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 (January 2014)	
ASX code	BNO
Share price (30/1/14)	A$0.72
52 week high	A$0.89
52 week low	A$0.315
Shares on issue	~412.2M
Market capitalisation	~A$297M
Cash 31/12/13	A$20.4M

6 MONTH SHARE PRICE PERFORMANCE

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

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

Our Business

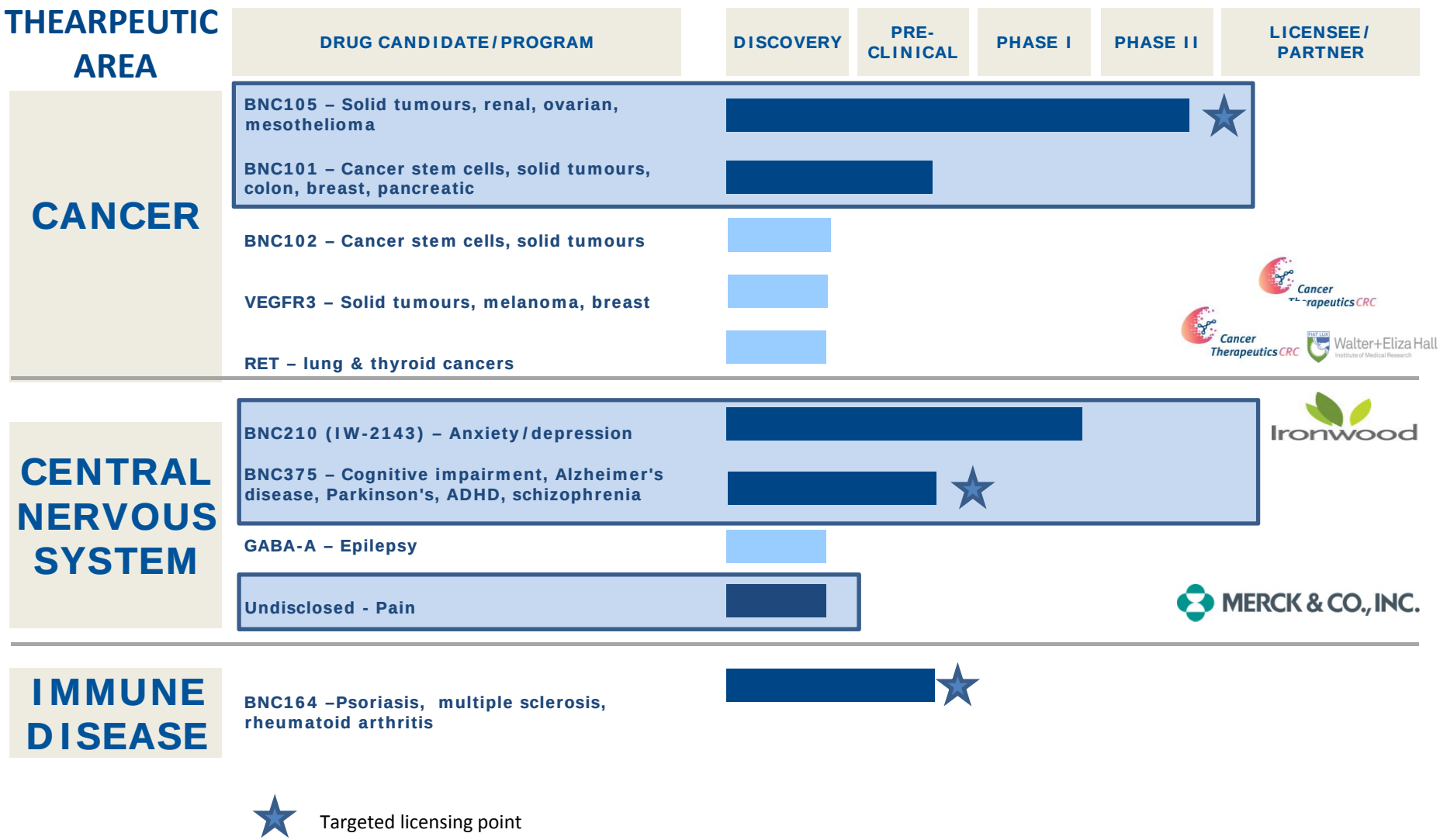
- Bionomics is a leader in the discovery and development of innovative biopharmaceuticals with operations in Australia, Europe and US.

- The company undertakes discovery, development and strategic partnering of first in class and best in class drugs:
  - Most recent partnership with Merck & Co on pain program.
  - Option and license agreement, up to US$172 million in fees and milestone payments, plus royalty on product sales.

