

ASX ANNOUNCEMENT 19 November 2013

# CEO & Managing Director, Dr Deborah Rathjen, Presentation to Bionomics' Annual General Meeting 2013

Welcome to Bionomics' 2013 AGM.

I am pleased to be reporting on the achievement of important milestones across our portfolio through 2013 including progress in drug development and key trials, new partnerships and a high level of market interest.

Bionomics is confident this momentum will continue and build in 2014.

#### **Our Business**

Bionomics is a leader in the development of biopharmaceuticals.

Our business model is to feed big pharma's need to secure new and innovative products and additional significant revenue streams in the face of growing competition from generic drugs once their blockbuster drugs come off patent.

Our model continues to be:

- Using our proprietary drug development platform to advance the most promising compounds in each class with a focus on multi-billion dollar market opportunities
- Focusing on serious diseases like cancer and central nervous system conditions
- Identifying and cementing strategic partnerships to help move drugs through regulatory and commercial pathways and ultimately into the market
- · Continuing to discover compounds and candidates that strategically build our portfolio



## **Bionomics Overview**

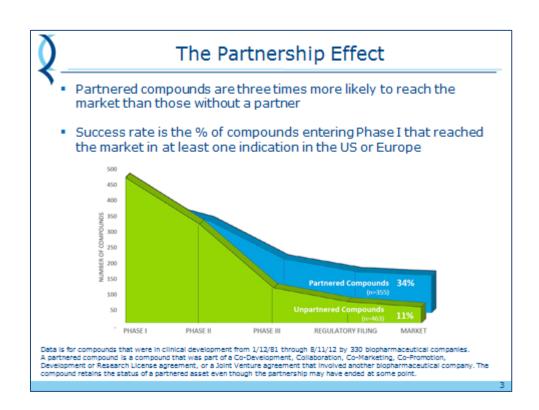
- Bionomics is a leader in the discovery and development of innovative biopharmaceuticals with operations in Australia, Europe and US.
- The company undertakes discovery, development and strategic partnering of first in class and best in class drugs.
- Focus is on serious medical conditions including cancer and central nervous system disorders; aim is to deliver treatments that offer substantially improved patient outcomes.
- Global, strategic partnerships facilitates the advancement of our compounds through regulatory and commercial pathways – leads to better outcomes for all stakeholders.

Strategy to partner our compounds at key value points to crystallise value, improve rate of success and manage risk.

We remain committed to our business model whereby new and existing partnerships play an integral role.

A study by Deloitte/Recap shows the positive effect such partnership deals have on the success rate of drug candidates. It is clear that partnerships exploiting the relative strengths of each partner help bring drug candidates to the market.

It is estimated that, based on data over 30 years and more than 300 biopharmaceutical companies, partnered compounds are three times more likely to be commercialised.



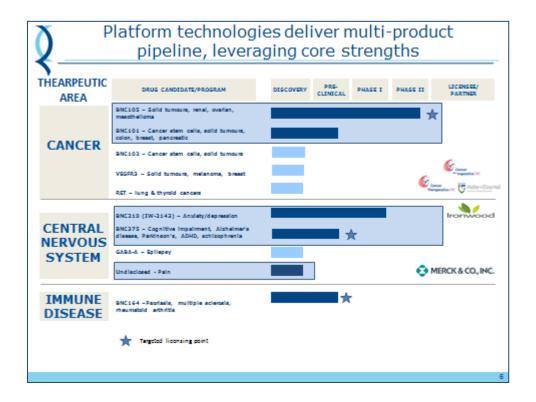
We also remain committed to a balanced portfolio of drug candidates.

Bionomics is focused on two core areas – therapies for cancer and the central nervous system.

We use our platform technologies, ionX<sup>®</sup> for drug discovery targeting ion channels, MultiCore<sup>®</sup> chemistry, Angene<sup>®</sup> and CSCRx<sup>™</sup> in our cancer drug discovery programs, to develop multi-product pipelines.

## 2013 Highlights

I'd like to touch of some of our key value creation points signalled by this overview including targeted licensing points and key partnerships.



Highlights for the year include:

- Steady progress on our phase II BNC105 trial targeting renal cancer that is now fully recruited and holds excellent partnership potential
- A Phase I clinical trial in women with ovarian cancer also completed recruitment this year. We look forward to reporting data from both of these trials early next year.
- The acquisition of world leading cancer stem cell assets as a result of our acquisition of Eclipse Therapeutics. This is coupled with the progression of our first cancer stem cell program BNC101 through GMP manufacture and IND enabling studies, with the aim of

initiating the first clinical trial of BNC101 next year.

