

Bionomics



Creating and developing innovative therapies

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Safe Harbor Statement

Factors Affecting Future Performance

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Bionomics Overview

KEY STATISTICS (September 2014)

ASX code	BNO
Share price (2/9/14)	A\$0.635
52 week high	A\$0.89
52 week low	A\$0.37
Shares on issue	~417.3M
Market capitalisation	~A\$265M
Cash 30/6/14 <i>not inclusive of post-June Merck upfront payments (US\$20M) or the R&D Tax Incentive (\$7.5M)</i>	A\$10.5M

BOARD

Graeme Kaufman	Non-exec Chairman
Deborah Rathjen	CEO & MD
Trevor Tappenden	Non-exec Director
Errol DeSouza	Non-exec Director
Jonathan Lim	Non-exec Director

12 MONTH SHARE PRICE PERFORMANCE



MANAGEMENT

Deborah Rathjen	CEO & MD
José Iglesias	CMO
Melanie Young	CFO & Company Secretary



Our Business

- Bionomics is a leader in the discovery and development of innovative biopharmaceuticals with operations in Australia, US and Europe.
 - Focus is on serious medical conditions including cancer and central nervous system disorders; aim is to deliver treatments that offer substantially improved patient outcomes
 - Global operations have been built through the acquisitions of Eclipse Therapeutics (US), Neurofit (France) and Prestwick Chemical (France)
- The company undertakes **discovery, development and strategic partnering** of first in class and best in class drugs:
 - **Two major partnerships with Merck & Co in FY14:**
 - ***BNC375*** program targeting memory loss in Alzheimer's Disease, Parkinson's Disease, Schizophrenia, ADHD and other conditions
 - Chronic and neuropathic pain
- Broad and deep portfolio of clinical and preclinical drug candidates with near-term catalysts:
 - ***BNC101*** Cancer Stem Cell (CSC) targeting antibody entering clinic in 2015 (***colon, pancreatic cancer***)
 - ***BNC420***, a modulator of VEGFR3 in preclinical development for treatment of ***melanoma and breast cancer***
 - Additional, partnerable drug candidates - ***BNC164 (Kv1.3, psoriasis)*** and ***BNC105 (kidney cancer, ovarian cancer & other solid tumour types, chronic lymphocytic leukaemia)***








Strong financial position

FY 2014 results:

- Cash at 30 June 2014: \$10.5m
 - Cash position boosted post 30 June 2014:
 - US\$20m upfront payments from Merck
 - \$7.5m cash from Australian R&D Tax Incentive refund for FY14
- Revenue for the period: \$27.5m
- Operating profit after tax: \$3.2m



