Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	BNO
Price (A$)	0.48
12m High (A$)	0.64
12m Low (A$)	0.34
Shares (m)	482.9
Mkt Cap (A$m)	231.8
EV (A$m)	228.3
Free Float*	90%
Market	ASX

**As defined by AIM Rule 26*

Description

Bionomics is an Australian biopharmaceutical company specialising in development of ion channel drugs for disorders of the central nervous system. In addition to a strong proprietary pipeline that includes ion channel allosteric modulators for anxiety, BNO offers contract drug development services

Company information

CEO	Deborah Rathjen
CFO	Steven Lydeamore
Chairman	Errol De Souza

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Key shareholders

Directors	0.7%
BVF Partners	9.8%
Ausbil Investment	9.0%
PPM	4.8%

Diary

2H'18	PTSD trial data
1Q'19	Agitation trial data
2H'18	Merck Phase I trial data

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BIONOMICS

FY'18 – focus on PTSD drug development

Bionomics (BNO) is an Australian biopharmaceutical company specialising in ion channel drug discovery for central nervous system (CNS) disorders such as anxiety and post-traumatic stress disorder (PTSD). BNO also offers contract and partnered discovery based on its proprietary technology platforms: MultiCore and ionX. The group sales model includes fees-for-service, licensing income, and royalties from successful partnered products. In fiscal 2018, its strategy has been to focus on the development of its lead candidate, BNC210, to completion of Phase II in PTSD – the RESTORE trial is due to read out next month, a potential value inflection point.

- **Strategy:** BNO's recently refined strategy is to focus on development of its ion channel drug candidates, particularly allosteric modulators. It intends to partner its priority CNS candidate for late-stage development and commercialisation, and to monetise its clinical-stage, non-ion channel oncology programmes.
- **Full-year results:** Sales (R&D payments and service-fees) declined 28% to A$4.0m in FY'18, as payments from Merck & Co (MRK) ceased on BNO's successful completion of research activities. Other income totalled A$1.4m, returning to underlying levels following the $10m/A$13m milestone in FY'17.
- **R&D investment:** Operational focus in the period was on clinical trials, with the lead candidate, BNC210, progressing in the Phase II PTSD RESTORE trial to full recruitment and to completion of treatment. Data are due to be read out next month. The trial of the oncology candidate BNC101 ceased, pending a deal.
- **Risks:** BNC210 has therapeutic potential in large patient populations with unmet need. However, there are significant risks in development of any drug, and late-stage clinical trials are expensive. In addition, there are no approved specific cancer stem cell-targeting drugs, and BNC101 is yet to be out-licensed.
- **Investment summary:** BNO has a clear strategy to invest in developing its CNS drug candidates to a stage that both interests big pharma and generates good potential returns for shareholders. Hardman & Co estimates the post-tax NPV of the whole drug pipeline to be ca.A$650m. The next inflection point is likely to be the BNC210 data in CY 2H'18, or potentially news about the oncology assets.

Financial summary and valuation

Year-end June (A$m)	2015	2016	2017	2018	2019E	2020E
Sales	6.79	7.14	5.53	3.95	3.60	3.30
R&D investment	-23.18	-24.77	-24.22	-25.25	-20.20	-12.12
Other income	1.35	2.59	14.62	1.36	47.56	34.46
EBITDA	-22.65	-24.95	-10.99	-25.20	25.45	19.91
Underlying EBIT	-24.37	-26.88	-12.73	-26.87	23.79	18.24
Reported EBIT	-24.35	-27.42	-13.23	-27.43	23.25	17.70
Underlying PBT	-24.28	-26.28	-13.50	-28.35	22.42	17.36
Statutory PBT	-24.27	-26.82	-13.13	-32.82	21.89	16.83
Underlying EPS (A¢)	-4.06	-3.51	-1.48	-4.28	5.57	4.12
Statutory EPS (A¢)	-3.27	-3.42	-1.43	-5.10	5.56	4.12
Net (debt)/cash	11.78	23.14	24.26	3.50	31.81	52.08
Capital increase	0.27	28.22	0.14	0.41	0.00	0.00

Source: Hardman & Co Life Sciences Research

2018 full-year results

Financials – key features

- Sales: Sales to June 2018 were A$3.95m (A$5.53m), a decline of 29% at CER on FY'17. This was the result of the end of payments from MRK on successful completion of research activities, and a small decline in service fees.