- A new US\$172m agreement with Merck & Co focused on the treatment of chronic and neuropathic pain.
- Our partner Ironwood Pharmaceuticals commenced the first US clinical trial of IW-2143.
- Attracting world-wide attention to our BNC375 candidate to tackle cognitive impairment and
  memory loss associated with diseases like Alzheimer's and Parkinson's has led to very
  significant partnership interest as we have planned for its clinical development in a dual
  strategy; and I am pleased to report that there is also very strong partnership interest in our
  Kv1.3 immune diseases drug candidate BNC164.
- And finally our partnership with the CRC for Cancer Therapeutics that has made significant progress towards a new drug candidate for the treatment of melanoma.



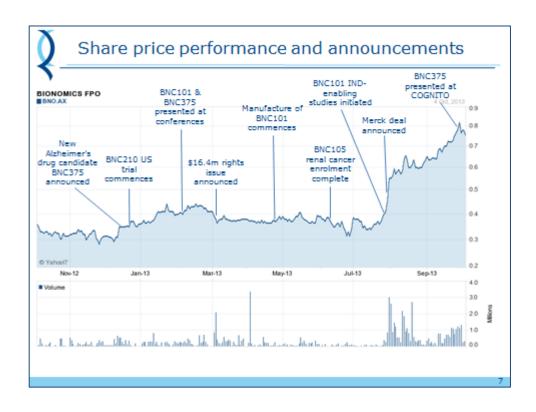
## Value creation: past 12 months

- BNC105 RCC phase II trial reaches key clinical milestone, nearing partnership phase
- Acquisition of Eclipse Therapeutics positions BNO in Cancer Stem Cells (CSC)
- BNC101 CSC antibody pre-IND filing with FDA, feedback from the FDA just received, moves program closer to the clinic
- US\$172M pain partnership with Merck & Co
- Ironwood partnership IND lodged with FDA, phase I trial commences
- Advancing partnership discussions on BNC375 and Kv1.3 drug candidate BNC164
- Partnership with CRC-Cancer Therapeutics yields potential new cancer drug candidate for the treatment of melanoma

A steady stream of announcements on new drug candidates, trial milestones and partnerships has resulted in a share price that better reflects the quality and number of drug assets within our pipeline.

By raising \$16.4m via a rights issue in March we have put the Company in a very healthy financial position moving forward.

As can be seen in the chart, market support following the announcement of the Merck partnership was particularly strong, underlining the potential for even some of our earlier stage programs to attract the best names in the world with big price tags.



Bionomics has a solid cash position. At the end of the financial year we had \$22.45m and net cash inflows of almost \$5m in the 12 months to 30 June.

We had revenue of \$3.72m and an operating loss after tax of \$10m. We anticipate \$7m Australian R&D tax incentive refund for FY13 which may be received in this quarter, and a similar R&D tax incentive refund is anticipated for FY14.

We also anticipate additional licensing income over this financial year and beyond.



## 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
- \$7.0m anticipated FY13 Australian R&D Tax Incentive refund
- Anticipated \$7.0m cash from Australian R&D Tax Incentive refund in FY14
- Anticipated additional licensing income

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### **Clinical Progress**

I will now discuss our highlighted drug candidates and the key developments in our programs during 2013.

BNC105 targets a range of solid tumours and is a best in class vascular disrupting agent. We believe it has the potential to be a blockbuster drug able to be combined with many current cancer treatments and to be used in the treatment of many different solid tumour types including for example breast, prostate and lung cancers.

Bionomics' development program for BNC105 has included a Phase I/II clinical trial in patients with advanced or metastatic renal cancer.

As previously announced, the Phase I renal cancer trial of 12 patients treated at four different dose levels yielded encouraging signals of clinical benefit. The combination of BNC105 and Novartis' Afinitor was well tolerated. Eight patients achieved stable disease and one patient received 24 cycles of treatment representing 18 months free of disease progression.

In June 2013 we completed recruitment of 139 patients for the Phase II component of this trial. All patients enrolled in the trial had failed the standard Tyrosine Kinase Inhibitor or TKI therapy.

Recruitment was also completed for the phase I ovarian cancer trial and we are looking forward to announcing the results of these trials in the coming period.



