Bionomics

AN UPDATE FOR OUR SHAREHOLDERS

BIONOMICS NOW

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MAY 2015

LETTER FROM THE CEO

DEAR SHAREHOLDERS

With the launch of two clinical trials of BNC210 this newsletter provides an update on this first in class drug candidate. Phase Ib and Phase II clinical trials are now underway with results expected next quarter and in the second half of 2017 respectively.

The profound advantage Bionomics is striving for in BNC210 is a highly effective new drug to treat anxiety and depression without common side effects including withdrawal symptoms (addiction), sedation and memory impairment.

BNC210 has a solid foundation of preclinical animal studies and is building a compelling body of clinical "proof of biology" having to date been evaluated in over 160 subjects.

POTENTIAL 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	✓	✗	✓	✗	✗	✓

*Based on data from preclinical animal studies and Phase I clinical trials

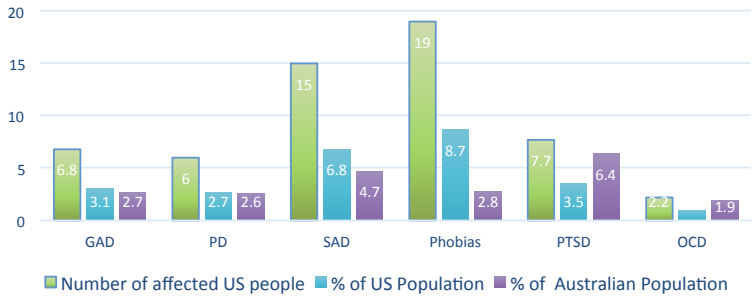
Both clinical trials have been designed to provide a data package for partnering with a global pharmaceutical company and further development.

If successful BNC210 will challenge existing products such as Valium and Prozac. The global market for anxiety treatments has been estimated at US $17 billion annually (BCC Research, 2014) and in 2008 global sales for depression treatments reached US $11 billion.

CEO REPORT CONTINUED

PREVALENCE OF ANXIETY DISORDERS

ADAA ANXIETY AND DEPRESSION ASSOCIATION OF AMERICA



BNC210 Market Opportunity

- Anxiety disorders affect ~40 million US adults ≥18 years (about 18%;) and ~14% Australians in a given year.
- Women are 60% more likely than men to experience an anxiety disorder.
- ~8% of teens (13-18) have an anxiety disorder, symptoms often emerging around age six.
- ECONOMIC BURDEN of anxiety disorders estimated to be >$46.6 billion annually in the USA (DuPoint, 1996; Greenberg, 1999).
- MARKET global anxiety disorders market ~$17.3 billion in 2004 (BBC Research).

While 2015 is a big year for BNC210 we have teams working on several other drug pipeline candidates, including BNC101 which has successfully completed IND enabling studies and is tracking well towards clinical trial.

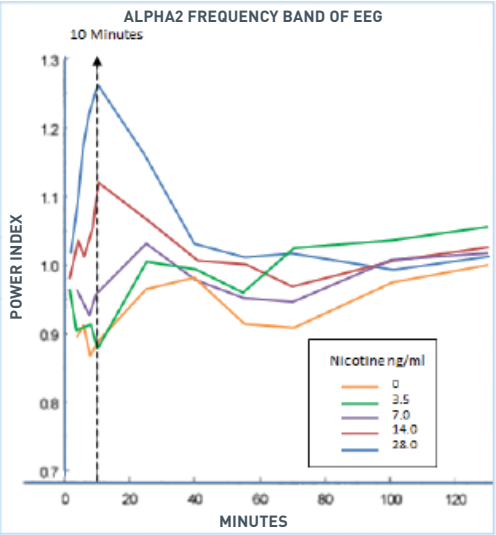
In April Bionomics' scientists presented four poster presentations across three oncology drug projects emphasizing the depth of our pipeline.

Dr Deborah Rathjen
CEO & Managing Director

BNC210 PHASE IB STUDY KICKED OFF IN FEBRUARY

In February Bionomics announced the commencement of the BNC210 multiple ascending Phase Ib study investigating its safety, tolerability, pharmacokinetics and pharmacodynamics.

Target engagement by BNC210 is also being studied through the use of a nicotine challenge with the subject's response to nicotine monitored by brain EEG. Nicotine, which binds to the alpha7 nicotinic acetylcholine receptor and other nicotinic receptors, induces changes in the brain that can be monitored by EEG. This component of the trial is designed to show that BNC210 can modulate or inhibit nicotine-induced changes in the brain. Evidence of target engagement via modulation of the nicotine response, is anticipated to provide valuable data for future partnering of BNC210.