- Other income: The decline in other income (licensing fees, including royalties, and grants) to A$1.36m (A$14.6m) represented a return to normal levels after the MRK milestone (A$13m) in FY'17. Other income is lumpy period-by-period on timing of licensing and grants; FY'18 other income was mainly grant income.

- R&D spend: Investment in R&D was A$25.3m, a 4.2% increase on FY'17, and above our forecasts, made at the half-year, by A$1.25m. This was due to initiation of the agitation trial in May (FY'18 results include one month's development costs), the Phase II trial in PTSD, and early-stage discovery work.

- Underlying EBIT: The increased loss to -A$26.87m (-A$-12.73) mainly reflects the MRK milestone in FY'17. Given that sales (fees-for-service in Europe) are 100% margin, the impact of other income falls straight to the bottom line.

- Net cash/debt: At the period end, BNO had net cash of A$3.5m, composed of long- and short-term debt of A$21.4m (up from A$18.6m) and a cash balance of A$24.9m. Some of the debt matures in the coming fiscal year and, although no decision has been made, we are anticipating that BNO will seek to refinance it.

- Cash runway: Without licensing deals, BNO is forecast to require capital of ca.A$50m in the next 24 months, funded by an equity raise and/or an additional loan. We have included licensing income in 2019 and 2020 on the assumption that there will be a deal in oncology or involving BNC210.

Note on financial presentation

For clarification, and to make all companies directly comparable, Hardman & Co treats licensing fees, royalties, research grants, etc. as other income. In the case of BNO, Hardman presents as sales: service fees from research contracts, R&D payments from partners such as MRK, and rental income from its facility in Australia. Sales are therefore mostly paid in Euros. Hardman presents as BNO's other income: licensing fees from partners such as MRK, royalty payments, and foreign research grants. Moreover, unlike BNO, Hardman & Co treats government R&D incentives as tax credits rather than sales. Interest income is included in net interest and unrealised forex gains/losses are included in other financials.

Summary of actual vs. forecast results					
Year-end June (A$m)	2017 actual	2018 actual	Growth %	2018 forecast	Delta
Sales	5.53	3.95	-29.0% CER	5.90	-1.95
SG&A	-8.66	-6.94	-19.9%	-8.80	1.86
R&D	-24.22	-25.25	4.2%	-24.00	-1.25
Other income	14.62	1.36	-90.7%	14.85	-13.49
EBITDA	-10.99	-25.20	129.4%	-10.31	-14.89
Underlying EBIT	-12.73	-26.87	111.1%	-12.05	-14.82
Long-term debt	-10.01	-15.74	57.1%	-10.1	-5.73
Net cash/debt (x)	24.26	3.50	-86.6%	17.68	-14.18
Change in net debt	1.12	-20.76		-6.57	-14.19
Hardman FCF/sh. (A¢)	0.67	-4.81		-1.37	-3.44

Source: Hardman & Co Life Sciences Research

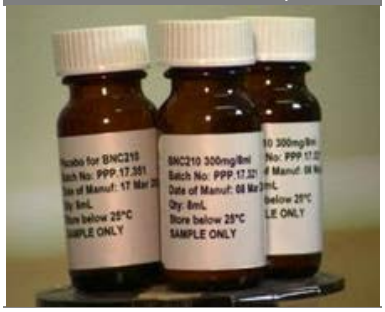
Operations – key features

In fiscal 2018, BNO has concentrated on its research and development activities as a pure-play CNS biopharmaceutical company. It has focused on the discovery and development of its ion channel-targeted drugs, progressing its lead candidate, BNC210, through ongoing Phase II trials of anxiety-related symptoms in PTSD (its priority indication) and in agitation in elderly, hospitalised patients.

In addition, BNO is progressing with discovery-stage ion channel programmes targeting pain and depression, among other indications. Management expects identification of a new potential candidate in 1H'19.

