426      | 490      | 490      | 490      |
| Debtors  |        | 9,893    | 8,982    | 12,791   | 14,080   |
| Cash & cash equivalents                        |        | 42,874   | 24,930   | 2,467    | 8,868    |
| Other  |        | 1,286    | 1,518    | 1,518    | 1,518    |
| Current Liabilities                            |        | (13,889) | (13,285) | (9,198)  | (9,299)  |
| Creditors                                      |        | (3,673)  | (5,860)  | (7,470)  | (7,570)  |
| Tax and social security                        |        | 0        | 0        | 0        | 0        |
| Short term borrowings                          |        | (8,496)  | (5,696)  | 0        | 0        |
| Other  |        | (1,720)  | (1,729)  | (1,729)  | (1,729)  |
| Long Term Liabilities                          |        | (29,733) | (34,823) | (38,752) | (77,516) |
| Long term borrowings                           |        | (10,014) | (15,736) | (21,433) | (61,433) |
| Other long term liabilities                    |        | (19,719) | (19,087) | (17,319) | (16,084) |
| Net Assets                                     |        | 40,454   | 16,958   | (2,719)  | (35,074) |
| Minority interests                             |        | 0        | 0        | 0        | 0        |
| Shareholders' equity                           |        | 40,454   | 16,958   | (2,719)  | (35,074) |
| <b>CASH FLOW</b>                               |        |          |          |          |          |
| Op Cash Flow before WC and tax                 |        | (3,214)  | (22,539) | (17,696) | (28,396) |
| Working capital                                |        | 51       | 2,251    | (619)    | 2,339    |
| Exceptional & other                            |        | 1,723    | (166)    | (4,585)  | (7,427)  |
| Tax  |        | 0        | 0        | 0        | 0        |
| Net operating cash flow                        |        | (1,440)  | (20,453) | (22,900) | (33,485) |
| Capex  |        | (248)    | (487)    | (487)    | (487)    |
| Acquisitions/disposals                         |        | 0        | 0        | 0        | 0        |
| Net interest                                   |        | 1,201    | 569      | 924      | 373      |
| Equity financing                               |        | 144      | 411      | 0        | 0        |
| Dividends                                      |        | 0        | 0        | 0        | 0        |
| Other  |        | 0        | 0        | 0        | 0        |
| Net Cash Flow                                  |        | (342)    | (19,960) | (22,463) | (33,599) |
| Opening net debt/(cash)                        |        | (24,281) | (24,364) | (3,498)  | 18,965   |
| FX   |        | (10)     | (206)    | 0        | 0        |
| Other non-cash movements                       |        | 435      | (700)    | 0        | 0        |
| Closing net debt/(cash)                        |        | (24,364) | (3,498)  | 18,965   | 52,564   |

Source: Bionomics, Edison Investment Research

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