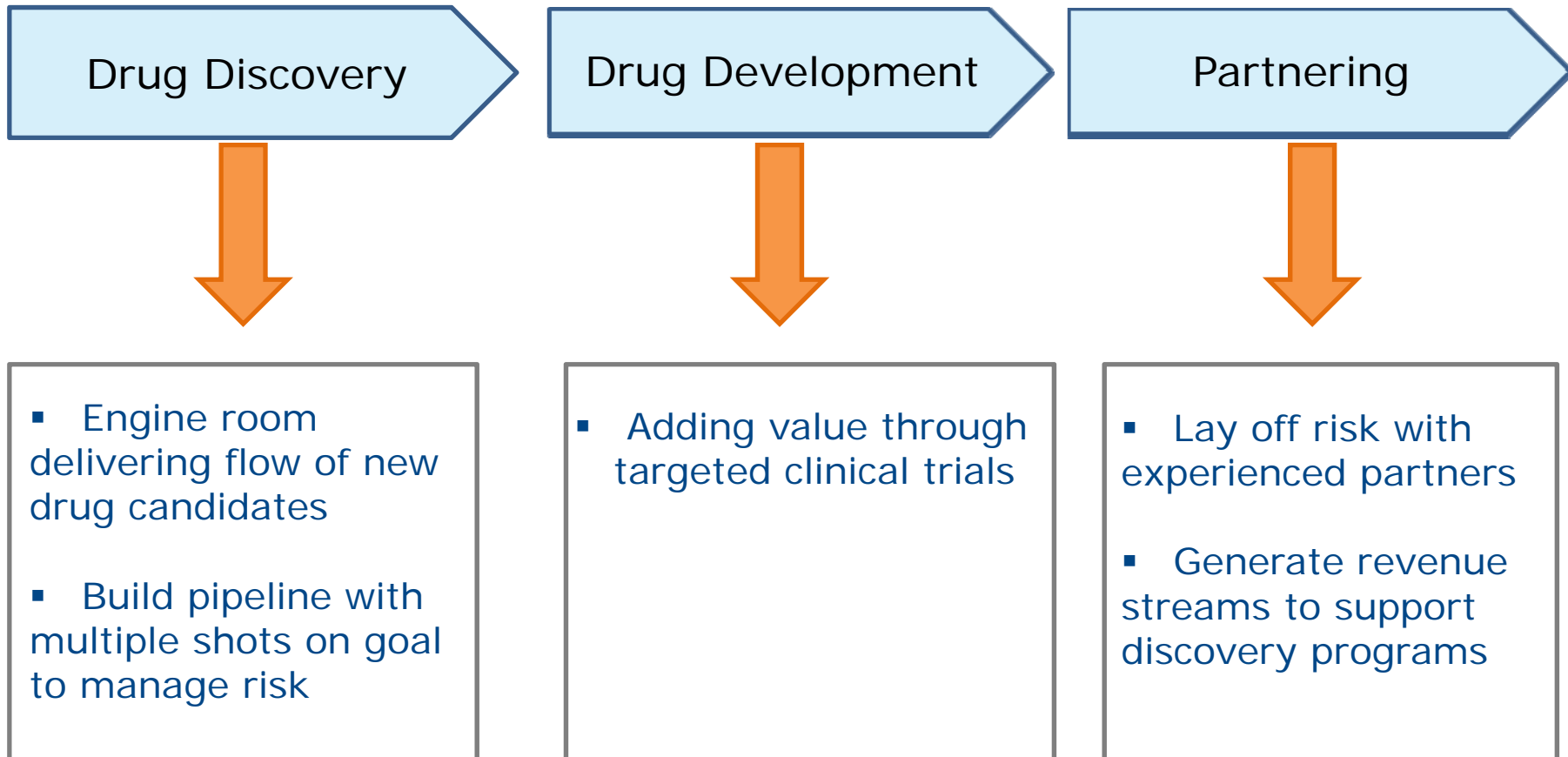
Platform technologies deliver multi-product pipeline, leveraging core strengths

THERAPEUTIC AREA	DRUG CANDIDATE/PROGRAM	DISCOVERY	PRE-CLINICAL	PHASE I	PHASE II	LICENSEE/PARTNER
CANCER	BNC105 – Solid tumours, renal, ovarian, mesothelioma					 
	BNC101 – Cancer stem cells, solid tumours, colon, breast, pancreatic					
	BNC102 – Cancer stem cells, solid tumours					
	BNC420 – Solid tumours, melanoma, breast					
	MELK. PRMT1					
CENTRAL NERVOUS SYSTEM	BNC210 – Anxiety/Depression					  
	BNC375 – Cognitive impairment, Alzheimer's disease, Parkinson's, ADHD, schizophrenia					
	GABA-A – Epilepsy					
	Undisclosed - Pain					
IMMUNE DISEASE	BNC164 –Psoriasis, multiple sclerosis, rheumatoid arthritis					

★ Targeted licensing point



Managing the Execution Risk: The Bionomics Business Model





Bionomics Acquires Prestwick Chemical

- Acquisition expands BNO capacity to rapidly generate high-value drug candidates for partnering and development
 - Prestwick worked on Bionomics BNC375 program and is currently engaged on Bionomics' pain program, both programs are partnered with Merck & Co
- Prestwick is a premium provider of medicinal chemistry services and smart screening libraries to major pharmaceutical companies
 - Founded in 1999 by Professor CG Wermuth, a world renowned expert in medicinal chemistry, and senior scientists from Strasbourg University
 - Reported revenues for the year to 31 December 2013 of €4.292 million
 - Assets purchased for €270,000
 - Prestwick will continue its business as a CRO, in the same way that Bionomics' wholly owned subsidiary Neurofit operates
- Co-located with Neurofit, expertise and customer base are highly synergistic



Prestwick Customers

Prestwick is a premium provider of chemistry services to:

- Big pharma



- Mid-sized pharma:
in France, Germany, Switzerland, USA ...
- Biotech firms:
in Austria, Australia, France, Germany, Israel, Switzerland,
USA ...