BNC210

BNC210 clinical trial samples



Source: Bionomics

BNO's lead candidate is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor. We discussed its mode of action and clinical development history in our initiation note '*Channelling expertise in CNS drugs*', published 7 February 2018[1]; in summary, BNC210 has met all primary endpoints in its seven clinical trials to date, and with a third Phase II trial ongoing, BNO expects that the drug could be on the market by 2021 if it continues to be successfully developed.

In PTSD

Over the past 12 months, the Phase IIb RESTORE trial in PTSD (initiated in fiscal 2H'16) has progressed well, with full recruitment achieved in April 2018 and all treatment completed in July 2018. Management has reiterated its expectations that top-line data will be reported late-September 2018 (fiscal 1H'19). PTSD and agitation are thought to provide a more rapid path to market than either Generalised Anxiety Disorder or Panic Disorder, the indications tested in previous trials.

In agitation

In May 2018 (2H'18), BNO initiated a further trial of BNC210, this time in agitation in hospitalised elderly patients. The trial is described in our note '*Third Phase II trial of BNC210 begins*'[2]; it has been designed for a short time-period between initiation and data collection, with a five-day treatment period and rapid recruitment of approximately 40 patients.

[1] http://www.hardmanandco.com/docs/default-source/company-docs/bionomics-ltd-documents/07.02.18-channelling-expertise-in-cns-drugs.pdf

[2] http://www.hardmanandco.com/docs/default-source/company-docs/bionomics-ltd-documents/30.05.18-third-phase-ii-trial-of-bnc210-begins.pdf

Merck & Co collaboration

Phase I trial in Alzheimer's disease

BNO and Merck & Co (MRK) have a partnership agreement for the discovery and development of candidate drugs in important CNS indications such as Alzheimer's disease. The first milestone payment, of $10m, was made to BNO from MRK during fiscal 2017, when the first patient was treated in a Phase I clinical trial for cognitive dysfunction, with an undisclosed compound discovered as part of the partnership. In fiscal 2018, BNO completed successfully its research activities associated with the partnership, and accordingly, payments from MRK for these activities ended in the period.

Joint symposium

Reflecting the strength of the MRK partnership, in October, BNO and MRK hosted their 5th annual joint symposium in Adelaide: '*Frontiers in neuroscience research: feelings and forgetting*'. Attendees included researchers, scientists and clinicians, patient support groups, and the investment community. It was closed by the SVP of Global Business Development and Licensing at MRK, Mr Ben Thorner. The 6th symposium: '*At the Frontiers of Neuroscience: Signs & Symptoms*' will take place in October 2018.

Oncology assets

No deal announced

Early in the 2018 fiscal year, the company made the decision to divest its oncology programmes. Management is in discussions for monetisation of the BNC101 and BNC105 programmes – it reports in the 2018 full year results announcement that numerous parties are in active due diligence, and that it expects a value-accretive deal. BNC101 was acquired in 2012 for $10m, as discussed in our report published 4 June 2018[3].

Clinical trials

The Phase I trial of the BNC101 anti-LGR5 humanised monoclonal antibody (clinicalTrials.gov: NCT02726334) in metastatic colon cancer was fully recruited in 1H'18, with the recommended Phase II dose level confirmed (15mg/kg) in the Phase Ia (dose escalation and expansion) monotherapy arm in October 2017. Some preliminary data have been released, including: evidence of target engagement in patient biopsies; and, in a poster from the AACR conference on 17 April 2018, indication of the potential pharmacodynamic effect of BNC101, as measured by the ratio of MMP-9 to TIMP-1 levels in blood plasma, and of BNC101 safety, with no gut toxicity associated with treatment as measured using the biomarker zonulin. Full data from the trial had been expected by June 2018.

In addition, a trial of BNC105 in chronic lymphocytic leukemia (CLL) was started in March 2018. The candidate is administered in combination with ibrutinib as its disodium phosphate ester form, BNC105P, as a pro-drug, meaning that it is metabolised soon after administration to the active compound BNC105. The study is expected to be completed by 2020, with results on tolerability, safety, and efficacy.

