EDISON

Bionomics

Clinical update

RESTORE trial completed, data this quarter

Pharma & biotech

Bionomics announced on 9 July 2018 that it had completed treatment in its 193-patient Phase II clinical study of BNC210 for post-traumatic stress disorder (PTSD). The RESTORE clinical study completed the treatment phase on time and the company stated that it intends to provide topline data by the end of calendar Q318.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/16	8.1	(16.7)	(0.04)	0.00	N/A	N/A
06/17	18.6	(4.4)	(0.01)	0.00	N/A	N/A
06/18e	5.0	(19.6)	(0.03)	0.00	N/A	N/A
06/19e	17.6	(16.1)	(0.03)	0.00	N/A	N/A

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

PTSD Phase II complete

The RESTORE trial enrolled 193 patients at 25 clinical sites in the US and Australia. Patients were evaluated using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) as the primary endpoint. CAPS-5 is the approvable endpoint for PTSD, so results from the study should be highly predictive. The study is also examining anxiety and depression endpoints, which could provide insight into other avenues of treatment for the drug.

Novel mechanism brings new potential

Part of the potential of BNC210 is that it has a novel anxiolytic mechanism that has previously been unexplored for the treatment of PTSD. BNC210 is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor, a protein that has been implicated in the stress response, but has previously not been targeted in the clinic. In earlier exploratory studies the compound suppressed activation of regions of the brain associated with anxiety and reduced the intensity of panic.

Agitation results expected in calendar Q119

BNC210 is also being tested for the treatment of agitation in geriatric patients in a hospital setting. Agitation is a common neuropsychiatric symptom typically associated with dementia. It is estimated that 13-24% of dementia patients suffer from agitation, but there are currently no approved medications for this condition. The double-blind, placebo controlled Phase IIa study will enrol 40 patients across Australia. The company reaffirmed the timing of results from the study and stated that it expects results to be available in calendar Q119.

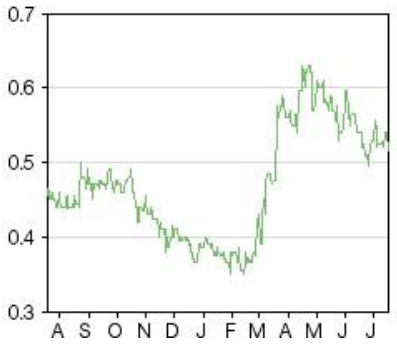
Valuation: A$491m or A$1.02

Our valuation has been adjusted to A$491 from A$492m, with no impact on value per share at A$1.02. We previously modelled the first milestone from the Merck collaboration in FY18, and it has now been moved to FY19. We expect to update our valuation with the release of results from the Phase II study in calendar Q318. We expect the company to require an additional A$35m in capital to complete its development plan, although we expect this to be met through licensing activity.

17 July 2018

Price	**A$0.52**
Market cap	**A$251m**
	A$1.25/US$
Net cash (A$m) at 31 March 2018	12.9
Shares in issue	482.8m
Free float	84%
Code	BNO
Primary exchange	ASX
Secondary exchange	OTCQX

Share price performance



%	1m	3m	12m
Abs	(4.6)	(18.3)	13.2
Rel (local)	(6.5)	(23.3)	3.9
52-week high/low		A$0.6	A$0.4

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 US$506m in upfronts and milestones.