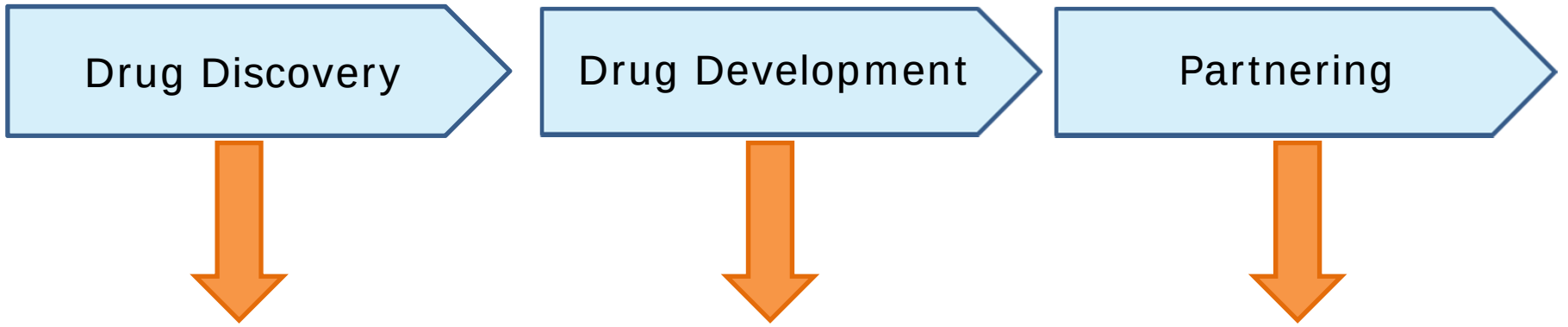
- Focus is on serious medical conditions including cancer and central nervous system disorders; aim is to deliver treatments that offer substantially improved patient outcomes.

- Broad and deep portfolio of clinical and preclinical drug candidates:
  - ***BNC105*** solid tumour targeting agent in Phase II trials for renal and ovarian cancer with key data in 2014
  - ***BNC210 (IW-2143)*** targeting anxiety and depression partnered with Ironwood Pharmaceuticals
  - ***BNC101*** and ***BNC102*** Cancer Stem Cell (CSC) targeting antibodies, ***BNC101*** entering clinic in 2014
  - Partnerable ***BNC164 (Kv1.3, psoriasis)*** and ***BNC375 (α7 nicotinic acetylcholine receptor modulator, Alzheimers Disease and Parkinson's Disease)*** drug candidates anticipated to generate additional near term value inflection points

Platform technologies deliver multi-product pipeline, leveraging core strengths



Managing the Execution Risk: The Bionomics Business Model



- Engine room delivering flow of new drug candidates
- Build pipeline with multiple shots on goal to manage risk

- Adding value through targeted clinical trials

- Lay off risk with experienced partners
- Generate revenue streams to support discovery programs

Value creation: past 12 months

- Positive results from BNC105 Phase I ovarian cancer trial, supports continued development in ovarian cancer setting
- BNC105 renal cancer phase II trial completed enrolment, data anticipated in Q1, nearing partnering phase
- BNC101 cancer stem cell (CSC) antibody pre-IND filing, IND filing and Phase I clinical trial initiation anticipated in 2014
- US$172M pain partnership with Merck & Co
- Advancing partnership discussions on BNC375 and Kv1.3 drug candidate BNC164, with increased competitive field
- Partnership with CRC-Cancer Therapeutics yields potential new cancer drug candidate for the treatment of melanoma

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

TREATMENT	▪ **Solid Cancers: New paradigm with blockbuster potential** through rational combination with molecular targeted therapies that benefit from induction of tumour hypoxia
MARKETS	▪ The current market size in treatment of all solid tumours is >US$10b ▪ Renal cancer market size >US$2.5bn; includes TKIs Sutent (*Pfizer*), Nexavar (*Bayer/Onyx),* Afinitor (*Novartis)* ▪ Ovarian cancer market size ≈US$2.2bn; includes carboplatin (*BMS*), gemcitabine (Gemzar, *Eli Lilly)*

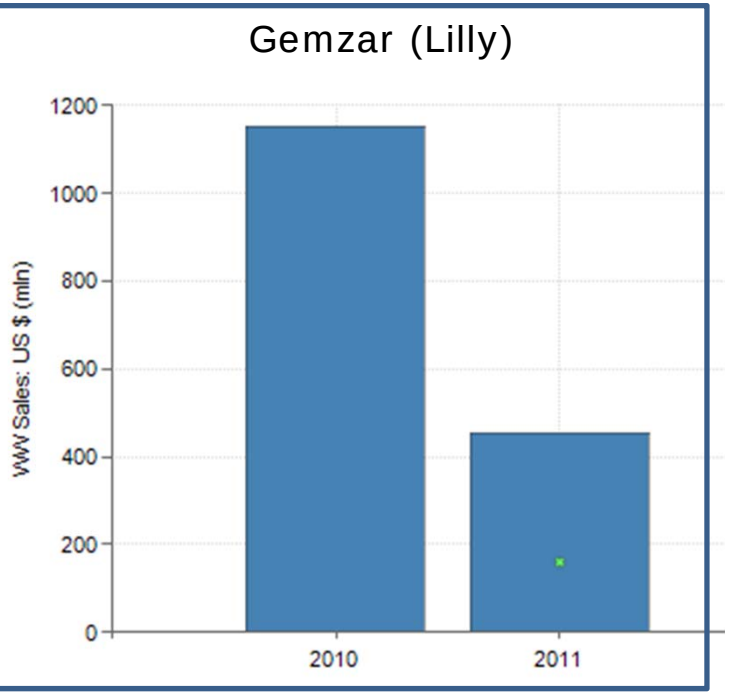
CLINCAL	▪ Phase II Renal cell cancer (US, Australia, Singapore)
	  ▪ Trial design: randomized 2-arm; Afinitor+/- BNC105; enrolment of 139 patients completed; patients previously failed TKI therapy; Primary endpoint 6 month PFS; data anticipated 1Q, 2014
	  ▪ **Phase I results:** combination BNC105 + Afinitor safe and well tolerated; 12 patients enrolled across 4 BNC105 dose levels (4-16mg/m^2); 8 patients achieved stable disease; 1 patient still on study having received 24 treatment cycles (72 weeks, 18 months)
	  ▪ Phase II data imminent
	▪ Phase II Mesothelioma (Australia): single arm; BNC105 following Alimta + cisplatin failure; 30 patients enrolled; 1 patient with durable & sustained partial response with corresponding reduction in mesothelin levels; 13 patients with stable disease
	▪ Phase I/II Ovarian cancer (Australia, New Zealand, US)
	  ▪ Phase I enrolment completed; carboplatin (*BMS*) and gemcitabine (*Lilly*) + BNC105; population partially sensitive to platinum-based therapy
	  ▪ Phase I data highly encouraging, supportive of further development in this indication