Bionomics - Merck & Co BNC375 Program Partnership

- Targeting cognitive impairment – Alzheimer's disease, Parkinson's disease & other conditions
- Covers Bionomics' research program on BNC375 and related compounds
- Potential for up to US\$506 million in payments to Bionomics *plus* royalties on net product sales
 - Upfront payments of US\$20 million Market opportunity includes many neurodegenerative & psychiatric disorders
- BNC375 targets a receptor critical to cognitive processes
- BNC375 has demonstrated potent in vivo memory enhancing properties in animal models
 - Both episodic and working memory improved
 - 100-fold therapeutic dose range & wide safety window in studies to date



BNC375 Program: Market Potential

- Market opportunity includes many neurodegenerative & psychiatric disorders

	Prevalence	Estimated global sales pa
Alzheimer's disease	9.7m	\$10.2b (2012)
Cognitive Dysfunction in Schizophrenia	3.4m	No approved products
ADHD	44.9m	\$4.9b
Parkinson's disease	7m	\$3.5b

- Alzheimer's disease is the most common form of dementia and the 6th leading cause of death in the US
- 40% growth in Americans over 65 with Alzheimer's by 2025
- Direct cost of Alzheimer's care in the US in 2014 \$214b
- Need for new treatments, with no new drug for a decade.



BNC375: Potential Competitive Advantages*

Characteristics	Bionomics BNC375	Competing Agents+
Potent	✓	✓
Rapid onset of action	✓	✗
Potentiates endogenous receptor ligand	✓	✗
Preserve the normal signalling patterns of the receptor	✓	✗
Do not cause receptor desensitization	✓	✗
No potential for development of tolerance	✓	✗

*Based on data from preclinical animal studies

+Published information & Bionomics' in-house data



US\$172m pain partnership with Merck & Co

- Deal further validates ionX® & MultiCore® drug discovery platforms
- Value creation through strategic partnering business model
- Future success based revenue streams & royalties secured

Partnership Deal	<ul style="list-style-type: none">▪ Option & license agreement with Merck & Co▪ <u>US\$172m</u> in option exercise fees, development/regulatory milestone payments, plus royalties
Compound Target	<ul style="list-style-type: none">▪ Treatment of chronic & neuropathic pain
Market Size & Positioning	<ul style="list-style-type: none">▪ Pain market: ~US\$22b sales in 2010▪ Neuropathic pain segment expected to grow from ~US\$2.4bn in 2010 to~ US\$3.6bn by 2020▪ Current medications have limited effectiveness<ul style="list-style-type: none">▪ Estimated that only 1 in 4 patients achieve >50% reduction in pain levels▪ side-effects eg drowsiness, somnolence & dizziness



BNC210: A next generation compound with potential in the treatment of anxiety and depression

TREATMENT	Anxiety and Depression
MARKETS	<ul style="list-style-type: none">Anxiety – global sales of US\$5-7bn annuallyDepression – global sales US\$11bn in 2008
CLINICAL/ REGULATORY	<ul style="list-style-type: none">Phase I trial program included a trial assessing panic attack symptoms; BNC210 prevented panic attack and reduced panic attack symptomsBNC210-related changes in human brain activity observed, indicative of efficacy in absence of sedationBNC210 has an excellent safety profile

POTENTIAL COMPETITIVE ADVANTAGES OF BNC210*						
DRUG	NO SEDATION	NO WITHDRAWAL SYNDROME	NO MEMORY IMPAIRMENT	FAST ACTING	NO DRUG/DRUG INTERACTIONS	ONCE-A- DAY DOSING
BNC210	✓	✓	✓	✓	✓	✓
VALIUM	✗	✗	✗	✓	✓	✓
PROZAC	✓	✗	✓	✗	✗	✓

*Based on data from preclinical animal studies and Phase I clinical trials



BNC210 Phase I trial: BNC210 vs Lorazepam

- BNC210 was compared with Valium-like anti-anxiety drug Lorazepam in a double-blinded, placebo controlled trial involving 21 subjects.
- BNC210 clearly outperformed Lorazepam in tests measuring attention, memory, co-ordination, sedation & potential for addiction.
- EEG data showed BNC210-related changes in human brain activity indicative of efficacy.

