

pharmaceuticals

Developing innovative new medicines for acute and chronic neurological and psychiatric conditions

Larry Glass, CEO

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Neuren Pharmaceuticals

- Created to commercialize University of Auckland intellectual property
- Focused on acute and chronic indications in neurology and psychiatry
- Two molecules in Phase II clinical trials under US INDs
- Trial costs covered by grants from US Army and NHMRC—\$23 million total
- Subsidiary (Perseis Therapeutics) developing mAbs for breast, other cancers
- Operations in US, New Zealand and Australia
- Experienced management team (all with >5 years at Neuren)

Larry Glass, Chief Executive Officer

30⁺ years of life sciences experience in management and business development; former CEO of CRO supporting major pharmaceutical and biotechnology companies and US government agencies including NIH, CDC and the US Army

Maggie Scott, RN, CCRP, Director, Clinical Operations

25⁺ years of management experience in global clinical trials and regulatory affairs; former manager of Greenlane Clinical Research organization; led 3 clinical development programs resulting in NDAs

Mike Bickerdike, PhD, Director, Preclinical R&D

20⁺ years of research, drug discovery and non-clinical development in the neurosciences; former research project leader and department director at Vernalis Research (UK)

Rob Turnbull, Chief Financial Officer

20⁺ years experience in corporate finance; former PricewaterhouseCoopers accountant in Auckland, Toronto and London specializing in financial reporting by foreign registrants in the U.S. and securities regulation

Douglas Wilson, MB, ChB, PhD (Director and CMO)

40⁺ years in academic medicine and the pharmaceutical industry in the US and EU ; former CMO of Boehringer Ingelheim responsible for all clinical development and FDA interactions

James Bonnar, Director, QA and Regulatory Affairs

 $20^{\rm +}$ years of experience in quality assurance and regulatory affairs for drug development and manufacturing in NZ, China, the US and the UK



Product Pipeline

Disco	overy \	Validated Lead		Formulation		Phase I		Phase III	
	Pre-Clinic Efficacy		Manufact	uring	Pre-Clinica Toxicology		Phase II		Commercialization
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NNZ-2566 product overview

- IGF-1(1-3) is a naturally occurring neuroprotective peptide
- NNZ-2566 is a synthetic analog of IGF-1(1-3)
- Phase II for moderate to severe traumatic brain injury (Fast Track)
- Direct costs covered by grants from US Army
- 18 Level I and II trauma centers in the US and AU (10 active)
- 3 cohorts (20 mg/kg bolus plus 72 hr infusion at 1, 2, 6 mg/kg/hr)
- Cohort 1 (30 patients) completed; cohort 2 underway
- IND for exception from informed consent filed May 2011
- Forecast completion: Q4 2012
- Regulatory strategy: single Phase II, single pivotal trial under SPA
- Oral formulation in development for mild TBI; Phase II Q1 2012
- Oral formulation also targeting Rett Syndrome/Autism



NNZ-2566 clinical profile

Mechanism of action

- Inhibits upregulation of inflammatory cytokines (IL-6, IL-1β, TNF-α, E-Selectin, IFN-δ)
- Normalizes pro-apoptotic Bax and anti-apoptotic Bcl-2 expression
- Inhibits microglial activation
- Attenuates post-injury seizures (convulsive and non-convulsive)



Clinical trial design

- Double-blind, placebo controlled, rising dose
- 260 acute, non-penetrating TBI patients (Glasgow Coma Scale 4-12); 16-75 years
- Randomized 2:1 drug to placebo
- Administration of drug within 8 hours of injury
- Endpoints
 - Safety
 - Pharmacokinetics
 - Functional outcomes: Glasgow Outcome Scale-Extended (GOS-E); ADL (Mayo-Portland Adaptability Index); neurocognitive function; mood
 - Biological outcomes: seizures detected by continuous EEG; serum biomarkers of neuronal, glial and axonal cell damage; intracranial pressure



NNZ-2566 commercialization strategy

Market

- 1.5 million brain injuries per year in the US alone
- No approved therapies
- At \$12,000 for IV and \$3,000 for oral:
 - Moderate severe = ~\$2 billion
 - Mild = ~\$2 billion

Competitive advantages

- Only product that addresses the full range of TBI from mild to severe
- Only competitive product at Phase II or beyond is progesterone
- Two approvable outcomes: neurological function and prevention of seizures
- Broad MOA reflects polypharmacology of a naturally occurring neuropeptide
- Excellent safety profile; no known or expected drug interactions
- KOLs already involved and committed

Partnership status

- US Army supporting development; will be a major client (no residual rights)
- Partnership discussions underway

First sales expected — 2016





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525.000

Not Hospital-

treated

Financials

- Market cap = US\$13 million
- Cash on hand = US\$3.3 million
- Burn rate = US\$200k per month (net of clinical development costs covered by grants)
- Shares on issue = 618 million
- Share price = A\$0.02