[3] http://www.hardmanandco.com/docs/default-source/company-docs/bionomics-ltd-documents/04.06.18-a-big-deal-in-oncology.pdf

Outlook

Post-period events

BNC101 trial Phase Ia concluded

On 28 July 2018, the clinicaltrials.gov record of the Phase I Metastatic Colorectal Cancer trial were updated to 'terminated'. This classification means that the full protocol has not been completed – in this case, the Phase Ib combination arm has not proceeded. The Phase Ia (dose escalation and expansion) monotherapy arm has concluded, successfully identifying a recommended Phase II dose in October 2017; however, full data have not been released. BNO has said in interim updates that it would complete Phase Ia, with Phase Ib to be carried out by a partner. Presumably, Phase Ib has not proceeded because no partner has been secured to date, and because the company has made the decision to exit oncology.

Trial in agitation – initiated in May 2018

Recruitment is ongoing, with data on safety and tolerability, and on the effect of the drug candidate on resolution of agitation, expected between January and March 2019 (2H'19). A news article in August 2018 reported that treatment is currently taking place at the Prince of Wales Hospital in Sydney, the Royal Melbourne Hospital, and Modbury Hospital in Adelaide. Positive feedback from one of the patients in the trial was highlighted in the Australian channel 9 national news.

Changes to forecasts

Licensing and other deals

We had originally included A$13/$10m in other income in FY'18 in anticipation of the monetisation of BNC101. This has been moved into FY'19 forecasts, which also includes payments of the same amount for monetisation of BNC105 and of an anticipated second milestone from MRK (on start of a Phase II trial). A potential upfront payment of $25m has been included on the assumption that a partnership deal involving BNC210 is concluded in 2020.

R&D spend

We have increased from A$12m to A$20m the expected R&D spend in 2019, to cover for the BNC210 agitation trial and completion of analysis of the BNC210 PTSD trial in 1H'19. Since the BNC101 trial was being funded by an individual grant to its partner at the Norris Cotton Cancer Centre, Dartmouth College in the US, there is no need to adjust R&D spend to account for the termination of the trial.

Changes to forecasts

Year-end June	2018	----- 2019E -----		*Change*	----- 2020E -----		*Change*
(A$m)	actual	*Old	New	*%*	*Old	New	*%*
Sales	3.95	6.20	3.60	*-42%*	6.50	3.30	*-49%*
COGS	0.00	0.00	0.00	*0%*	0.00	0.00	*0%*
SG&A	-6.94	-9.10	-7.18	*-21%*	-9.30	-7.40	*-20%*
R&D	-25.25	-12.00	-20.20	*68%*	-12.00	-12.12	*1%*
Other income	1.36	34.41	47.56	*38%*	34.60	34.46	*0%*
EBITDA	**-25.2**	**21.25**	**25.45**	*20%*	**21.55**	**19.91**	*-8%*
D&A	-1.67	-1.74	-1.67	*-4%*	-1.74	-1.67	*-4%*
Underlying EBIT	**-26.87**	**19.51**	**23.79**	*22%*	**19.80**	**18.24**	*-8%*
U/lying EPS (A¢)	-4.28	4.73	5.57	*18%*	4.90	4.12	*-16%*
Free cashflow	-23.19	23.55	28.31	*20%*	24.26	20.27	*-16%*
Net cash/(debt) (x)	**3.50**	**41.23**	**31.81**	*-23%*	**65.50**	**52.08**	*-20%*

**From research report published 4 June 2018*
Source: Hardman & Co Life Sciences Research

News flow

We have not updated our discounted cash flow valuation on the full-year results. There are a number of value inflection points in the foreseeable future, on which we will update our valuation of the company. These include:

- **Data from the RESTORE trial:** Read-out of top-line safety and efficacy data are expected towards the end of 1Q'19 (July - September 2018) from the Phase II RESTORE trial of BNC210 in PTSD.
- **Partnering of BNC210:** Positive data from the RESTORE trial could accelerate BNC210 partnering discussions. BNO intends to out-licence the programme when it is Phase III ready, in return for licensing fees and royalties if commercialised successfully.
- **Divestment of oncology assets:** Discussions for monetisation of BNC101 and BNC105 are ongoing.
- **MRK trial:** A milestone payment from MRK is expected once the partnered programme enters Phase II. Data from the ongoing trial are expected in fiscal 1H'19.