DRUG/EEG ACTIVITY	δ	γ	α	$\alpha 1$	$\alpha 2$	β	$\beta 1$	$\beta 2$	$\beta 3$
BNC210			↓		↓	↑			↑
LORAZEPAM	↑	↓	↓	↓	↓	↑	↑	↑	↑

Increased sedation

Reduced anxiety



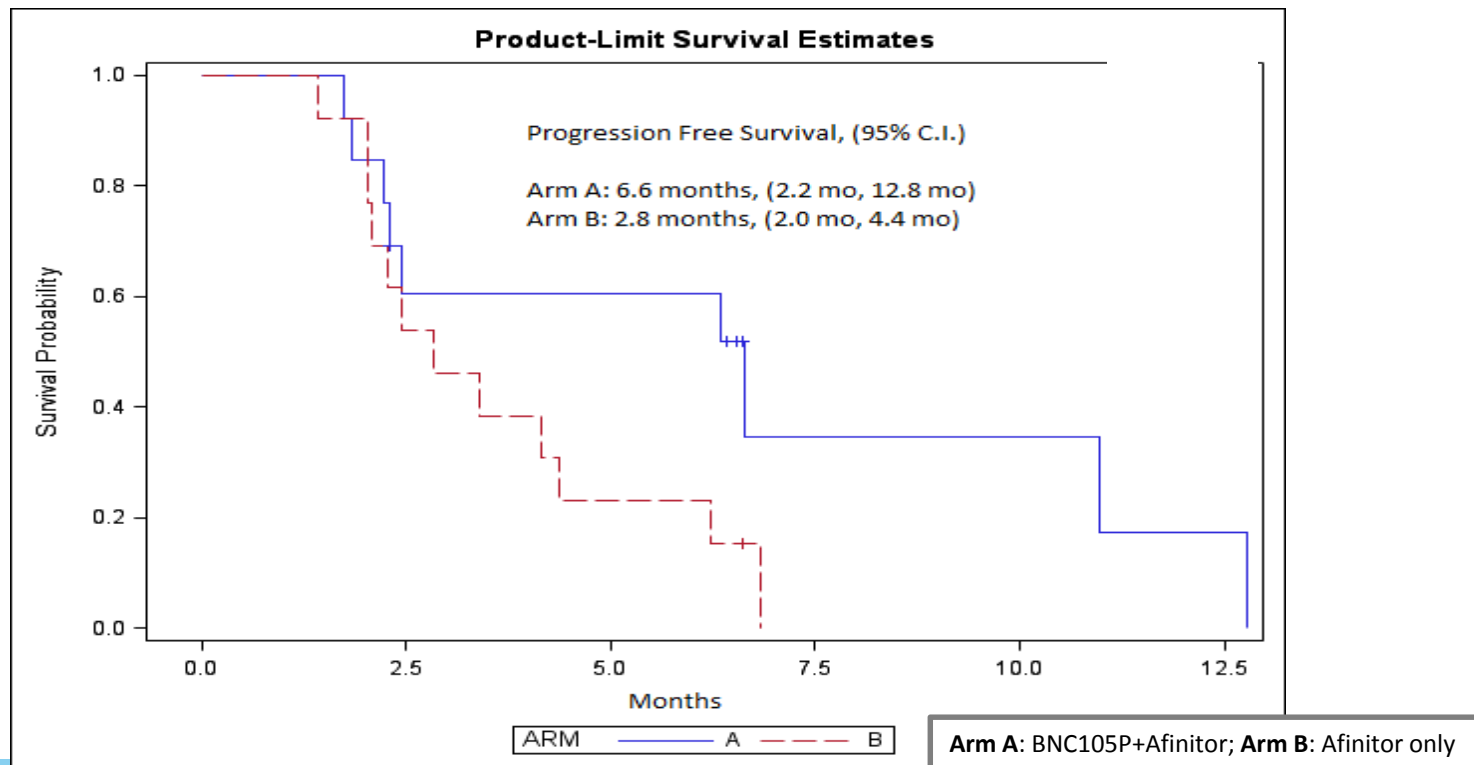
BNC105: “Best in Class” vascular targeting agent with unique mechanism of action