## BNC105: Key Clinical Milestones Achieved

- BNC105 Phase I renal cancer trial indicates clinical benefit
  - Results updated at ASCO: combination BNC105 + Afinitor safe & well tolerated; 12 patients enrolled across 4 BNC105 dose levels (4-16mg/m2); 8 patients achieved stable disease; 1 patient still on study having received 24 treatment cycles (72 weeks, 18 months)
- Recruitment for Phase II trial for renal cancer completed
  - 139 patients enrolled; patients previously failed TKI therapy; primary endpoint 6 month PFS
- Recruitment in Phase I ovarian cancer trial completed

There is a strong value proposition backing BNC105.

Over the past year we have come to understand even more about the biology driving its powerful anti-cancer action. We now know that it has a three pronged attack on solid tumours – firstly as a pulsatile activator of tumour hypoxia it shuts down the blood supply within tumours, secondly as a direct cytotoxic agent it directly kills tumour cells and thirdly it induces apoptotic proteins and cancer cell apoptosis.

This drug offers a potential paradigm shift for renal cancer patients.

It has potential to work with existing treatments, particularly the targeted therapies that tackle tumour adaptive responses to hypoxia as demonstrated in the Phase I trial with Afinitor.

It is safe with limited side effects and its action is focused selectively on tumour tissues.

We have obtained granted patents in major potential markets to protect our intellectual property and a strong and expanding patent portfolio underpins BNC105.

Ultimately, we believe BNC105 has outstanding revenue potential with the possibility to dominate the market as a high margin component of existing or emerging renal cancer therapies.



## **BNC105 Value Proposition**

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

- Ability to combine with existing, treatments: A Pulsatile
   Activator of Tumour Hypoxia (PATH), BNC105 synergizes with
   targeted therapies that exploit tumour adaptive responses to
   hypoxia (i.e., combinable with all targeted agents currently
   marketed for Renal Cancer including Avastin, Afinitor, Votrient and
   Inlyta 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

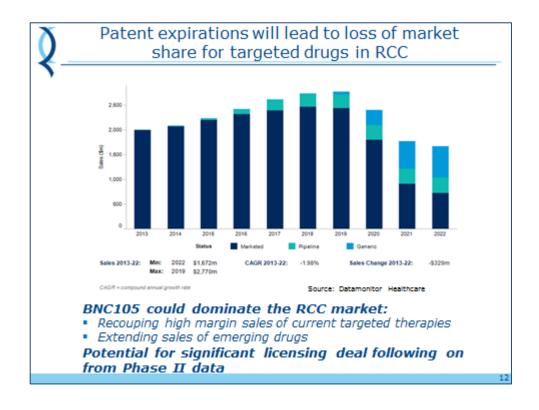
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The need for the "paradigm" shift offered by BNC105 is clear when you look at the low survival rates for late stage, metastatic renal cancer – just 12.3% of sufferers achieve five year survival and existing options available to patients are poor.

Q	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 ar http://seer.cancer.gov/statfacts/ Based on NCI SEER Cancer Statis Updated June 14, 2013 http://seer.cancer.gov/csr/1975	'html/kldrp.html tics Review 1975-2010	11	

Bionomics believes BNC105 could dominate the renal cancer therapy market, a market which faces its own patent cliff.

As this graph demonstrates, generic drugs are anticipated to make up a growing percentage of the renal cancer treatment market from 2019. Large Pharma will be seeking targeted drugs like BNC105 to help recoup high margin sales.

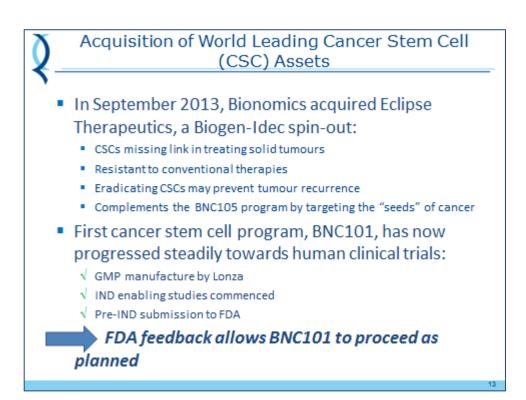


Moving now to our cancer stem cell program. In September 2012 we completed the acquisition of Eclipse Therapeutics, a spin-out from global biopharmaceutical company Biogen-Idec. With the acquisition, Bionomics gained access to world leading cancer stem cell technology and expertise, and a US foothold.

Cancer stem cell therapies complement drugs such as BNC105, offering a more holistic treatment approach. Bionomics now has the capability to tackle cancer at the level of cancer stem cells with the potential to inhibit tumour recurrence.