BENEFITS	▪ ***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)

Significant Market Opportunity for BNC105

- Potential to extend sales of existing drugs through combination
- Many marketed drugs face patent expiries within the next 5 years

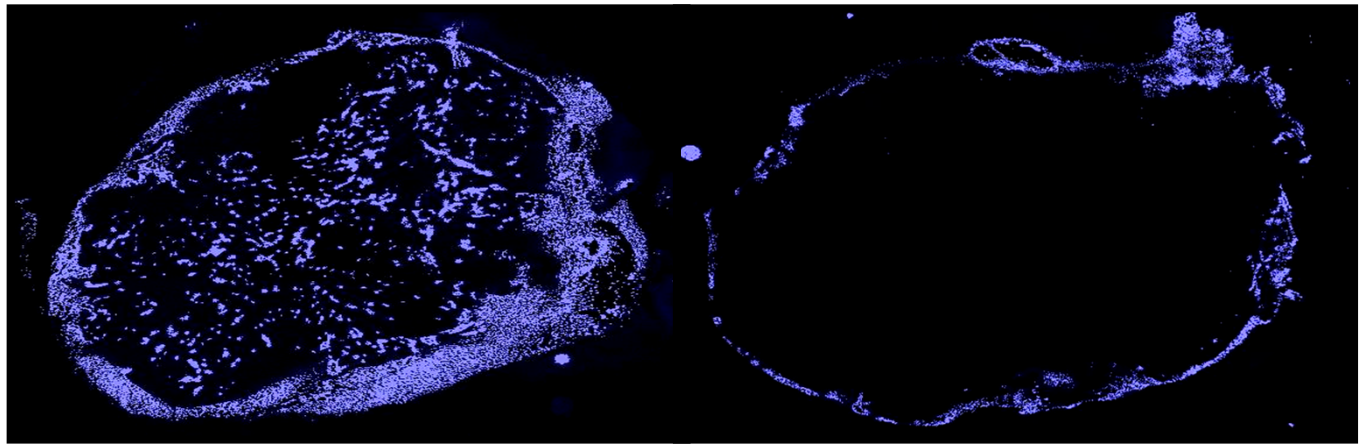
Drug	Company	2012 Sales (US$ MM)
Sutent	Pfizer	$1,300
Avastin	Roche	$2,400
Afinitor	Novartis	$800
Inlyta	Pfizer	$180
Nexavar	Onyx/Bayer	$1,000
Votrient	GSK	$340



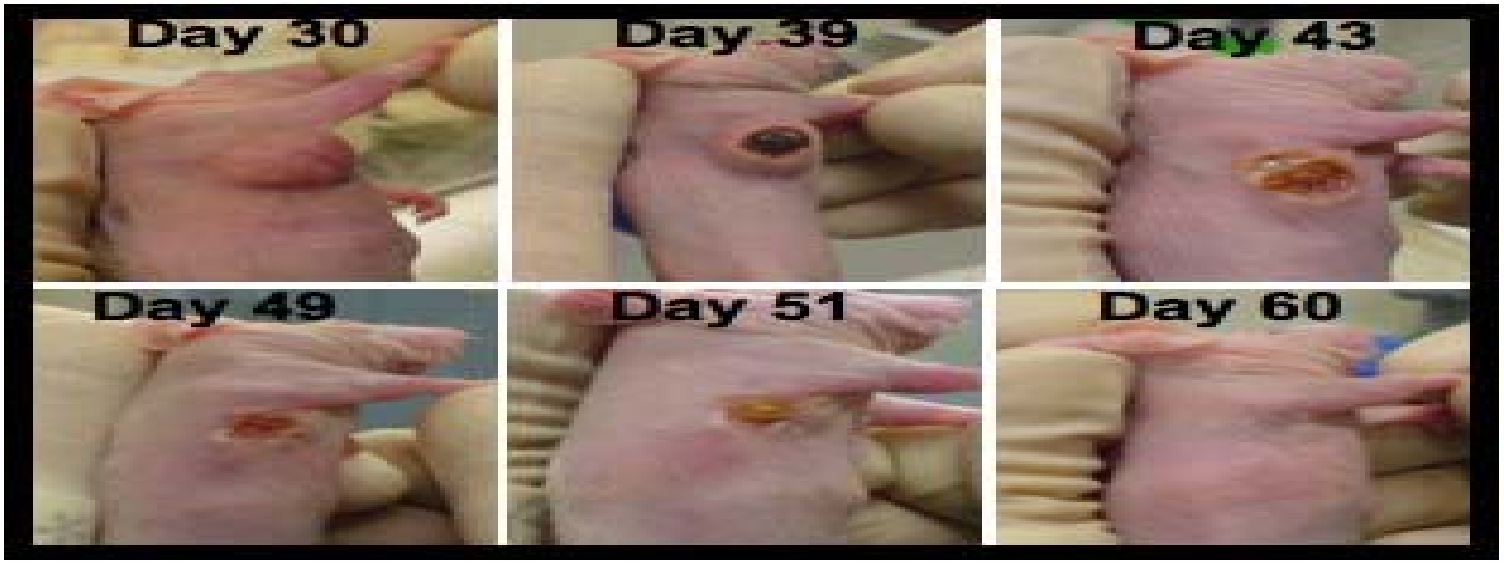
BNC105: Targeting Solid Tumours

By selectively shutting down tumour blood vessels, BNC105 rapidly inhibits tumour growth

