Neuren Pharmaceuticals (ASX: NEU)

Dr Parmjot Bains and Dr Robin Congreve
Presentation
Annual Shareholders’ Meeting 29 May 2008
An emerging global leader in the treatment for central nervous system disorders and brain injury
Agenda

• Neuren Today
• Year in Review
• Opportunity Update
• The Year Ahead
Neuren Today

- Focus on three very promising late stage clinical candidates
- Grant funded development of preclinical candidates with the view to partnering
- Management focus on creating shareholder wealth through the fast and efficient progress of our clinical trial programs
The Year in Review

Achieved:

Capital Raising and Business Development

• Raised AU$7.1M in January 2008
• Secured US$4M US Department of Defense funding for NNZ-2566 Phase II
• Acquisition of Hamilton and Motiva™
• Leading US life science investors join share register

Team Changes

• New joint-CEOs appointed
• Reorganised in-house pre-clinical team
The Year in Review, continued

Trial Progress

• Glypromate® trial under US IND enrolment on target with 272 patients and positive DSMC safety review

• NNZ-2566 successful Pre-IND meeting with an IND filing pending in Q3 2008

• NNZ-2566 Phase II sites and world-class investigators recruited

• Motiva™ Phase II under an open IND, and a new protocol being finalised and study set up activities underway
# Product Development Status

Current stage of program

<table>
<thead>
<tr>
<th>Lead Programs – central nervous system and brain injury</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td>Glypromate® – Cognitive impairment post cardiac bypass surgery</td>
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<td>Pivotal results expects Q2 2009 PIIib in 2010</td>
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<tr>
<td>Motiva™ – Post Stroke Apathy and Depression</td>
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<td>PIIb results expected Q4 2009</td>
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<td>PIII to begin 2010</td>
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<tr>
<td>– Post Traumatic Brain Injury Apathy and Depression</td>
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<td>PII to begin Q1 2009, results in early 2010</td>
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<tr>
<td>– Parkinson’s Disease Apathy and Cognitive Impairment</td>
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<td>PII to begin Q3 2009, results in 2010</td>
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<tr>
<td>– Epilepsy (specific indication to be confirmed)</td>
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<td>PII to begin Q3 2009, results in 2010</td>
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<tr>
<td>NNZ – 2566 (IV) – Traumatic Brain Injury</td>
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<td>PII to begin Q3 2008</td>
<td>PIIb/III to begin 2010</td>
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<tr>
<th>Preclinical Programs</th>
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<tr>
<td>NNZ – 2591 (DKP) – Parkinson’s Disease and Dementia</td>
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<td>NNZ – 4945 (NRP) – Neuropathy</td>
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<td>Macrocyclics – Neuroprotection</td>
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<td>Anti-TFF mAbs – Oncology</td>
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<td>Anti-hGH mAbs – Oncology</td>
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<td>GH Variants – Metabolism</td>
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Motiva™

- **Dysmotivational syndrome common to many acute and chronic CNS disorders**
  - Results from damage or neurodegeneration, particularly in the frontal lobe
  - A primary obstacle to rehabilitation and improved functional performance

- **Large and unmet need**
  - Recognized need but no drugs approved for the indication or effective off-label
  - No competition from drugs in development or Phase IV studies of approved drugs
  - Potential patient population of >4 million patients (depression, AD, PD, stroke, schizophrenia, TBI)

- **Significant upside potential**
  - Revenue estimate of US$~700m 5 years post-launch
  - Target providers are virtually all psychiatrists and neurologists
  - Potentially strong pharmacoeconomic justification for third party payers
  - FDA approval path fairly straight forward
NNZ-2566

- Traumatic brain injury (TBI) is a major problem
  - 1.5 million head injuries per year in the US
  - 850,000 mild-moderate, 155,000 severe
  - US$50 billion in direct and indirect costs to healthcare system
  - No approved therapy and few drugs in development
Pre-IND Meeting: 21 May 2008

• Met with Russell Katz, MD (Director) and medical, pharmacology/toxicology, Chemistry reviewers from Neurology Products Division

• Chemistry Manufacturing and Controls (CMC)
  – no concerns expressed

• Regulatory
  – Fast Track status likely to be granted
  – Orphan Disease status possible
  – Single pivotal trial possible with very robust and persuasive results

• Clinical
  – Selected global outcome measures, neuropsychological outcomes and physiological outcomes (cEEG and biomarkers) acceptable for Phase II
  – Open to use of novel endpoints (e.g., seizures, neuropsychological outcomes) in pivotal trial with evidence of clinical benefit for patients
  – Confirmed that there are no a priori standards for magnitude of effect and that, in the TBI indication, a small but clinically meaningful effect could be approvable
World-Class NNZ-2566 Advisory Team

- **Ross Bullock, MD, PhD**
  - Professor and Director of Neuroscience Intensive Care, Division of Neurosurgery, University of Miami; leading expert in TBI clinical trial design and execution

