



**JULY 09**  
**IN THIS ISSUE**

Bionomics  
CEO Report

BNC105  
Named in  
SMART 100 Index

Phase 1 Clinical  
Trial - BNC105  
meets objectives

BNC210: Phase 1  
Clinical Trial ahead  
of schedule

# BIONOMICS



## CEO Report

Dear Shareholders,

It gives me great satisfaction to report your company's progress over recent months. Highlights reported in this issue of Bionomics NOW are:

### HIGHLIGHTS

- The achievement of two key milestones in the clinical development of BNC105 for the treatment of solid tumours – firstly our proposed Phase II trial in patients with renal cell cancer in association with the Hoosier Oncology Group and secondly the selection of the dose level to be used in this trial
- The initiation of the first clinical trial of BNC210, Bionomics drug candidate for the treatment of chronic and acute forms of anxiety.

These highlights for Bionomics followed hot on the heels of presentation of BNC105 data at key North American Conferences – the annual meeting of the American Association for Cancer Research (AACR) and the American Society for Clinical Oncology (ASCO). The AACR presentation is available on Bionomics' website at [www.bionomics.com.au](http://www.bionomics.com.au). The new data presented at AACR extended the types of cancer BNC105 is effective against in animal models to head and neck, brain, prostate, breast, colon and lung and showed that in contrast to many of the current chemotherapeutic drugs, BNC105 is not susceptible to common mechanisms of cancer resistance. The data also showed that BNC105 delays the growth of throat cancer when used as a single agent in an animal model of human disease. BNC105 was also shown to effectively combine with radiation therapy to generate an enhanced anti-tumour response in the throat cancer model. Finally, the data presented showed that in a model of human lung cancer BNC105 effectively combines

with the cytotoxic agent cisplatin to produce an enhanced anti-tumour response.

We are all very excited by the progression of BNC105 to Phase II clinical trial, in association with the Hoosier Oncology Group. Identifying a dose for the BNC105 renal cancer trial and having one of the top US cancer groups engaged in the further clinical development of BNC105 has overcome a near-term risk for our lead drug candidate. Renal cell cancer is a strong market opportunity with blockbuster potential which presents a rapid path to market.

Turning now to BNC210 which is a very important quiver in our bow – BNC210 is on target now that the first clinical trial is underway at the Royal Adelaide Hospital.

**In less than two years Bionomics been able to progress two newly discovered drugs into human clinical trials –**

illustrating not only the capacity of our powerful drug discovery engine to generate high value drug candidates, but also the disciplined approach we employ to effectively execute the transition of new drugs into the clinic. We are not resting on our laurels. Shareholders can look forward to further near term developments, including presentation of the very latest BNC210 data by Dr Sue O'Connor at Neuroscience 2009. We anticipate that the current BNC210 clinical trial will be completed by the end of the year and that this will be a significant step forward for the program. •

**Dr Deborah Rathjen**  
Chief Executive Officer



australian  
**anthill**



## BNC105 NAMED IN 'SMART 100' INDEX

In April BNC105 was named third most innovative product, according to 1,600 judges, in one of the largest innovation awards of its kind in Australia – the Anthill Magazine's inaugural 'SMART 100' index.

This award follows on from the recognition of BNC105 as one of the "Top Five Most Promising Drugs Entering Phase I Trials" in the international review The Ones To Watch released by Thomson Pharma® in May last year.

CEO Deborah Rathjen was interviewed by ABC Radio Australia on the 'SMART 100' award and you can **hear the podcast of this interview in the 'News' section of Bionomics' website: [www.bionomics.com.au](http://www.bionomics.com.au)**



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### See Bionomics

**23 – 27 August, 2009**

7th AFMC International  
Medical Chemistry  
Symposium  
Cairns, Australia

**9 – 11 September, 2009**

Rodman & Renshaw  
11th Annual Healthcare  
Conference  
New York, USA

**17 – 21 October, 2009**

Neuroscience 2009  
Chicago, USA

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## PHASE I CLINICAL TRIAL OBJECTIVES MET – US PHASE II CLINICAL TRIAL OF BNC105

The objectives of the Phase I trial, conducted in Australia, were to evaluate the safety, tolerability, and pharmacokinetics of BNC105 in cancer patients and to identify a dose level of BNC105 to be used in future clinical trials of BNC105. These objectives have now been met and a dose of 12.6 mg/m<sup>2</sup> has been selected for the next clinical trial of BNC105.

For the first Phase II clinical trial of BNC105, Bionomics will utilize the expertise of the Hoosier Oncology Group Inc (HOG) network, which is headquartered in Indianapolis, to evaluate its efficacy in renal cell carcinoma.

Dr. Nasser Hanna, Chairman of HOG, said,

*"The Hoosier Oncology Group is enthusiastic to bring potentially innovative treatments to its members and patients, and Bionomics is a welcomed partner in that pursuit with its novel compound."*

Renal cell cancer accounts for 2-3% of human malignancies and accounts for 85% of kidney cancers. The five year survival rate for patients with metastatic disease is less than 2%. In choosing renal cancer as the setting for the initial Phase II trial of BNC105, Bionomics is responding to the need for new and effective treatments for this cancer. •

## BNC210 PHASE I CLINICAL TRIAL INITIATED AHEAD OF SCHEDULE



Anxiety is a common debilitating mental condition, affecting nearly 1 in 10 Australians each year. Many of the largest blockbuster drugs are used for treating anxiety including Valium, Xanax, Prozac, Paxil, Buspar and Zoloft. These drugs can form lethal cocktails when misused, as the recent death of rock star Michael Jackson indicates. Last year Heath Ledger's death was blamed on a cocktail of drugs including Valium and Xanax.

Phase I clinical trial of Bionomics' anti anxiety drug, BNC210 was initiated on the 25th June, conducted in groups of healthy male volunteers at the Pain and Anaesthesia Research Clinic (PARC) within the Royal Adelaide Hospital. The trial is expected to be completed by the end of the calendar year. The Principal Investigator on the trial is Paul Rolan, Professor of Clinical Pharmacology at the University of Adelaide and a co-founder of PARC. Professor Rolan commented, "There have been no fundamentally new and effective treatments for anxiety for decades. Of the treatments we do have, many patients are burdened by side-effects.

**BNC210 appears to be entirely novel in its action and remarkably free of the sedation associated with other treatments for anxiety.**



I am delighted to be leading this first study of BNC210 in man".

**Factors Affecting Future Performance** This publication contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this publication that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' development candidates BNC105 and BNC210, its 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, 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 publication.