untreated



BNC105 treated

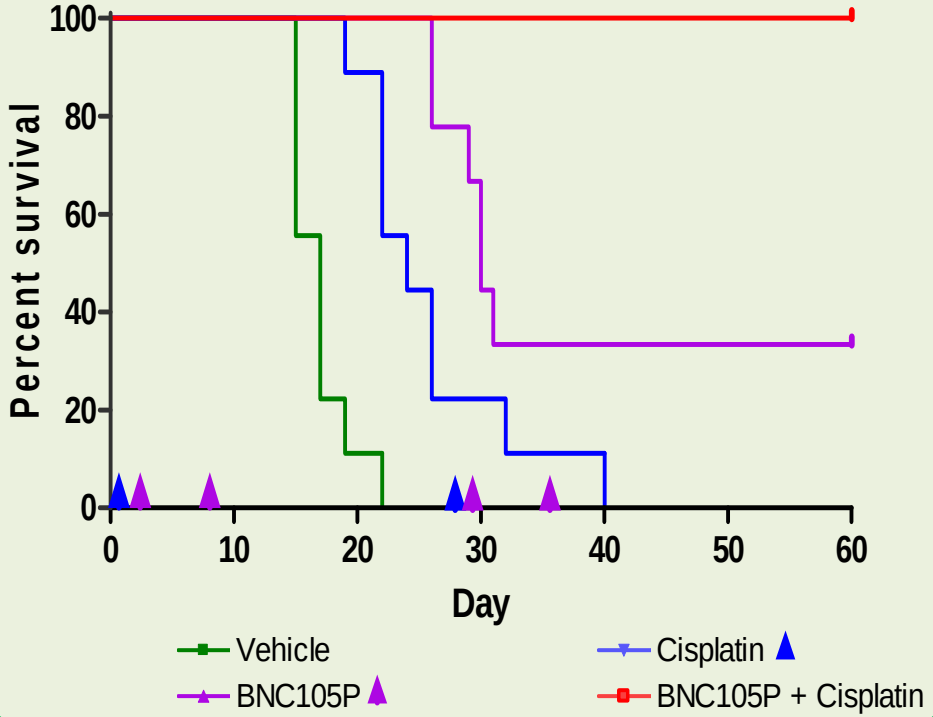


BNC105: Ovarian cancer

Ovarian cancer is 5th leading cause of cancer-related death among women. In the US Ovarian Cancer is responsible for:

- **21,880 new cases & 13,850 deaths (2010)**
- **~US$2.2b pa spent in treatment.**

- BNC105 preclinical data supports ovarian cancer trial:
  - Potent cytotoxic for platin sensitive and resistant ovarian cancer cells
  - Inhibits tumour growth and improves survival in cisplatin-resistant ovarian cancer model
  - **Treatment of lung cancer-bearing animals with BNC105 + cisplatin results in 100% survival**



BNC105 Phase I clinical trial in women with ovarian cancer

Name of Trial	Phase I/II BNC105 combination study in partially platinum sensitive ovarian cancer patients in first or second relapse
Primary Endpoints	Phase I: To determine the Recommended dose of BNC105 given with gemcitabine and carboplatin.
Correlative Endpoints	1. Effect of combining these drugs on the pharmacokinetics of BNC105 2. Associations between baseline biomarkers, ORR, PFS, OS and AE
Study Design	Single-arm Phase I (3-6 participants per dose level)
Treatment Method (route/frequency/dose levels)	Phase I: Carboplatin AUC 4 day 1, Gemcitabine escalations 800 and 1000mg/m^2 days 1 and 8, BNC105P at days 2 and 9, all q21 days for a maximum of 6 cycles, followed by single agent maintenance 16mg/m^2 BNC105 for a maximum of 6 additional cycles..
Number of Trial Subjects	Phase I: 15 participants.
Patient Population	The target population for Phase I was women with ovarian cancer with a progression-free interval > 4 months after first or second line platinum based chemotherapy.
Trial Locations	Australia, New Zealand, USA.
Trial Standard	ICH-GCP