BNC210 Nicotine Shift Assay

- Nicotine has a signature peak in the alpha2 (10-12.5 Hz) frequency band on qEEG
- Tmax at 10 minutes
- Peak amplitude is dose dependent = dose response
- Administer nicotine doses using nasal spray
- Subjects are non-smokers
- Look for shift in nicotine dose response in subjects treated with BNC210 = target engagement

Domino EF et al. Int J Psychophysiol. 2009 Dec;74(3):192-8.
Teter CJ, et al. Eur J Clin Pharmacol. 2002 Aug;58(5):309-14.
Lindgren M et al. Psychopharmacology (Berl). 1999 Aug;145(3):342-50.

The trial, which involves over 50 healthy volunteers, is randomised and placebo controlled.

Results are expected third quarter 2015.

BNC210 PHASE II UNDERWAY FROM APRIL

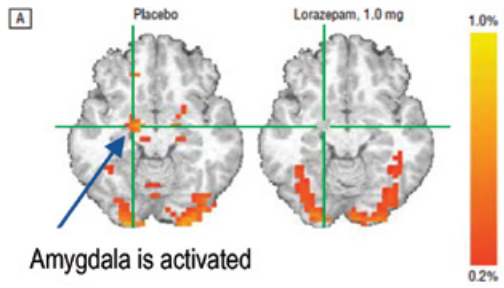
The Phase II study is assessing the effects of BNC210 on brain activity in patients suffering anxiety by using functional magnetic resonance imaging (fMRI).

Existing treatments for anxiety do not meet the need for fast-acting anxiolytic agents that lack or have minimal side effects. The treatments available to anxiety sufferers generally have side effects including sedation and addiction as well as effects on memory and movement co-ordination.

The Phase II study is being conducted by Principal Investigator Professor Allan Young at the Institute of Psychiatry, Psychology and Neuroscience at King's College in London. It will enrol 24 patients with untreated Generalised Anxiety Disorder (GAD).

The trial will evaluate the capacity of BNC210 to engage brain systems relevant to anxiety with the primary endpoints of the study including both significant changes in cerebral perfusion as measured by arterial spin labelling and in task-related brain activity using the Emotional Faces task during fMRI.

A particular focus for this brain imaging study will be the amygdala, the emotional centre of the brain. The amygdala is a central component in processing threat-related stimuli and the amygdala plays a predominant role in fear conditioning and processing of facial and vocal signals of fear. Drugs to treat anxiety and depression reduce amygdala activation (as measured by fMRI) in the Emotional Faces paradigm; for example, Lorazepam, Citalopram and Escitalopram. fMRI has the potential to serve as a biomarker for predicting anxiolytic function.



PAULUA 2005, ARCH GEN PSYCHIATRY

HARIRI, 2009

BNC210 Emotional Faces

- Human studies have identified the amygdala as a central component in processing threat-related stimuli
- It plays a predominant role in fear conditioning and processing facial signals of fear
- Angry faces also represent highly potent signals of threat, and are often rated as equally arousing and unpleasant as fearful faces
- Drugs used to treat anxiety reduce amygdala activation in the Emotional Faces task e.g., Lorazepam, Gabapentin, Citalopram, Escitalopram

In addition to the Emotional Faces task, patients will undertake a Joystick Operated Runway Task (JORT) which will examine flight behaviour and risk assessment behaviour, in a computer game format similar to a Pac Man game.

The study is a randomised four-way crossover with the effects of two dose levels of BNC210 being compared to those of placebo with 1.5 mg lorazepam being used as a positive control. The dosage levels for BNC210 span 300-2000mg.

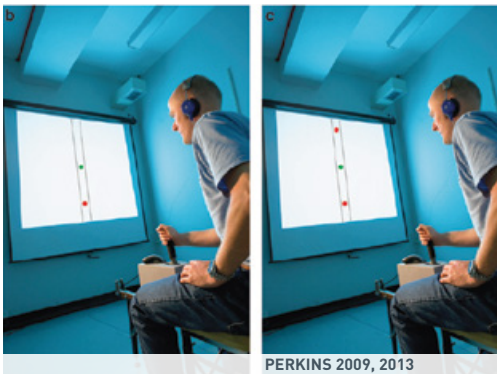
The clinical study should be completed in approximately 12 months with trial results due third quarter 2016.