TREATMENT	<ul style="list-style-type: none">▪ Solid Cancers: New paradigm with blockbuster potential
MARKETS	<ul style="list-style-type: none">▪ The current market size in treatment of all solid tumours is >US\$10b▪ Renal cancer market size >US\$2.5bn; includes TKIs Sutent (<i>Pfizer</i>), Nexavar (<i>Bayer/Onyx</i>), Afinitor (<i>Novartis</i>)▪ Ovarian cancer market size ≈US\$2.2bn; includes carboplatin (<i>BMS</i>), gemcitabine (<i>Gemzar, Eli Lilly</i>)
BENEFITS	<ul style="list-style-type: none">▪ Multi Action – selectively targets both tumour blood vessels and cancer cells▪ Rapid, Potent Action – works rapidly to shut down tumour blood vessels, potent anti-tumour action as a single agent, tumour less likely to escape treatment▪ Enhances Effectiveness of Other Cancer Treatments – delivers synergistic anti-cancer effects in numerous combinations (e.g., anti-VEGF therapies and platin based drugs)



DISRUPTOR-1: BNC105 combination treatment benefited patients with advanced disease

- Addition of BNC105 to Afinitor treatment in unselected patient population did not improve PFS
- Addition of BNC105 to Afinitor treatment delayed disease progression in patient subgroups identified on the basis of metastases, previous nephrectomy and Fuhrman tumour differentiation grade
- Biomarker changes correlated with progression-free survival in a statistically significant manner (p-values of 0.0136 to 0.0348)
- ***Biomarker data will be presented at ESMO end September***
3.8 month increase in PFS in patients with liver metastases





BNC105: Phase I Ovarian Trial Results

- Combination study (carboplatin + gemcitabine chemotherapy + BNC105) in partially platinum sensitive ovarian cancer patients in first or second relapse
- 15 patients enrolled
- 10 patients achieved a positive response according to RECIST 1.1 and/or GCIG CA125 criteria
- 12 patients completed six cycles of combination therapy and commenced with BNC105 monotherapy
- 1 patient has completed the protocol-prescribed 12 cycles of treatment comprised of 6 cycles of combination therapy and 6 cycles of BNC105 monotherapy, and continued on BNC105 monotherapy
- Side-effects related to gemcitabine + carboplatin treatment backbone; haematological origin
- Recommended BNC105 Phase II dose: 12mg/m² in combination with carboplatin and gemcitabine



BNC101: Targeting cancer stem cells in solid tumours

TREATMENT	Solid tumours; colon & pancreatic are priority indications
MECHANISM OF ACTION	<ul style="list-style-type: none">▪ Humanised monoclonal antibody▪ BNC101 binds selectively to LGR5; LGR5 marks tumour-initiating cells in colon & gastric cancer▪ LGR5 highly overexpressed in colon, ovarian, liver, breast, lung & other solid tumours▪ High expression of LGR5 in colon cancer has been linked to tumour recurrence & poor prognosis
MARKETS	Market for cancer stem cell therapeutics estimated as US\$8B by 2018
DEVELOPMENT STAGE	IND filing and Phase I clinical trials target 2015
BENEFITS	<p>Inhibition of tumour recurrence</p> <p>Specific targeting of cancer stem cells which are not killed by either chemotherapy or radiotherapy</p>



VEGFR3 Program: BNC420

- Innovative therapeutic strategy - suppressing tumour progression by targeting lymphangiogenesis and tumour-induced immune tolerance
- VEGFR3 is a well validated target for tumour lymphangiogenesis and was recently demonstrated to drive tumour-induced immune tolerance
- BNC420 inhibits VEGFR3 phosphorylation, with favorable PK and safety profile, orally active
 - Displays selectivity over VEGFR2 and this provides broad scope for long term use in maintenance and adjuvant settings as well as potential for safe inclusion in combination regimens
- Indications include Melanoma and Triple Negative Breast Cancer



Investment Highlights

- Robust business model with multiple revenue generating streams through strategic partnering
- Demonstrated in FY14 through two partnership deals with Merck & Co:
 - Cognition eg Alzheimer's Disease: Research collaboration and license agreement, up to US\$506 million in upfront, research and milestone payments, **plus** royalties on product sales
 - Pain: Option and license agreement, up to US\$172 million in fees and milestone payments, **plus** royalties on product sales.
- Further significant partnerships anticipated which will continue to validate business model and technology – 3 programs targeted for partnering
- Addressing major market opportunities:
 - Pain market: ~US\$22bn sales in 2010
 - Alzheimer's disease - \$10.2bn in 2012
 - Anxiety – global sales of US\$5-7bn annually
 - Depression – global sales US\$11bn in 2008
- Near-term value inflection points with key data releases at upcoming ESMO, Society for Neuroscience etc in addition to partnership opportunities
- Well financed, first profit in FY14



ASX:BNO

www.bionomics.com.au