

## Chairman's Address - Dr. Richard Treagus

### **Annual Shareholders' Meeting**

Of

# Neuren Pharmaceuticals Limited, 20 May 2013

Good afternoon Ladies and Gentlemen. This is my first Annual Shareholders' Meeting with Neuren, having accepted the role of Chairman at the beginning of

February this year. I would like to express my pleasure at being here and being

able to present not only the results in respect of the financial year ended 31

December 2012, but also importantly, how we see the prospects for the

business over the next couple of years.

We have spent the last few months reviewing all aspects of the business with the management team and the Board and I am pleased to report that we have identified and agreed a clear path forwards; one that is firmly premised on maximising our prospects of success and delivering value back to our shareholders.

I will preface my remarks with a view that the equity markets have yet to recognise the full potential of Neuren's underlying technology and we therefore acknowledge the task we have in terms of building a more representative company valuation.

In my report to you this afternoon I wish to touch on four key areas. These are:

1. Neuren's unique, patented science

- 2. Our strategy and investment thesis
- 3. Our organisational structure
- 4. Financial position

#### Neuren's unique, patented science

As an organisation we have come to learn that inflammation, microglial dysfunction and deficits in synaptic plasticity (the connections between brain cells) play a major role in the development and progression of many, if not most brain disorders and are hallmarks of traumatic brain injury, concussion and Rett Syndrome. These are precisely the processes targeted by our lead clinical compound, NNZ-2566. In animal models, NNZ-2566 has been shown to significantly and favourably impact inflammation, cellular pathology, and functional or behavioural outcomes.

In November last year, we added further to this understanding by announcing the results of testing NNZ-2566 in a mouse model of Fragile X Syndrome, a genetically linked neurodevelopmental disorder. Neuren was able to demonstrate that NNZ-2566 normalized the anatomic, biochemical and behavioural features of the disorder with results that achieved statistical significance in all measures.

We are currently undertaking research into our cyclic dipeptide NNZ-2591, and more specifically testing it in a mouse model of Fragile X to better elucidate the clinical potential of this unique synthetic analogue.

Our pre-clinical results on NNZ-2566 have to date provided us with a compelling scientific basis from which to actively pursue evidence of clinical outcomes in human subjects.

Central to the value of our company is the fact that the Neuren technology has a broad and robust patent position. For NNZ-2566 and its related analogues, a total of seven patents have been issued, including composition of matter as well as methods of use and oral formulation. The first to expire is 2022. Three

patents covering composition of matter and method of use claims for NNZ-2591 and its related analogues are issued with the first to expire in 2024.

#### **Neuren's Strategy**

Let me now turn to our strategy.

To date, and with significant financial support from the US army, Neuren has been conducting a Phase 2 clinical study into the clinical effect of NNZ-2566 in Traumatic Brain Injury (TBI). The INTREPID study as it is referred to is utilising a short-term, or acute, intravenous NNZ-2566 therapy. During the course of 2012 we completed a Phase 1 pharmacokinetic study of an oral dose form of NNZ-2566 and this we believe gives us good grounds to investigate the use of NNZ-2566 in the broader indication of acute concussion. Larry will detail this more fully in his CEO review.

Neuren's strategy is to maximise the commercial value of the NNZ-2566 drug molecule by extending the therapeutic application from acute brain injury, or inflammatory conditions, to include chronic neurodegenerative conditions that will almost certainly require longer-term treatment, possibly even life-long therapy.

To this extent, and in collaboration with the International Rett Syndrome Foundation, Neuren recently commenced a Phase 2 clinical trial in the neurological disorder referred to as Rett Syndrome. This study is actively recruiting subjects and we expect to deliver a clinical trial result in mid-2014.

Furthermore, in light of the compelling pre-clinical results that I referred to earlier, Neuren recently made a decision to proceed with the planning and implementation of a Phase 2 clinical study in the genetic neurodevelopmental disorder of Fragile X. We expect to commence this study in the second half of this calendar year, and to complete enrolment in the fourth quarter of 2014.

The point that I wish to emphasise is that our decision to proceed with these opportunities represents an objective assessment of the scientific rationale, a

determination of the unmet medical need as well as the overall commercial feasibility. Because TBI and Rett Syndrome are serious medical conditions, drugs being developed to treat them qualify for accelerated regulatory review and approval with the FDA. It is possible that NNZ-2566 may qualify for Orphan drug status for one or more of our target indications.

With two Phase 2 clinical trials already underway and two further Phase 2 studies in the planning, Neuren has a well-defined strategy squarely aimed at eliciting a clinical signal in human subjects. We believe that to the extent we are successful in the clinic, it will place Neuren in an enviable position with respect to potential strategic partnerships with pharmaceutical companies.

#### **Organisational Structure**

In April we announced our decision to locate Neuren's investor relations and some administrative functions in Australia. We are well advanced in this regard and I expect to announce the appointment of a Melbourne-based CFO to our executive team in the very near term. Over coming months we will be raising the profile of the company within the broader Australian and New Zealand investment communities.

In addition, we have chosen to consolidate all clinical development and clinical operations in the US. We expect that this move will ensure greater operational effectiveness and accountability, particularly as we embark on an expanded number of clinical programs.

Although it is not possible to mitigate every technical risk, we will always seek to place emphasis on having the best clinical study design, attention to detail in the execution of our clinical and regulatory strategies, and the prudent use of the company's resources.

#### **Financial Position**

Current cash on hand as at the end of April 2013 was NZD4.24 million.

Given that we have a number of clinical opportunities to execute on over the coming 18 months, we are giving our full consideration to a range of funding alternatives, including but not limited to additional army funding, grant monies, as well as the potential for introducing strategic investors. The company is not under any immediate pressure to raise funds and we are confident that we have the full support and commitment of our major shareholders in the event that additional equity funding is considered necessary.

As at the end of April 2013, the company had 299 million outstanding options at an average weighted exercise price of 2.9c. I can advise that retiring Directors have exercised 10 million options at 3.77c and a further 15 million options related to these parties have either not vested or are due to lapse upon their retirement.

Of the total outstanding options, 65 million are currently "in the money" and will either be exercised, or they will lapse before the end of 2013.

Before closing, I would like to acknowledge our two retiring Directors, Dr. Doug Wilson and Dr. Robin Congreve. Robin has been a Director of the company since its formation in December 2001 and Doug has served as a Director and a medical consultant since June 2004. On behalf of the Board I extend our gratitude to them for their service and commitment to Neuren over an extended period of time.

In summary, we remain ever mindful of the challenges that drug development presents, however we are now putting the right elements in place to effectively execute on our strategy over the next two years. We have a committed and capable management team, an experienced Board and a supportive shareholder base. We will continue to rapidly pursue our key clinical projects, motivated by the belief that we have a rare opportunity to make a profound difference to patients' lives and at the same time realise the full potential and value of Neuren's underlying assets.

I wish to thank our CEO, Larry Glass and his team for their concerted efforts, my fellow Board members for their invaluable guidance and our many shareholders for the support and faith they have placed in Neuren.

Thank you.

Richard Treagus