Next events

PTSD Phase II results	Late Q318
Merck collaboration Phase I complete	H218
Agitation Phase I results	Q119

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Phase II PTSD study treatment complete

193 patients with PTSD have been enrolled and treated as part of the RESTORE Phase II clinical study. Overall, the execution of the trial has been precisely as planned, meeting all its timing and enrolment targets, which is encouraging and suggests interest in the study on the part of the 25 clinical sites that enrolled patients. Three doses of BNC210 (150mg, 300mg, 600mg) were compared against placebo over 12 weeks of twice-daily treatment. The primary endpoint of the study is improvement in CAPS-5. CAPS-5 is a battery of 30 questions designed to determine whether the patient meets the criteria for PTSD as defined under the DSM-5 ranked on a scale of zero to four for severity. Improvement in CAPS-5 is the FDA-approvable endpoint for PTSD. The trial will also measure the impact of the drug on anxiety using the Hamilton Anxiety Rating Scale (HAM-A), and on depression using the Montgomery-Asberg Depression Rating Scale (MADRS) as secondary endpoints. Depression and anxiety are significant comorbidities with PTSD, and these secondary endpoints may provide additional support for this indication, but we expect them to also provide insight into future indications where the drug may find traction.

There is a high unmet medical need for PTSD patients. It is both common, affecting 6.8% of people over the course of their lifetime, and difficult to treat, given the limited effectiveness of available medications. Paroxetine and sertraline, both SSRIs, are the only drugs currently approved for the disorder in the US, which have a modest effect in a number of patients but carry the associated side effects of SSRIs. There is significant off-label treatment of this disorder in an attempt to fill the gaps in treatment. Although they are effective in other anxiety centric disorders, benzodiazepines are contraindicated in PTSD, likely due to the interference of their sedating and memory impairing effects. Therefore, there is significant potential for a non-sedating anxiolytic drug in this indication.

Valuation

Our valuation has been adjusted slightly lower to A$491 from A$492m, although this has no impact on value per share at A$1.02. This adjustment was made because we have moved the milestone associated with the Merck collaboration programme to FY19, because the company has not made any announcements regarding the programme before July 2018. We are encouraged that the clinical programme is progressing on schedule and we expect to update our valuation with the release of results from the PTSD study in calendar year Q318. We may potentially include other indications based on the secondary endpoints provided. We also expect to update our valuation with the release of data from the agitation study in calendar Q119.

Exhibit 1: Valuation of Bionomics

Programme	Market	Prob. of success	Launch year	Peak sales (A$m)	Margin/ Royalty	rNPV (A$m)
BNC210	PTSD	30%	2022	916.3	54%	349.7
BNC210	Agitation	20%	2023	259.0	52%	47.6
BNC101	CRC	10%	2025	1103.3	55%	80.2
Merck collaboration milestones	Alzheimer's associated cognitive dysfunction	10%	2025	1821.0	5%	16.1
CRO business				6.6	4%	1.3
Unallocated costs						-16.7
Total						$478.2
Net cash and equivalents (Q318) (A$m)						$12.9
Total firm value (A$m)						**$491.1**
Total shares (m)						482.8
Value per share (A$)						**$1.02**
Dilutive warrants and options (m)						52.34
Total diluted shares (m)						535.1
Value per diluted share (A$)						0.97

Source: Edison Investment research, Bionomics reports

Financials

The only adjustment in our forecasts is moving the A$12.5m Merck milestone to FY19. We do not consider this a material delay in the programme and it has not affected the company's financing schedule. We believe Bionomics has sufficient capital to provide a runway into FY20. It ended Q318 with A$32.3m in cash and A$19.4m in debt. We forecast a financing shortfall of $35m if the company intends to continue development of its assets internally (which we record as illustrative debt in FY20), but we expect this financing need to be met through the licensing of its assets.