- **James Ecklund, MD (COL, USA, retired)**
  - Chief, Neurosurgery, Fairfax Inova Medical Center; former Chief, Neurosurgery, Walter Reed Army Medical Center and Professor, Department of Neurosurgery, Uniformed University of the Health Sciences

- **COL Geoffrey Ling, MD, PhD**
  - Program Manager, DARPA/Defense Science Office; previously, Professor and Acting Chair, Department of Neurology, Uniformed University of the Health Sciences

- **COL Charles Hoge, MD**
  - Director, Division of Psychiatry and Neurobiology, Walter Reed Army Institute of Research; Army psychiatrist and epidemiologist and leading expert on military TBI and PTSD

- **Frank Tortella, PhD**
  - Chief, Dept of Applied Neurobiology, Walter Reed Army Institute of Research; leading expert in experimental pharmacology of TBI

- **Paul Vespa, MD**
  - Associate Professor of Neurology and Neurosurgery and Director of Neurocritical Care, UCLA Medical Center; leading expert on EEG monitoring in TBI

- **Jeffrey Vaught, PhD**
  - Executive VP, Research and Development, Cephalon, Inc.; expert in regulatory development of drugs for CNS conditions
Glypromate®

- **CABG and CPB result in over 350,000 patients with persistent cognitive impairment**
  - Equivalent to the difference in function between a 40-year old and a 60-year old
  - >50% impaired at discharge, >20% at 6 months, >40% at 5 years\(^1\)
  - Primary factor diminishing quality-of-life benefits of the surgery
  - Increases risk of Alzheimer’s disease\(^2\)

- **Significant pharmaco-economic benefit**
  - Potential to reduce costly utilization of hospital/intermediate care services and total cost of care

- **Unmet medical need**
  - Accepted target for therapeutic intervention by FDA and EMEA
  - Defined as a therapeutic goal by the ACC and AHA
  - No approved drugs (US$1.5 billion worldwide market opportunity)

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The Market Opportunity

- Three compounds with few or no competitors
- Indications with a large, unmet need (Coronary Artery Bypass Grafts, Traumatic Brain Injury, Apathy)
- Cumulative conservative $US3bn estimated market
- Compounds in late stage clinical development
  - Proven human efficacy in Motiva™
  - Glypromate® in pivotal Phase III trial
  - NNZ-2566 to enter Phase II trial, with fast track status
- Major milestones to development already met
  - Safety
  - CMC scale up
  - Open IND for Motiva™ and Glypromate®
The Year Ahead

• Resolve long-term capital needs to the benefit of all shareholders

• Promising lead compounds Glypromate®, Motiva™ and NNZ-2566 on track for major valuation milestones
  • Confirmed efficacy of Glypromate® in Phase III / major efficacy trial
  • Confirmed efficacy of Motiva™ in Phase IIb – moving into pivotal trials (Phase III)
  • Confirmed efficacy of NNZ-2566 in Phase II – moving into pivotal trial under Fast Track

• Confirm significant partnering opportunities for pre-clinical pipeline

• Management’s total focus is the creation of shareholder value, minimizing our risks and maintaining tight control over our costs.
## Future Milestones

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<th>Timing</th>
<th>Status</th>
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<tbody>
<tr>
<td><strong>Glypromate®</strong></td>
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<tr>
<td>100 patients data safety review</td>
<td>Q2 2008</td>
<td>✓</td>
</tr>
<tr>
<td>300 patient data safety and sample size review</td>
<td>Q4 2008</td>
<td>on track</td>
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<tr>
<td>Completed recruitment</td>
<td>Q4 2008</td>
<td>on track</td>
</tr>
<tr>
<td>Announce results</td>
<td>Q2 2009</td>
<td>on track</td>
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<tr>
<td><strong>Motiva™</strong></td>
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<tr>
<td>Form committee around clinical strategy</td>
<td>Q2 2008</td>
<td>✓</td>
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<tr>
<td>Complete amended protocol</td>
<td>Q3 2008</td>
<td>on track</td>
</tr>
<tr>
<td>File protocol amendment</td>
<td>Q3 2008</td>
<td>on track</td>
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<tr>
<td>Start Phase IIb in post-stroke psychiatric sequelae</td>
<td>Q3 2008</td>
<td>on track</td>
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<tr>
<td><strong>NNZ-2566</strong></td>
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<tr>
<td>Pre IND Meeting</td>
<td>Q2 2008</td>
<td>✓</td>
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<td>IND submission</td>
<td>Q3 2008</td>
<td>on track</td>
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<tr>
<td>Initiate NNZ-2566 Phase II</td>
<td>Q3 2008</td>
<td>on track</td>
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<tr>
<td>Results</td>
<td>Q1 2010</td>
<td>on track</td>
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Financial Snapshot

ASX code: NEU
Shares on issue: 219.96 million
Market Cap: ~ $24M
Cash on hand: A$4.2M (31 March)
Number of employees: 16
Top 20 shareholders: > 67 % of shares
Summary

• An emerging global leader in treatments for central nervous system disorders and brain injury

• Three very promising late stage clinical candidates moving closer to registration

• Confident we have a very promising year ahead of us
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