Bionomics' first cancer stem cell program BNC101 will focus on the treatment and prevention of recurrence of colon and pancreatic cancers.

We are progressing steadily towards human trials for BNC101 after initiating GMP manufacturing by Lonza and commencing IND enabling studies. I am pleased to announce that Bionomics has now received feedback on its pre-IND submission lodged with the US FDA last month and that very importantly based on this feedback Bionomics can confidently move forward towards starting the first clinical trial of BNC101 in 2014 as planned.



BNC101 is a humanised monoclonal antibody which binds specifically to LGR5, a cell surface protein that marks tumour initiating cells for colon and gastric cancers. LGR5 is also highly overexpressed in a range of other solid tumour types, including pancreatic and breast cancers.

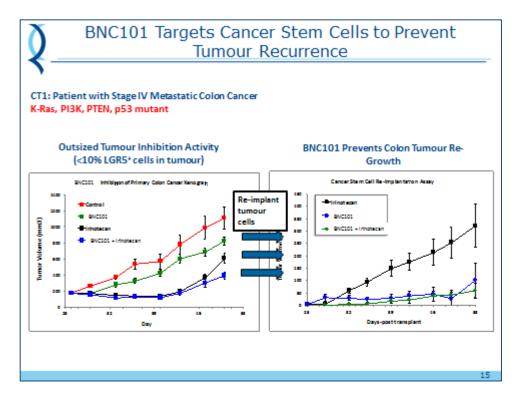
In line with our focus on large market opportunities the emerging market for cancer stem cell therapeutics is estimated to accelerate to US\$8 billion by 2018.

BNC101 reflects our philosophy to develop 'first in class' drugs – in this case, the most promising therapeutic antibody against an established cancer stem cell target. We believe that Bionomics is the only company to date to have discovered and have in development a fully functional antibody to LGR5.

TREATMENT	Solid tumours; colon, breast, pancreatic are priority	
MOA	Humanised monodonal antibody     BNC101 binds selectively to LGR5; LGR5 marks tumour-initiating cells in colon & gastric cancer	
	<ul> <li>LGR5 highly overexpressed in colon, ovarian, liver, breast, lung &amp; other solid tumours</li> </ul>	
	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	

With BNC101 we are aiming to prevent tumours from recurring.

As these graphs showing data from a patient derived colon cancer model illustrate, BNC101 inhibits the capacity of tumours to re-occur even in the absence of chemotherapy by specifically depleting the cancer stem cell population. This is something that existing treatments such as Irinotecan are not able to do, in fact prior Irinotecan treatment appears to speed the growth of the cancer in this setting. We now have confirmatory data from a range of these patient derived tumour models, including in models of pancreatic cancer. Encouragingly we have been told in preliminary partnering discussions where this data has been presented that we are the first biotech company to provide evidence of specific targeting of cancer stem cells in patient derived tumour or PDX models.



## **Partnerships**

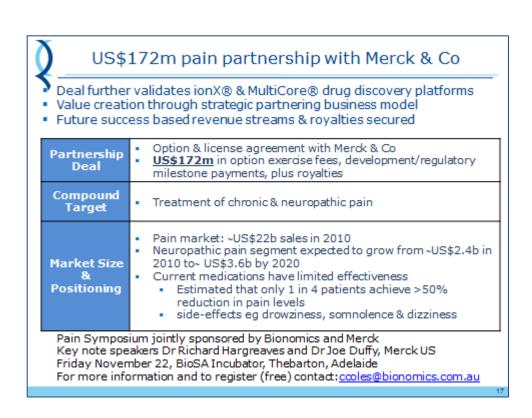
I would now like to focus on our key partnerships, including our most recent partnership on our pain program.

Our strategic and mutually beneficial agreement with Merck & Co (known as MSD outside the US) reflects the value of our proprietary drug discovery platforms, ionX and MultiCore, and also builds our future revenue and royalty position.

The US\$172m agreement includes the potential for option exercise fees, development and regulatory milestone payments. In addition royalties on net sales will apply to a successfully marketed product.

We will focus on the substantial and growing global market for pain treatments estimated in 2010 at US\$22b. We are also focusing on new treatments for neuropathic pain, a market which is estimated to grow to US\$3.6b by 2020.

Current medications for this market are characterised by significant side effects and for a large number of patients, limited efficacy. Many of you will also be aware that the FDA is moving to restrict further the prescribing and use of oxycontin and other opioid drugs, particularly long-acting opioids. There is a very real need for new treatments and this is why Bionomics is undertaking this important research.



