





PRESWICK CHEMICALS ACQUIRED

THE 2ND ANNUAL PAIN SYMPOSIUM

**BNC105 KEY DATA REVEALED** 

JANUARY 2015

### LETTER FROM THE CEO

**DEAR SHAREHOLDERS** 

We move into 2015 after what was undoubtedly one of the best years for Bionomics from a number of standpoints, including the progression of an increasingly robust product pipeline, impressive licensing deals and the confirmation of our first ever annual profit.

The Bionomics model of feeding the appetite of big pharma companies looking to secure new products continues to be rewarded – as evidenced by a second license deal with Merck & Co for our BNC375 program targeting Alzheimer's and Parkinson's disease. The deal is worth up to US\$506m for Bionomics in milestone payments plus additional potential royalties, making it the largest deal ever done for an Australian pre-clinical drug candidate. This is another major vote of confidence following our initial licensing deal with Merck, which brought with it the potential to receive up to US\$172m in option exercise fees and milestone payments and additional royalties on product sales - on a program which is directed towards the discovery and development of chronic pain treatments.

To attract partners of this calibre, Bionomics continues to vigorously push our drug candidates through the various stages of development. Important progress was made during 2014 on the BNC101 cancer stem cell program, which is anticipated to enter the clinic in 2015, on BNC105 where the clinical focus in 2015 will be on biomarkers which may predict patient benefit in renal cancer patients treated with BNC105 and on Chronic Lymphocytic Leukaemia, and on the reacquisition of BNC210, with a Phase II trial anticipated to be initiated in 2015.

In September, we were delighted to report the acquisition of the French chemistry business, Prestwick Chemical, which adds an extra dimension to our drug discovery capabilities. A tried and tested provider of medicinal chemistry services and smart screening libraries, Prestwick maintains a blue-chip client list of major pharmaceutical companies, and Bionomics was extremely pleased to finalise the acquisition at the modest price of €270,000.

Bionomics will continue to capitalise on our business model and secure further revenue streams by way of strategic partnering of our compounds, with at least three possibilities earmarked for 2015, each addressing significant unmet clinical need and major market opportunity.

Clinical development will also be a focus for Bionomics in 2015 with new studies expected for each of our lead candidates, BNC210, BNC105 and BNC101. We are well financed to support these studies, with more than \$33m cash in the bank at the end of the September quarter, and an additional US\$10 million in project specific financing for the development of BNC210 from Silicon Valley Bank secured in November.

The Bionomics board and management would like to thank all our shareholders for their loyal support, and we look forward to reporting further successes to you during 2015.

Dr Deborah Rathjen

CEO & Managing Director

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### BIONOMICS TO ACCELERATE BNC210 HUMAN TRIALS AFTER REACQUISITION

In November Bionomics reached agreement with Ironwood Pharmaceuticals Inc to reacquire the exclusive worldwide rights to develop and commercialise our highly prospective anti-depression and anxiety compound, BNC210.

Bionomics executed the move with a view to rapidly progressing further human trials, the first of which is a Phase Ib trial in France to be conducted by Biotrial International.

This will be a single-centre, multiple ascending dose clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of BNC210 in healthy male volunteers.

The trial will also examine target engagement of BNC210 in the brain and help to further refine dose levels to be evaluated during a Phase II trial in human patients suffering from anxiety, which, pending approval, is expected to commence in the UK in early 2015.

Funding for the development of BNC210 has been secured with a US\$10 million loan from Silicon Valley Bank. The project specific non-dilutive loan will be paid back over a 30-month period.

"Much has been achieved during our collaboration with Ironwood to build BNC210 towards Phase II trials, including formulation and an extensive toxicology program," said Bionomics' CEO, Dr Deborah Rathjen. "The compound is now well positioned for both development and future partnering opportunities."

For its part, Ironwood will retain a royalty interest in BNC210, while Bionomics has reacquired exclusive rights to develop and commercialise its original discovery.

The BNC210 molecule was recently showcased at the Neuroscience 2014 conference in Washington DC, held annually by the Society of Neuroscience. The poster presentation outlined the results of several experiments demonstrating the efficacy of BNC210 as a negative allosteric modulator of the alpha 7 nicotinic acetylcholine receptor – a key to the treatment of multiple anxiety disorders.

In clinical studies to date, BNC210 has demonstrated compelling anti-anxiety activity, substantially reducing the number and intensity of panic symptoms, with none of the negative side effects associated with traditional benzodiazepines such as Valium. To date, BNC210 has been evaluated in 148 healthy volunteers and has proven to be safe and extremely well tolerated.