Exhibit 2: Financial summary

A$'000	2015	2016	2017	2018e	2019e
30-June	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue	6,827	8,143	18,606	5,000	17,600
Cost of Sales	0	0	0	0	0
Gross Profit	6,827	8,143	18,606	5,000	17,600
EBITDA	(15,665)	(15,449)	(3,214)	(18,505)	(14,640)
Normalised operating profit	(16,176)	(16,071)	(3,671)	(18,961)	(15,096)
Amortisation of acquired intangibles	(1,203)	(1,316)	(1,286)	(1,286)	(1,286)
Exceptionals	532	1,131	0	0	0
Share-based payments	(515)	(400)	(504)	(504)	(504)
Reported operating profit	(17,362)	(16,656)	(5,461)	(20,751)	(16,886)
Net Interest	85	(668)	(766)	(677)	(965)
Joint ventures & associates (post tax)	0	0	0	0	0
Exceptionals	0	0	0	0	0
Profit Before Tax (norm)	(16,091)	(16,738)	(4,437)	(19,638)	(16,062)
Profit Before Tax (reported)	(17,277)	(17,324)	(6,227)	(21,428)	(17,851)
Reported tax	328	732	(523)	2,184	754
Profit After Tax (norm)	(15,786)	(16,031)	(4,810)	(17,637)	(15,383)
Profit After Tax (reported)	(16,949)	(16,592)	(6,750)	(19,244)	(17,097)
Minority interests	0	0	0	0	0
Other comprehensive income	3,313	968	(114)	0	0
Net income (normalised)	(12,473)	(15,063)	(4,924)	(17,637)	(15,383)
Net income (reported)	(13,637)	(15,624)	(6,864)	(19,244)	(17,097)
Basic average number of shares outstanding (m)	418	457	481	505	531
EPS - basic normalised (c)	(3.78)	(3.51)	(1.00)	(3.49)	(2.90)
EPS - diluted normalised (c)	(3.78)	(3.48)	(0.98)	(3.41)	(2.84)
EPS - basic reported (c)	(4.06)	(3.63)	(1.40)	(3.81)	(3.22)
Dividend (c)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	31,251	31,723	29,597	28,096	26,676
Intangible Assets	27,416	28,504	26,595	25,229	23,943
Tangible Assets	3,451	2,835	2,618	2,484	2,350
Investments & other	384	384	384	384	384
Current Assets	37,881	58,086	54,478	37,849	22,192
Stocks	410	439	426	426	426
Debtors	9,069	11,003	9,893	8,731	11,879
Cash & cash equivalents	26,558	45,450	42,874	27,406	8,601
Other	1,844	1,194	1,286	1,286	1,286
Current Liabilities	(13,706)	(11,386)	(13,889)	(6,885)	(8,431)
Creditors	(6,466)	(5,855)	(3,673)	(5,231)	(6,777)
Tax and social security	0	0	0	0	0
Short term borrowings	(5,460)	(2,732)	(8,496)	0	0
Other	(1,780)	(2,799)	(1,720)	(1,654)	(1,654)
Long Term Liabilities	(23,460)	(34,260)	(29,733)	(37,089)	(35,060)
Long term borrowings	(9,317)	(18,437)	(10,014)	(19,365)	(19,365)
Other long term liabilities	(14,143)	(15,824)	(19,719)	(17,724)	(15,695)
Net Assets	31,966	44,163	40,454	21,972	5,378
Minority interests	0	0	0	0	0
Shareholders' equity	31,966	44,163	40,454	21,972	5,378
CASH FLOW					
Op Cash Flow before WC and tax	(15,665)	(15,449)	(3,214)	(18,505)	(14,640)
Working capital	17,290	(327)	51	2,435	(937)
Exceptional & other	3,310	417	1,723	(1,393)	(3,864)
Tax	0	0	0	0	0
Net operating cash flow	4,936	(15,360)	(1,440)	(17,463)	(19,441)
Capex	(846)	(197)	(248)	(323)	(323)
Acquisitions/disposals	(391)	69	0	0	0
Net interest	941	1,232	1,201	1,204	958
Equity financing	269	28,222	144	283	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	4,908	13,967	(342)	(16,298)	(18,806)
Opening net debt/(cash)	(6,856)	(11,781)	(24,281)	(24,364)	(8,042)
FX	17	(9)	(10)	(24)	0
Other non-cash movements	0	(1,457)	435	0	0
Closing net debt/(cash)	(11,781)	(24,281)	(24,364)	(8,042)	10,764

Source: Edison Investment research, Bionomics reports

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