Our partnership with Ironwood Pharmaceuticals focused on anti-anxiety drug candidate IW-2143 was, as I noted last year, the largest deal for an Australian biotechnology company at the phase I trial stage.

This agreement is for up to US\$345m in upfront and development and regulatory milestone payments plus a royalty on net sales if IW-2143 is successfully developed and reaches market. Ironwood also is responsible for funding all development, including clinical trials.

An IND was lodged with the FDA by Ironwood and a US phase I trial initiated. The Phase I program is designed to assess the safety and pharmacokinetics in healthy volunteers, using single and multidose administration. A US\$2m milestone payment could be triggered through progression of the Phase I trial.



## BNC210 partnership with Ironwood Pharmaceuticals

#### The Ironwood IW-2143 (BNC210) Partnership:

- Up to US\$345 million in upfront, development (clinical trials) and regulatory milestone payments (i.e. all milestone payments are presales).
- Royalty on net sales of products incorporating BNC210 (IW-2143).
- · Ironwood will fund all clinical trials and other development activities.

IND lodged with the FDA and Phase I clinical trial initiated

Phase I program designed to assess safety and pharmacokinetics of IW-2143 in healthy volunteers, using single and multi-dose administration

US\$2M payment could be triggered through progression of the Phase I clinical trial

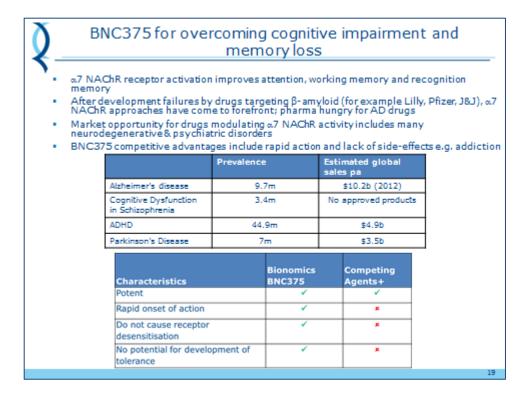
## Additional Drug Candidates to Deepen the Pipeline and for Partnering

I would also like to highlight two drug candidates which have further demonstrated our capabilities, deepened our development pipeline and added to our partnerable assets in 2013.

The first of these is BNC375. BNC375 works to overcome cognitive impairment and memory loss, and has potential to be useful in the treatment of diseases such as Alzheimer's disease, Schizophrenia and Parkinson's disease. In the US one person develops Alzheimer's disease every 69 seconds; by 2050 an American will develop the disease every 33 seconds. Also by 2050, 115 million people world-wide are projected to live with Alzheimers disease. According to Alzheimers Disease International, the annual societal costs of dementia worldwide reached US\$604 billion in 2010 alone.

BNC375 has several important potential benefits for patients suffering memory loss such as rapid action and suitability for long term treatment.

BNC375 works by stimulating the  $\alpha$ 7 nicotinic acetylcholine receptor, a promising target for treatment of memory loss associated with Alzheimer's disease, which has risen to particular prominence following several high profile failures of drugs focused on reducing beta-amyloid in the brain.



Schizophrenia is a severe mental illness which affects about one of every 100 Americans, roughly three million people. There are many misconceptions about this disorder – in particular that it only involves hallucinations, but this is only part of the story. People with Schizophrenia also suffer from cognitive defects which affect their ability to think clearly. These include difficulties with memory, planning and decision making.

In Parkinson's disease it is now becoming more recognized that the underlying cognitive defects and late stage dementia suffered by patients has much in common mechanistically with Alzheimer's disease.

There is international recognition of Bionomics' science in this area and Bionomics presented at a number of major conferences throughout the year as part of its outreach to major companies and potential partners. For example, in September 2013 Bionomics' Vice President of Neuroscience, Dr Sue O'Connor, presented BNC375 at the invitation only international COGNITO conference in Denmark.



