CEO REPORT

DEAR SHAREHOLDERS

Following on from the licensing deal for our anxiety and depression drug candidate, BNC210, Bionomics welcomed to Australia in April Dr Mark Currie who holds the positions of Senior Vice President R&D and Chief Scientific Officer for our new partner, Ironwood Pharmaceuticals.

Dr Currie has an impressive track record having previously directed cardiovascular and CNS research as VP of Discovery Research at Sepracor Inc, and having initiated, built, and led discovery pharmacology and also served as Director of Arthritis and Inflammation at Monsanto Company. During his visit Dr Currie provided an update on BNC210 development activities to institutional investors and brokers during a three day roadshow in Sydney and Melbourne.

BNC-210/IW-2143 DEVELOPMENT UPDATE

Newly named IW-2143, the BNC210 program has been formally incorporated into Ironwood’s pipeline of innovative medicines for symptomatic disorders, which also includes linaclotide, currently awaiting FDA regulatory approval for irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC), and IW-9179 which is in early phase development for gastrointestinal disorders. Dr Currie praised the solid foundation that Bionomics had achieved for the anxiety program.

“We have been most impressed by the quality of the animal data that Bionomics had generated in its preclinical studies”

Dr Mark Currie, Ironwood Pharmaceuticals.

Building on that foundation, current activities are directed towards increasing understanding of the underlying biology, formulation development, manufacture of sufficient quantities of the drug to support the clinical trial program, advancing the Investigational New Drug (IND) application with the FDA, initiating Phase Ib and planning for Phase Ila trials and expanding the preclinical safety program to enable later stage trials. All of this activity is aimed at driving to human proof of concept in
anxiety and ultimately the completion of pivotal studies which could lead to marketing approval.

A fully fledged development team is dedicated to the IW-2143 (BNC210) program comprised of Program Management, Discovery Pharmacology, Preclinical, Pharmaceutical Development, Quality Assurance, Clinical Research, Clinical Operations, Patient Reported Outcome (PRO) Research and Development, Regulatory Affairs, Regulatory Operations, Corporate Development, Commercial, Drug Safety, and Intellectual Property. Additional specialist subteams support the IW-2143 team as needed.

We are confident in our choice of Ironwood as our partner as they have the necessary expertise for the next stages of clinical development, honed through their recent experience in developing linaclotide, a treatment for IBS-C and CC. Some insight into the good standing that Ironwood holds within industry and with the US Food and Drug Administration (FDA) is a result of its patient centric approach to drug development. Ironwood prides itself on being an industry leader in incorporating patient insights into the development process by developing and implementing new instruments for clinical trials in consultation with the FDA.

These new clinical trial outcome measures are called Patient Reported Outcomes (PROs). A PRO is any report of the status of a patient’s health condition (severity of a symptom, sign, or state of disease) that comes directly from the patient. Ironwood is a respected member of the PRO Consortium, a public-private partnership established by the Critical Path Institute in cooperation with the FDA and the pharmaceutical industry in 2008. The role of the consortium is to develop, evaluate, and qualify PRO instruments for use as primary or secondary endpoint measures in clinical trials designed to evaluate treatment benefit. Ironwood co-chairs two of the PRO Consortium’s working groups, the IBS and functional dyspepsia working groups, and is a member of a third working group.

Ironwood has been developing PROs for its many clinical programs since the draft FDA PRO Guidance was released in 2006 followed by the final Guidance in 2009, and has developed IBS-C and CC PROs for use in their linaclotide programs. Ironwood achieved positive results across the board for all primary and secondary endpoints measured in its four Phase III trials of linaclotide. Dr Currie indicated during this visit that Ironwood intends to adopt a similar approach in moving BNC210 forward.

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Rapid progress has been made since our last newsletter in the application of BNC105 for treating ovarian cancer. In March Bionomics received approval for a PhaseI/II clinical trial to evaluate BNC105 in combination with carboplatin and gemcitabine in a multi-centre trial in Australia and the US. The trial was launched on schedule in May under the auspices of the Australian and New Zealand Gynaecological Oncology group working with the National Health and Medical Research Council Clinical Trials Centre in Australia and the Hoosier Oncology Group in the US. We have been impressed with our experience of the Hoosier Oncology Group to date which is currently conducting the Phase II trial of BNC105 in renal cell cancer. It is anticipated that up to 134 women will be enrolled in the ovarian cancer trial at 18 sites across Australia, New Zealand and the United States.

The trial is based on robust preclinical data showing the synergy between BNC105 and platinum-based drugs. These data were presented at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois in April. They showed that BNC105 is very effective in inhibiting the proliferation of human ovarian cancer cells including cisplatin-resistant cells. Moreover, a single dose of BNC105 caused reduction of blood flow in platinum resistant solid tumours of mice resulting in suppression of tumour growth and a statistically significant survival benefit.

BNC105 has the potential to represent an entirely new treatment paradigm for patients with renal cancer.
More BNC105 clinical trial data was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in early June. Our ongoing US renal cancer trial pairs BNC105 with Novartis’ Afinitor with encouraging outcomes from the trials to date including data supporting the comparability of both compounds at full dosage levels. Of the 12 patients enrolled in the Phase I component of the trial, 5 patients have completed over 10 cycles (30 weeks) of treatment and 2 patients remain on treatment. The poster presentation was very well attended by key opinion leaders and it was clear that much of the momentum behind BNC105 in the oncology community is a recognition that BNC105 has the potential to represent an entirely new treatment paradigm for patients with renal cancer.

ASCO also provided the opportunity provide update results from the Mesothelioma Phase II trial. The trial enrolled 30 patients. One patient showed an objective response with corresponding reduction in mesothelin levels with 13 patients showing stable disease, giving rise to an overall 44% clinical benefit. In addition plasma biomarkers showed significant changes consistent with vascular activity of BNC105.

We are very happy with the robust pipeline of proprietary small molecule drug candidates Bionomics has built and I look forward to keeping you informed of the solid progress, both clinical and commercial, being made in our multiple programs in the new financial year.

Dr Deborah Rathjen
Chief Executive Officer