# ACQUISITION OF PRESTWICK CHEMICAL

Bionomics has boosted both its drug discovery capabilities and its links with big pharma, through the acquisition of the renowned French medicinal chemistry services and smart screening libraries provider, Prestwick Chemical.



A medicinal chemistry company

Based near Strasbourg, Prestwick's 30-strong team of research scientists are a perfect 'fit' with Bionomics, with whom we have been working on various drug discovery programs since 2009. Prestwick is currently involved in both our pain program and the BNC375 program.

Working alongside leading scientists from Strasbourg University, Prestwick has established a strong reputation for providing state-of-the-art R&D services in early drug discovery, including hit identification and validation, hit-to-lead, and lead optimization. The company boasts one marketed product from its contract research services, as well as several compounds in Phase III clinical trials.

Prestwick shares several clients with Bionomics' wholly-owned subsidiary Neurofit. Prestwick reported revenues of €4.292 million for the year to December 2013, with Bionomics acquiring the company's assets for just €270,000.

Prestwick boasts an enviable list of big pharma customers, including GSK, Johnson & Johnson, Bayer and Abbot, as well as dozens of smallmid size pharma and biotech clients. The company was founded in 1999 by Professor Camille G. Wermuth, a world-renowned expert in medicinal chemistry.



## 2ND ANNUAL PAIN SYMPOSIUM HOSTED BY MERCK AND BIONOMICS

More than 80 participants gathered at Adelaide's Crowne Plaza Hotel on November 10th to learn about the latest breakthroughs in chronic pain and migraine research from some of the world's leading academic and clinical experts.

The 2nd Annual Pain Symposium was co-hosted by Bionomics and Merck & Co, following the much-lauded success of the companies' inaugural Pain Symposium in November 2013.

Presentations were delivered by a number of pharmacology and neurological specialists from Australia and overseas, with topics spanning the complexity of migraine headaches to novel research on pain therapeutics.

Speakers included Dr Ian Bell from Merck's Department of Medicinal Chemistry, who discussed CGRP receptor antagonists for the treatment of migraine, and Professor Thierry Langer from the University of Vienna's Department of Pharmaceutical Chemistry, who highlighted several recent success stories in medicinal chemistry.

Bionomics encourages interested parties to keep an eye out for information on the third installment of the free event in November 2015.

## ESMO PRESENTATION SHOWS BIOMARKER DATA KEY IN BNC105 RENAL CANCER TRIAL



136 PATIENTS
ENROLLED IN PHASE II

44 BEFORE + AFTER
BLOOD SAMPLES TAKEN FROM
PATIENTS

4 BIOMARKERS
CORRELATED WITH CLINICAL
BENEFIT BNC105 + AFINITOR
TREATMENT

57% PATIENTS
POSITIVE
FOR THE 4 BIOMARKER SIGNATURE

60% PATIENTS
WITH BIOMARKER
PROGRESSION FREE AT 6 MONTHS
VS 5% WITHOUT BIOMARKER

The potential of Bionomics' BNC105 compound to successfully treat renal cancer patients with a specific set of biomarkers received a significant boost in September with the presentation of compelling data from the DisrupTOR-1 trial of BNC105 at the European Society for Medical Oncology (ESMO) congress in Spain.

Of the 136 patients enrolled in the Phase II trial, blood samples were taken from 44 patients before and after treatment with BNC105. The sample size allowed statistical correlation of blood biomarker changes with disease status after six months and revealed four biomarkers that may be used to boost successful treatment for patients administered with both BNC105 and Afinitor.

The results found that 57% of patients were positive for the four-biomarker signature, with 60% of these being progression free at six months. Conversely, just 5% of patients without the four-biomarker signature were disease free at six months.

Future clinical trials may now be designed to select renal cancer patients using this four-biomarker signature.

The new data was presented at ESMO by Dr Sumanta Pal, Co-Director of the Kidney Cancer Program at the City of Hope Comprehensive Cancer Center in Duarte, California.

"This is the first time that a biomarker signature associated with clinical outcomes for BNC105 plus Afinitor has been reported for renal cancer patients," said Dr Pal. "These biomarkers should be further evaluated in future studies, within the frame of personalised medicine, to guide drug administration in those patients with the highest chances of benefiting from a significant clinical outcome."



#### SEE BIONOMICS

12 - 14 January 2015

Annual Biotech Showcase Investor Conference in association with the 33rd Annual JP Morgan Healthcare Conference San Francisco, USA

9 - 10 February 2015 BIO CEO & Investor Conference, New York, USA

**5 March 2015** ASX Spotlight Conference New York, USA



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**CONTACT US** 

31 Dalgleish Street Thebarton, SA 5031 Australia Tel: +61 8 8354 6101

Deborah Rathjen CEO & Managing Director drathjen@ bionomics.com.au



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