## BNC375 has attracted world-wide attention

## COGNITO conference Denmark:

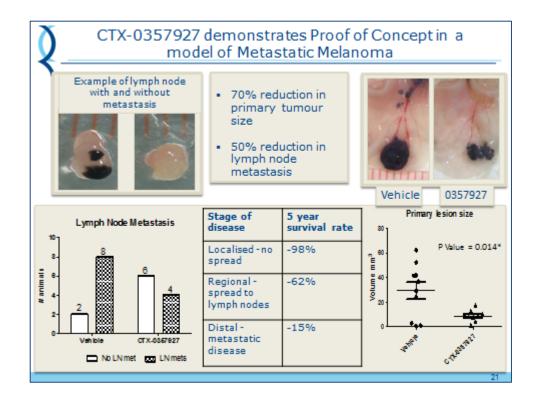
- Invitation only, focussed on the α7 nicotinic acetylcholine receptor
- Recognised foremost researchers in the field
- Dr Sue O'Connor, Bionomics VP Neuroscience Research, the only Australian invited to attend and present

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In our oncology program Bionomics is working with top Australian research institutes as part of the Co-operative Research Centre for Cancer Therapeutics, a Federal government initiative which received AU\$37.69 million in federal funding in 2007 to discover new treatments for cancer. Bionomics has been the sole Australian commercial partner of the CRC, which represents another side to our partnership model.

In May Bionomics announced the achievement of a milestone in one of our collaborative programs with demonstration of proof of concept by CTX-0357927 a compound with the potential to tackle metastatic melanoma. CTX -0357927 is an inhibitor of VEGFR3, a receptor closely linked to the development of lymphatic vessels which act as a conduit for tumour cells spreading to different sites of the body.

Survival rates for metastatic melanoma remain low and this candidate shows significant potential to induce tumour shrinkage and inhibit metastasis in lymph nodes.



## **Outlook**

The outlook for Bionomics is bright with important value creating milestones expected to be achieved in the year ahead.

Foremost will the BNC105 Phase II renal cancer clinical trial results, with its promising market and licensing potential.

BNC101, a first in class therapeutic antibody against a validated cancer stem cell target, brings the prospect of preventing tumour recurrence. It will complete IND enabling studies and progress to clinical trials. We anticipate commencement of the first clinical trial of this world-leading agent in the second half of calendar year 2014.

We will continue to seek partners for our current crop of drug candidates and note our ongoing negotiations in respect of BNC375 and our Kv1.3 clinical candidate BNC164. Moreover, in line with our business model, we will continue to strategically develop our pipeline of drug candidates in order to leverage our core strengths and to maximize the value from our platform technologies.

We are proud of our progress in tackling serious diseases with drug candidates which offer the prospect of significant benefits to patients and that appear to have very strong market potential. I look forward to reporting to you the ongoing success of Bionomics in 2014.



## The year ahead, what we expect

- BNC 105 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 Kv1.3
  - · Lay off risk and benefit from "The Partnership Effect"
- Enrichment of the pipeline of drug candidates for development and partnering
  - Leveraging our platform technologies and core strengths

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I would like to conclude by thanking our talented, passionate and dedicated Bionomics team, supported by our esteemed scientific and clinical development advisors. As a team we are very grateful to the participants in our clinical trials and their families and for the support of our shareholders who share our vision for bringing more effective medicines to sufferers of cancer, anxiety, Alzheimer's disease and other serious illnesses. Thank you again for your support in 2013.



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#### **About Bionomics Limited**

Bionomics (ASX: BNO) is an Australian based international biotechnology company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule and antibody product development programs in the areas of cancer, anxiety, and memory loss. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours.

BNC105, which is undergoing Phase II clinical development in a range of solid tumour types, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. BNC105 offers blockbuster potential if successfully developed. A clinical program is also underway for the treatment of anxiety disorders and depression based on IW-2143(BNC210), a novel compound which stimulates neurite outgrowth. IW-2143 is partnered with Ironwood Pharmaceuticals.

Bionomics' discovery and development activities are driven by its four proprietary technology platforms: Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels); MultiCore®, a diversity orientated chemistry platform for the discovery of small molecule drugs; ionX®, a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system; and CSC Rx Discovery™, which identifies antibody and small molecule therapeutics that inhibit the growth of cancer stem cells. These platforms drive Bionomics' pipeline and underpin its established business strategy of securing partners for its key compounds.

www.bionomics.com.au

#### Factors Affecting Future Performance

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this presentation that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' development candidates BNC105, IW-2143 (BNC210), BNC101 and BNC375, our acquisition of Eclipse Therapeutics and ability to develop products from their platform, its licensing deals with Ironwood Pharmaceuticals and Merck, drug discovery programs and pending patent applications are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements.

There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including risks related to our available funds or existing funding arrangements, a downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, Ironwood's decisions to continue or not continue development of IW-2143, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Results of studies performed on competitors products may vary from those reported when tested in different settings.

Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this presentation.