Phase I Ovarian Trial Results

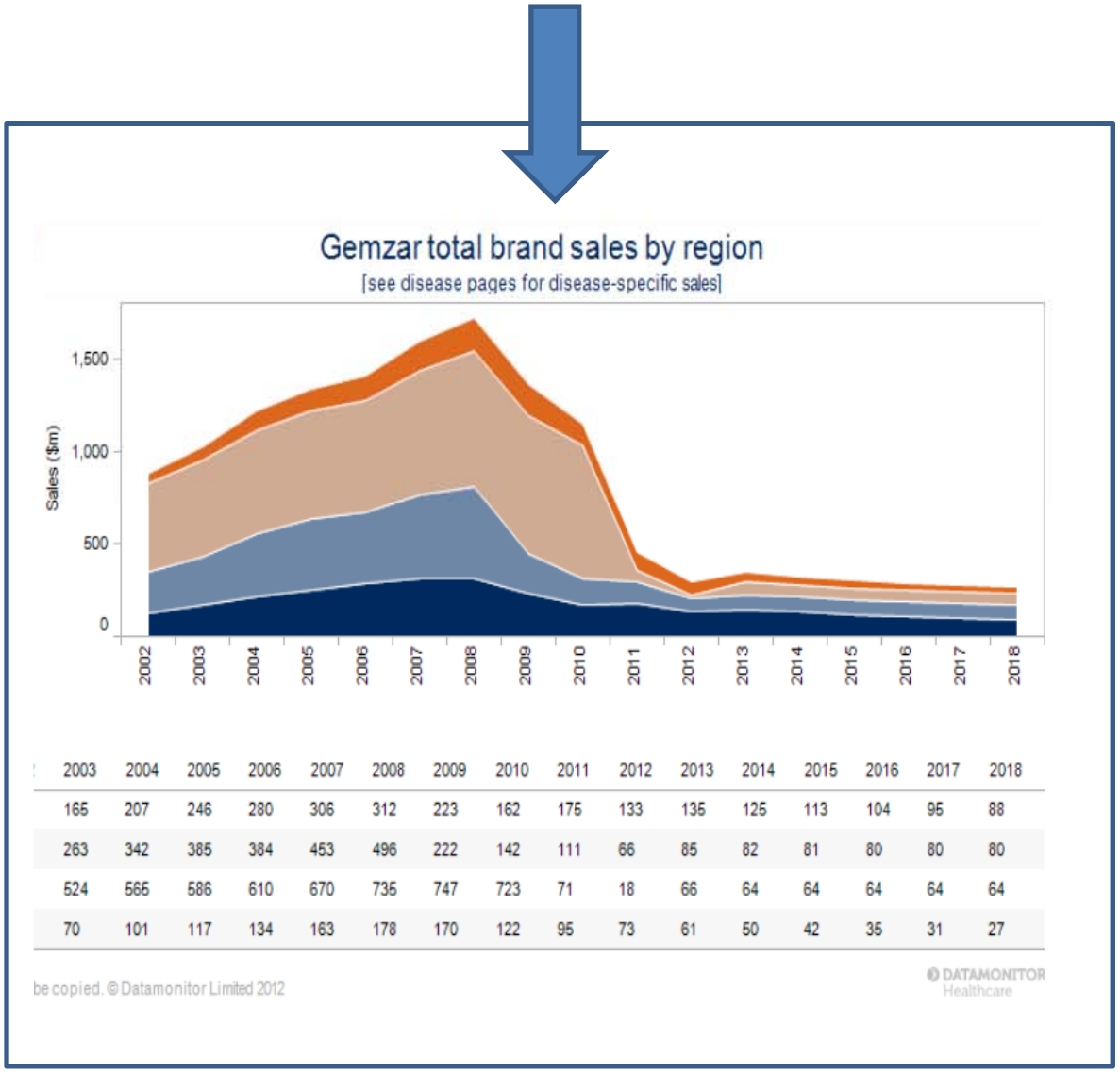
- 15 patients enrolled
- 10 patients achieved a positive response according to RECIST 1.1 and/or GCIG CA125 criteria
- 12 patients completed six cycles of combination therapy and commenced with BNC105 monotherapy
- 1 patient has completed the protocol-prescribed 12 cycles of treatment comprised of 6 cycles of combination therapy and 6 cycles of BNC105 monotherapy, has continued on BNC105 monotherapy since
- 3 patients currently continuing with treatment
- Mean number of treatment cycles across the study is 8.8, 1 treatment cycle = 3 weeks
- Side-effects related to gemcitabine + carboplatin treatment backbone; haematological origin
- Recommended BNC105 Phase II dose:12mg/m^2 in combination with carboplatin and gemcitabine

Biomarker analyses show BNC105 achieves a pharmacodynamic response

Biomarker responses have been observed in previous clinical trials with BNC105

Pharmacodynamic marker	Ovarian ($12mg/m^2$)	Mesothelioma ($16mg/m^2$)	Renal ($4.2\text{-}16mg/m^2$)
Ferritin	✓	✓	✓
Interleukin-8 (IL-8)	✓	✓	✓
Interleukin-10 (IL-10)	✓	✓	-
Interleukin-16 (IL-16)	✓	✓	✓
Macrophage Inflammatory Protein-1B (MIP-1Beta)	✓	✓	✓

Gemzar Patent Cliff



2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
165	207	246	280	306	312	223	162	175	133	135	125	113	104	95	88
263	342	385	384	453	496	222	142	111	66	85	82	81	80	80	80
524	565	586	610	670	735	747	723	71	18	66	64	64	64	64	64
70	101	117	134	163	178	170	122	95	73	61	50	42	35	31	27

BNC105 in Renal Cancer

BNC105 offers the potential for a paradigm shift in Renal Cancer therapy to improve patient outcomes:

- ***Ability to combine with existing, treatments:*** A **P**ulsatile **A**ctivator of **T**umour **H**ypoxia (**PATH**), BNC105 synergizes with targeted therapies that exploit tumour adaptive responses to hypoxia, combinable with all targeted agents currently marketed for Renal Cancer including Avastin (Roche), Afinitor (Novartis), Votrient (GSK) and Inlyta (Pfizer) for example
- ***Safe, effective, limited side effects:*** Mechanism of action that is sparing of non-tumour tissues
- ***Strong IP position:*** key patent claims have been granted in major markets
- ***Potential to dominate the Renal Cancer market*** as the high margin component of combinations comprising BNC105 therapy plus current or emerging targeted drug therapies

