

Neuren Pharmaceuticals

CEO Presentation AGM May 2007



Major progress has been made...

- Phase 3 Glypromate® US FDA trial underway
 - Major focus for the Company over the last year
 - FDA validation... highest hurdle
 - Very cost effective trial
 - First to market
- Phase 1a NNZ-2566 complete
 - Safe and well tolerated
- Phase 1b NNZ-2566 underway
 - Flexible design use for both Phase 2 trials
- Third lead candidate NNZ-2591
 - Multiple potential uses
- Set to deliver strong clinical trials programme...



More...

- Cancer technology significantly progressed
 - Significant interest
- Partnering programme developed
 - Under Due Diligence
 - Multiple CDA and MTA agreements signed
- Strong Trial infrastructure built
 - COO appointed... Dr Parmjot Bains
 - Other CD Staff appointed... 36 years experience in US FDA Phase 3 trials
 - Key opinion leaders appointed
- Drug supply and logistics for both trials finalised
- US army continued strong support
 - Mode of Action understood
- Funding raised A\$7.6 million



Our strategy

- The Glypromate[®] Phase 3 trial is on target to complete in 18 months
 - Examining other potential applications
 - Created significant US interest
- The NNZ-2566 TBI trials (2) planned to commence near term
 - Efficiency signals in next 18 months
 - US army support and Fast track/Orphan Status

We plan to have multiple trials complete with efficacy signals in the next 18 months

- Out-licensing programme underway
 - NB average time closure 18 months
 - Interest in Glypromate®, NNZ-2566, NNZ-2591 and Cancer
 - Currently under Due Diligence



Development pipeline



Multiple out-licensing opportunities

- NEU has an extensive pipeline as a result of its "Right to Own" agreement with the University of Auckland
- NEU has focused on developing four + product lines such that they are <u>attractive</u> <u>out-licensing or further investment opportunities</u>



neuren



Glypromate® **Safe, non-toxic and in Phase 3**



Glypromate® Phase 3 - Why is this important?

- Excellent drug design... pharmacology, safety profile, long therapeutic time window
 - Typical of naturally occurring compounds; evolution as an effective drug discovery strategy
 - Multiple modes of action = multiple opportunities for effect
 - Single action drugs will not work in acute CNS
- Post-operative cognitive impairment is a well-recognized area of medical need
 - Accepted as a target for therapeutic intervention by FDA and EMEA
 - Defined as a therapeutic goal by the American College of Cardiology and American Heart Association
 - End point in common use eg AD, ADHD
- Post-operative cognitive impairment is a serious problem for patients
 - Equivalent to the difference in function between a 40-year old and a 60-year old (Newman et al, NEJM, 2001)
 - Results in persistent cognitive impairment in ~200,000 patients per year (*NeuroInvestment*, Sept. 2003?
 - Increases risk of Alzheimer's disease (Lee et al, *J Alzheimer's Disease*, 2005)



Glypromate® Phase 3 - Why this trial?

- Adequately powered to detect an effect
 - Many trials have been underpowered (e.g., Pharmos dexanabinol)
 - FDA have agreed to ADAPTIVE DESIGN... at 300 patients it will be opened and patient numbers increased to ensure adequate trial power if needed
- Resources in place for cost-effective execution
 - Strong internal clinical trials management experience
 - US CRO with superb experience in hospital-based cardiology trials in Phase 3 FDA
 - Automated system for capturing cognitive performance (CDR) well-validated and proven
- Sophisticated trial design
 - Spent considerable time on trial design and logistics and working with the FDA



Commercial strength

- We believe this combination of
 - Drug properties and
 - Trial design

has a better combination than all others we know in this space and is very well matched to the endpoint...