BNC210 Joystick Operated Runway Task (JORT)

- Clinically effective panic disorder drugs preferentially alter rodent FLIGHT behaviour and reduce departure from threat
- Clinically effective anxiety drugs preferentially alter rodent RISK assessment behaviour and allow cautious approach to threat
- Theory tested in humans – evaluating citalopram and lorazepam on the defensive behaviour of healthy adult male humans using the JORT

JORT: FLIGHT The green cursor is pursued by a single threat stimulus (red dot); Participants receive an unpleasant but harmless shock if the red dot collides with the green dot.

JORT: RISK A second red dot travels ahead of the green dot at a constant velocity, causing a goal conflict whereby the participant has to travel fast enough to avoid the pursuing threat, but not so fast that they collide with the leading threat stimulus.

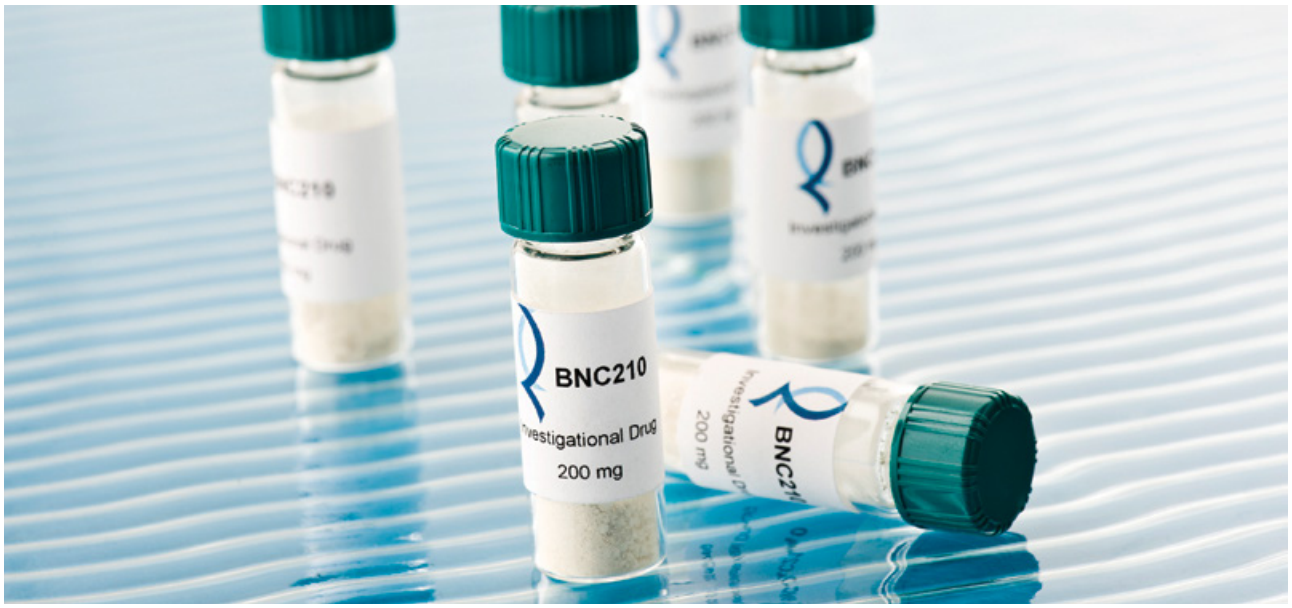


PERKINS 2009, 2013

BIONOMICS PRESENTS BNC210 AT PREMIER NEUROSCIENCE MEETING

In November 2014 Bionomics presented its poster "The novel anxiolytic compound BNC210 is a negative allosteric modulator of the alpha7 nicotinic acetylcholine receptor" at the Neuroscience conference.

The poster detailed BNC210 as a specific modulator of the alpha7 nicotinic acetylcholine receptor with effectiveness displayed in humans and rodents. The poster featured in the session titled "Mood Disorders: Novel Therapeutic Mechanisms" and outlined the experiments performed to demonstrate that the anxiolytic effect of BNC210 is produced by negative allosteric modulation of the alpha7 nicotinic acetylcholine receptor. The alpha7 nicotinic acetylcholine receptor is key to the possible treatment of multiple anxiety disorders.



BNC210 is free of benzodiazepine-like side effects and in a CCK-4 induced model in healthy volunteers it substantially reduced the number and intensity of panic symptoms and helped subjects recover faster.

The conference was held by the Society of Neuroscience in Washington, DC. The Society has over 40,000 members and is the world's largest organisation of scientists and physicians devoted to the study of the brain and nervous system.

SEE BIONOMICS

15 – 19 June 2015
BIO International Convention
Philadelphia,
PA, USA

17 – 18 July 2015
Bioshares Biotech Summit
Queenstown,
New Zealand

17 – 21 October 2015
Neuroscience (SfN)
Chicago, IL, USA

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