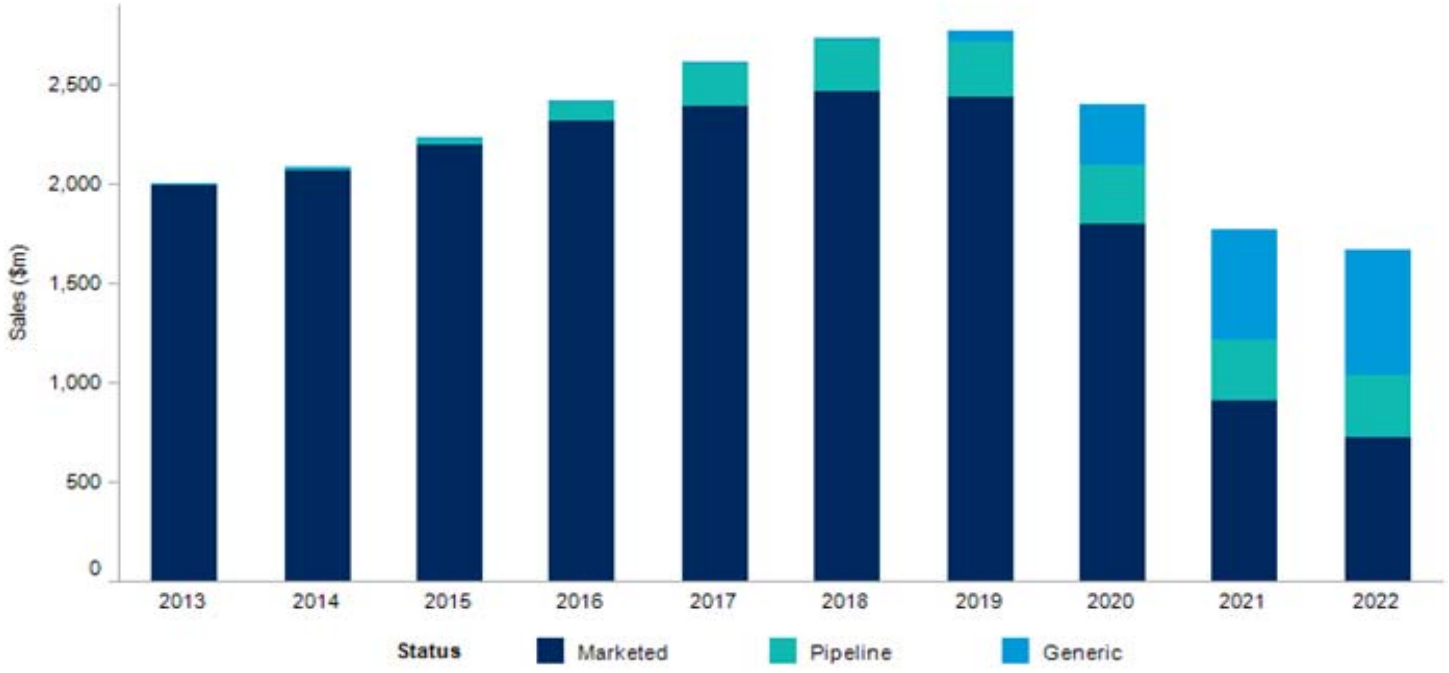
Prognosis remains poor for patients with advanced or metastatic Renal Cancer

Stage Distribution and 5-year Relative Survival by Stage at Diagnosis for 2003-2009, All Races, Both Sexes		
Stage at Diagnosis	Stage Distribution	5-year Relative Survival
Localized (confined to primary site)	63%	91.7%
Regional (spread to regional lymph nodes)	17%	64.2%
Distant (cancer has metastasized)	**17%**	**12.3%**

SEER Stat Fact Sheets: Kidney and Renal Pelvis
http://seer.cancer.gov/statfacts/html/kidrp.html

Based on NCI SEER Cancer Statistics Review 1975-2010
Updated June 14, 2013
http://seer.cancer.gov/csr/1975_2010/

Patent expirations will lead to loss of market share for targeted drugs in RCC



Sales 2013-22:	**Min:**	2022	$1,672m	**CAGR 2013-22:**	-1.98%	**Sales Change 2013-22:**	-$329m
	Max:	2019	$2,770m				

CAGR = compound annual growth rate

Source: Datamonitor Healthcare

BNC105 could dominate the RCC market:

- *Recouping high margin sales of current targeted therapies*
- *Extending sales of emerging drugs*

Potential for significant licensing deal following on from Phase II data

Acquisition of World Leading Cancer Stem Cell (CSC) Assets

- In September 2012, Bionomics acquired Eclipse Therapeutics, a Biogen-Idec spin-out:
  - CSCs missing link in treating solid tumours
  - Resistant to conventional therapies
  - Eradicating CSCs may prevent tumour recurrence
  - Complements the BNC105 program by targeting the “seeds” of cancer
- First cancer stem cell program, BNC101, has progressed steadily towards human clinical trials:
  - √ GMP manufacture by Lonza
  - √ IND enabling studies commenced
  - √ Pre-IND submission to FDA and response November 2013