And we have

- FDA validation...
 - everyone has to go to the FDA eventually!!!
- Affordable trial, A\$10 million
- Adaptive design reduces risk
- CABG alone is a \$1 billion+ potential market with no approved drugs
- CABG is accepted as a surrogate for stroke, a \$3.5 billion market Glypromate® is positioned to be first to market — good safety margin, potential pharmacoeconomic benefits and reasonable cost will encourage rapid adoption
- Trial backed by key international opinion leaders



Comprising a number of global leading clinicians and researchers in neurology, cardiology, cardiothoracic surgery and anaesthesiology.

The members of the Executive Committee are:

- Professor Harvey White (Auckland Hospital, Professor of Cardiology, Chair),
- Professor Alan Merry (Auckland Hospital, Professor of Anaesthetics)
- Professor John Knight (Flinders Medical Centre, Australian Cardiac Surgeon)
- Dr David Stump (Neuropsychologist, Wake Forest, USA)
- Dr John Hammon (Cardiac Surgeon, Wake Forest, USA)
- Dr Doug Wilson (Neuren's Chief Medical Officer) and
- Dr Keith Wesnes (Cognitive Drug Research, UK)





NNZ-2566 About to enter Phase 2 for TBI

NNZ-2566 TBI Program

Completed

- Complex pharmacology multiple modes of action in multiple pathways
- Obtained Consistent effects in multiple models stroke, closed-head injury, penetrating head injury
- Drug CMC logistics completed
- Flexible clinical trial strategy
 - Separate moderate from severe different types of injuries with different outcomes
 - Phase 1b will leverage into TWO trials... Cost effective
 - More sensitive endpoints validated neuropsychological and neurocognitive instruments, not just crude Glasgow Outcome Scale
- Better partners US Army and leading neurotrauma experts and centers
- Highly attractive market for drug development and commercialisation
 - 750,000 patients per year
 - Completely untapped market, highly concentrated for rapid penetration with small sales force
 - Accelerated/Orphan development under FDA and EMEA guidelines
- Continued high level of US Army support





NNZ-2591 Oral treatment for Chronic CNS

NNZ-2591 – Oral treatment for multiple diseases

Meets all requirements for a CNS drug candidate

- 100% oral bioavailability
- Safe, non-toxic, crosses into brain, therapeutic window
- Stable, low cost of goods

Key Results

- Parkinson's disease: long-term disease modifying effects as well as short-term
- Reduces memory loss/cognitive impairment
- Peripheral Neurology

Market position — significant opportunities in multiple indications, large markets

- Parkinson's disease benefits of conventional treatment decline over time; recent evidence of safety concerns with second line drugs; serious need for new drugs with new mechanisms
- Parkinson's disease dementia up to 70% of PD patients develop dementia; no current therapy
- Peripheral neuropathy no approved drugs that target underlying pathology; few oral drugs in development





NNZ-8000 *A treatment for solid tumours*

Cancer programme

- Neuren has developed unique IP in a set key molecules involved in many cancers
- The presence of these factors , called TFF's , lead to tumor growth and spread
- We have strong laboratory evidence reinforced by strong clinical evidence
- In vitro and in vivo proof of principle established via numerous methods
 - RNAi, peptidomimetic, polyclonal antibodies, monoclonal antibodies
- Also excellent opportunity for development of diagnostics
 - Support for patient selection and therapeutic response monitoring in clinical trials
 - Commercial development of clinical diagnostics for cancer detection, prognosis and monitoring
- Average discovery stage cancer licensing deal >\$100 million
- Currently significant third party interest



Tumor volume in xenograft model of human breast cancer (polyclonal antibody; MCF-7 cell line)





Our strategy

- Hasn't changed....
 - Well developed clinical trial programme and out-licensing strategy
 - A great deal of effort over the last year in preparing for Phase 3 US FDA trial
- A leader in the area of reducing acute brain damage
 - Large markets, high unmet need and limited competition
 - Well-designed, safe, well-characterised drugs
 - Cost effective and focused trial design
- Validation
 - Glypromate® ... with FDA Phase 3 approval
 - NNZ-2566... with continued US Army support
- Continue to build portfolio and partnerships
 - NNZ-2591, Cancer, NRP etc

» Exciting Future





Thank you for your continued support...