Financial summary

Cash position

The group had a cash position of A$24.9m on 30 June 2018. Its net cash/debt was A$3.5m, which includes a long-term bank loan from Silicon Valley bank. We assume that, in the forecast period, this loan will be refinanced. Cash burn at the operating level in 2018 was around A$22m and we expected it to remain between A$17m-A$22m in the forecast period. Without licensing deals, BNO is forecast to require capital of around A$52m in the next 24 months, funded by an equity raise and/or an additional loan. Given that discussions with potential partners are ongoing, other income in 2019 and 2020 includes licensing income from the deals outlined above.

Summary financials

Year-end June (A$m)	2015	2016	2017	2018	2019E	2020E
AUD:EUR	1.437	1.524	1.446	1.458	1.446	1.446
AUD:USD	1.200	1.374	1.326	1.312	1.326	1.326
Profit & Loss:						
Sales	6.79	7.14	5.53	3.95	3.60	3.30
COGS	0.00	0.00	0.00	0.00	0.00	0.00
SG&A	-9.32	-11.85	-8.66	-6.94	-7.18	-7.40
R&D	-23.18	-24.77	-24.22	-25.25	-20.20	-12.12
EBITDA	**-22.65**	**-24.95**	**-10.99**	**-25.20**	**25.45**	**19.91**
Depreciation/amort.	-1.71	-1.94	-1.74	-1.67	-1.67	-1.67
Other income	1.35	2.59	14.62	1.36	47.56	34.46
Underlying EBIT	**-24.37**	**-26.88**	**-12.73**	**-26.87**	**23.79**	**18.24**
Net interest	0.08	-0.67	-0.77	-1.48	-1.36	-0.88
Pre-tax profit	**-24.28**	**-26.28**	**-13.50**	**-28.35**	**22.42**	**17.36**
Tax	7.32	10.23	6.38	7.73	4.46	2.54
Net income	-16.97	-16.05	-7.12	-20.62	26.89	19.90
Weighted av. shares (m)	417.6	457.3	481.4	482.3	482.8	482.8
Underlying basic EPS (A¢)	**-4.06**	**-3.51**	**-1.48**	**-4.28**	**5.57**	**4.12**
U/l fully-diluted EPS (A¢)	-3.97	-3.43	-1.38	-3.87	5.04	3.73
Balance sheet						
Share capital	418.20	481.02	481.46	482.75	482.75	482.75
	-	-	-	-	-	-
Reserves	386.23	436.86	441.00	465.80	438.95	419.08
Capitalised R&D	54.85	65.02	72.63	79.18	79.29	70.95
Liabilities	10.29	12.35	16.56	17.68	17.68	17.68
Debt	9.32	18.44	10.01	15.74	15.74	15.74
less: Cash	26.56	45.45	42.87	24.93	53.24	73.51
Invested capital	**90.02**	**102.59**	**109.23**	**112.39**	**111.05**	**102.30**
Net cash/debt	11.78	23.14	24.26	3.50	31.81	52.08
Cashflow:						
Underlying EBIT	-24.37	-26.88	-12.73	-26.87	23.79	18.24
Working capital	21.64	-2.49	-0.87	2.50	-0.23	-0.19
Tax & interest	7.99	9.02	8.69	6.84	6.91	4.38
Operational cashflow	**12.73**	**-16.73**	**3.46**	**-22.70**	**28.80**	**20.76**
Capital expenditure	-0.85	-0.20	-0.25	-0.49	-0.49	-0.49
Free cashflow	**11.89**	**-16.85**	**3.21**	**-23.19**	**28.31**	**20.27**
Acquisitions	-0.39	0.00	0.00	0.00	0.00	0.00
Share issues	0.27	28.22	0.14	0.41	0.00	0.00
Change in net debt	**11.78**	**11.36**	**1.12**	**-20.76**	**28.31**	**20.27**
Hardman FCF/sh. (A¢)	2.85	-3.69	0.67	-4.81	5.86	4.20

Notes

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Some professional investors, who are subject to the new MiFID II rules from 3rd January, may be unclear about the status of Hardman & Co research and, specifically, whether it can be accepted without a commercial arrangement. Hardman & Co's research is paid for by the companies, legal entities and issuers about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

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The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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