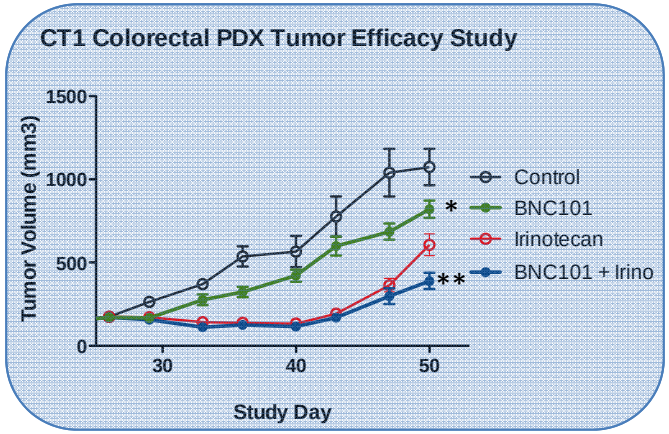
Anticipated IND filing and start of Phase I in 2014

BNC101: Targeting cancer stem cells in solid tumours

TREATMENT	Solid tumours; colon, breast, pancreatic are priority indications
MOA	▪ 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 2014
BENEFITS	First-in-class therapeutic antibody against a validated CSC target Specific targeting of cancer stem cells

BNC101 Targets Cancer Stem Cells to Prevent Tumour Recurrence

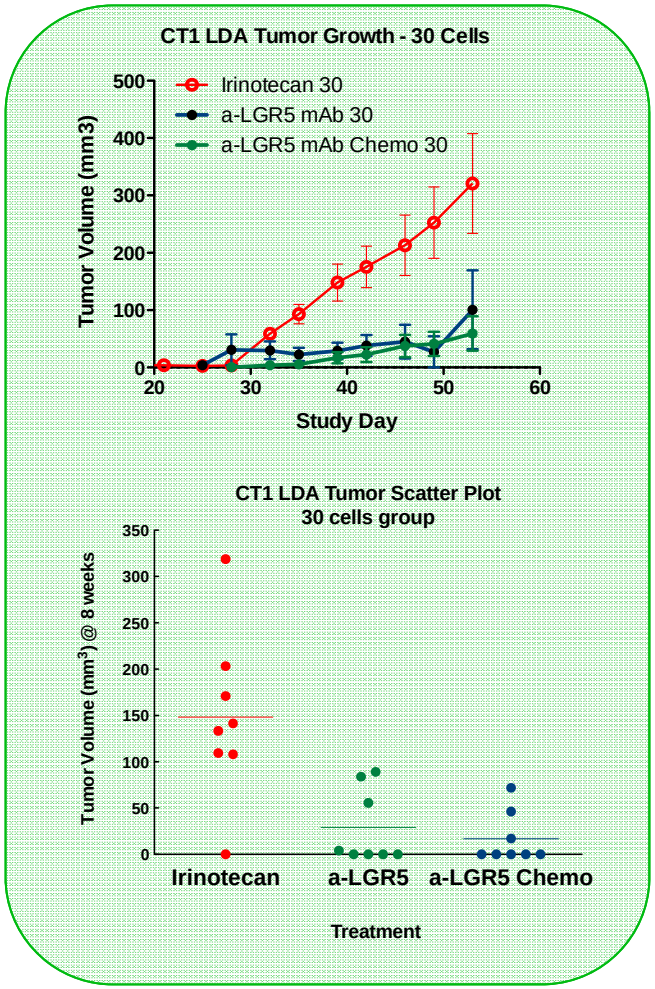
Primary Tumor Efficacy Study



* P < 0.001 vs Control; ** P < 0.001 vs Irinotecan
Ab dose 15pmk BIW; Irinotecan 10mpk Qdx5

	Patient CT1
Histologic Type **Histologic Grade**	Adenocarcinoma Poorly differentiated Invasive
Stage	IV
Mutations (Ion Torrent deep sequencing)	• K-Ras • PI3K • PTEN • p53
Notable	Patient had liver metastasis

Secondary Cancer Stem Cell LDA re-implant assay



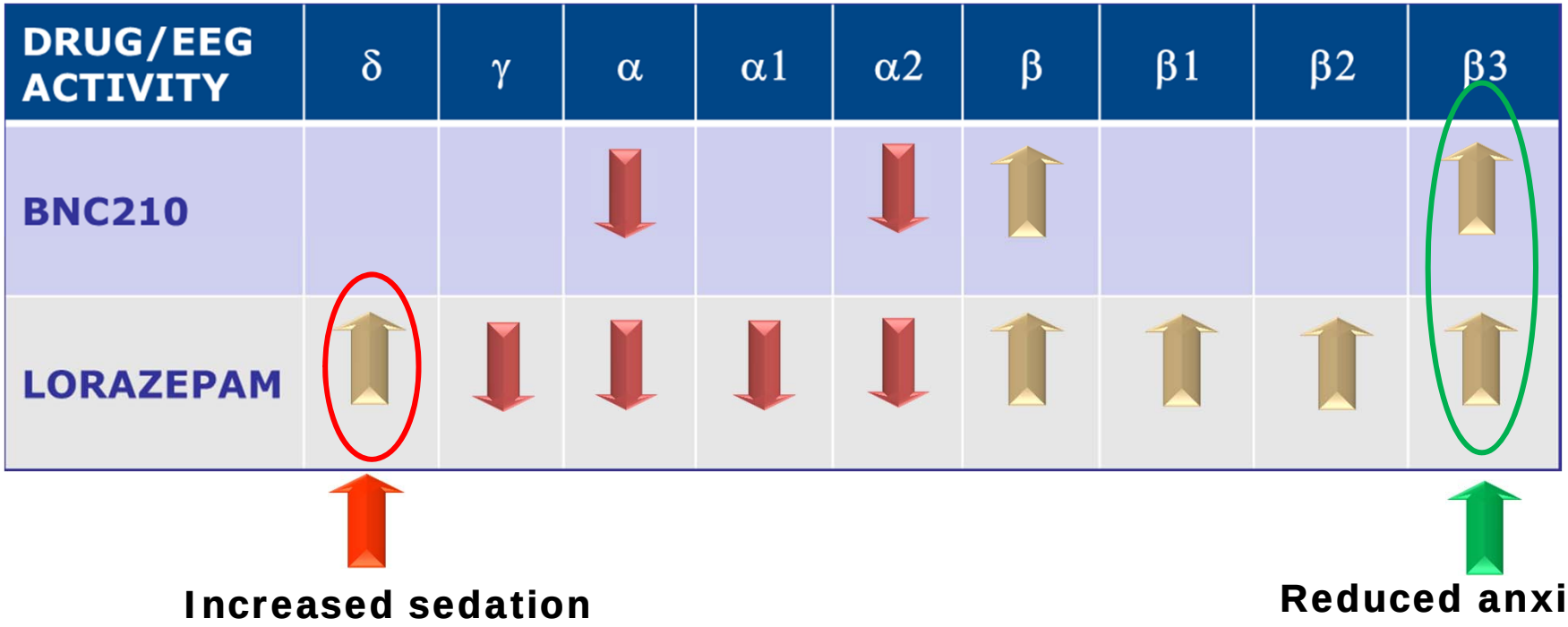
No Treatment in Secondary LDA Assay

BNC210 (IW-2143): A next generation compound with potential in the treatment of anxiety and depression

TREATMENT	**Anxiety and Depression**
MODE OF ACTION	▪ Modulates novel pathway, to promote anti-anxiety activity and neurite outgrowth *in vitro.*
PARTNER	▪ Ironwood Pharmaceuticals
CLINICAL/ REGULATORY	▪ Four Phase I trials completed, including a trial assessing panic attack symptoms: ▪ 59 subjects enrolled in double-blinded placebo controlled trial;15 subjects classified as having a panic attack upon CCK-4 administration ▪ Statistically significant decrease in both number & intensity of symptoms ($p<0.05$) ▪ BNC210 treated subjects returned to normal emotional status within 10 minutes, compared to 60 minutes on placebo ▪ This trend correlated with the statistically significant reduction in panic symptoms by BNC210 ▪ BNC210-related changes in human brain activity observed, indicative of efficacy in absence of sedation ▪ BNC210 has been administered to over 110 healthy subjects to date with excellent safety profile
BENEFITS	▪ Reduced panic symptoms ▪ No evidence of sedation
MARKETS	▪ Anxiety – global sales of US$5-7bn annually ▪ Depression – global sales US$11bn in 2008

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.



BNC210: Fewer side-effects expected to be a key product differentiator

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	✓	✗	✓	✗	✗	✓
BUSPAR	✗	✓	✓	✗	✓	✗

* Based on preclinical data and results of Phase I trial comparing BNC210 with Lorazepam

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	▪ Option & license agreement with Merck & Co ▪ **US$172m** in option exercise fees, development/regulatory milestone payments, plus royalties
Compound Target	▪ Treatment of chronic & neuropathic pain

Market Size & Positioning	▪ Pain market: ~US$22b sales in 2010
	▪ Neuropathic pain segment expected to grow from ~US$2.4b in 2010 to~ US$3.6b by 2020
	▪ Current medications have limited effectiveness
	  ▪ Estimated that only 1 in 4 patients achieve >50% reduction in pain levels
	  ▪ side-effects eg drowziness, somnolence & dizziness

BNC375 for overcoming cognitive impairment and memory loss

- BNC375 is a unique Positive Allosteric Modulator of the α7 NAChR receptor
- Activation of the α7 NAChR receptor improves attention, working memory and recognition memory
- Market opportunity for drugs modulating α7 NAChR activity 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

Competitive advantages of BNC375

Characteristics	Bionomics BNC375	Competing Agents+
Potent	✓	✓
Rapid onset of action	✓	✘
Do not cause receptor desensitisation	✓	✘
No potential for development of tolerance	✓	✘

Strong financial position

FY 2013 results:

- Cash at 30 June 2013: $22.45m
- Net cash inflow for the 12 month period: $4.99m
- Revenue for the period: $3.72m
- Operating loss after tax: $10m

- A$7.0m FY13 Australian government R&D Tax Incentive refund received December 2013
- Anticipated $7.0m cash from Australian R&D Tax Incentive refund for FY14
- Anticipated additional licensing income

Upcoming Milestones

- BNC105 Phase II renal cancer clinical trial results:
  - Encouraging signals of clinical benefit from Phase I
  - BNC105 could dominate the RCC market, recouping high margin sales of current targeted therapies which face patent expirations from 2019
  - Potential for significant licensing deal and further demonstration of Bionomics' business model
- BNC101 IND submission to the FDA, leading to commencement of the first human clinical trial
  - First-in-class therapeutic antibody against a validated Cancer Stem Cell target, specific targeting of the cells responsible for tumour initiation and recurrence
- Partnering of our drug candidates, with negotiations ongoing on BNC375 and BNC164
- Enrichment of the pipeline of drug candidates for development and partnering

ASX:BNO

www.bionomics.com.au