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With Lead Drug Candidates based on a Naturally Occurring Growth Factor in the Brain called IFG-1, Neuren Pharmaceuticals Limited is Developing Drug Candidates for Areas of Huge Unmet Medical Need such as Neurological Disorders and Cancer

Biopharmaceutical
Neurological Disorders, Metabolism and Cancer
(ASX: NEU)

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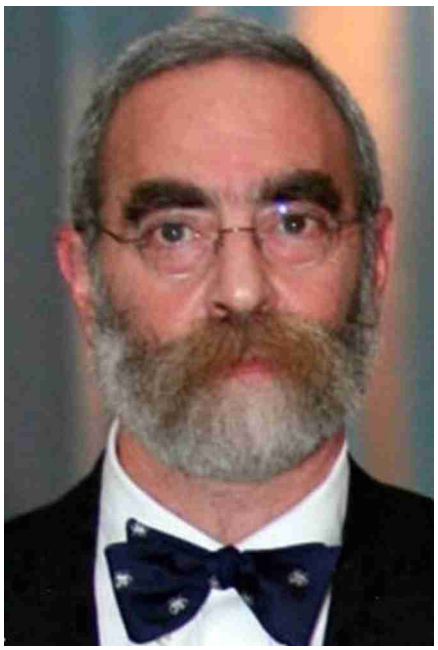

Larry Glass
CEO and Managing Director

BIO:
Mr Glass joined Neuren in early 2004 as Executive Vice President. He is a seasoned manager with more than 30 years in the life sciences industry. Before he joined Neuren, he worked as an independent consultant for a number of biotech companies in the US and internationally providing management, strategic and business development services. Prior to that, he was CEO of a contract research organization that provided preclinical research and clinical trials support for major pharmaceutical and biotechnology companies and the US government. For a number of years, the CRO operated as a subsidiary of a NYSE-listed company and was subsequently sold to a European biopharmaceutical enterprise which was then acquired by Johnson & Johnson. Since joining Neuren, Mr. Glass has led business development activities in the US and Europe and established operations in the US. Mr. Glass was appointed Managing Director in May 2012.

Company Profile:
Neuren Pharmaceuticals Limited (Neuren) is a New Zealand-based company. It is a biopharmaceutical company focusing on the development of drugs for neurological disorders and cancer. The drugs target acute indications of brain injury as well as chronic conditions such as neurodevelopmental disorders, Parkinson's and Alzheimer's diseases. Neuren has three candidates: Motiva and NNZ-2566 are in clinical development to treat a range of acute and chronic neurological conditions and NNZ-2591 is in preclinical development for Parkinson's disease dementia and other chronic neurodegenerative conditions. The Company has operations in New Zealand and the United States.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Glass, what is the main concept behind Neuren Pharmaceuticals Ltd?

Mr. Glass: Neuren is a biopharmaceutical company developing drugs for both acute and chronic neurological diseases and disorders and, through a subsidiary called Perseis Therapeutics, developing monoclonal antibodies for breast and other cancers. In the neurology area, all of the molecules that we are developing are synthetic analogs of naturally occurring molecules. We are not a classic drug discovery operation where we find a target and then screen large numbers of molecules to find out which ones light up when they are in the same test tube or petri dish with the target. Our lead drug candidates are all based on proteins that are naturally expressed in the brain. We like to say that evolution is our drug discovery platform. When we start out with a naturally occurring molecule we already know that it "works." What we have to do is turn that natural product into a drug and that is what we do. What we are primarily working on is related to a naturally occurring growth factor in the brain called IGF-1.

CEOCFO: Why do you want to work with that specifically?
Mr. Glass: Neuren was actually created by combining two companies that had been spun out of the University of Auckland to commercialize IP that was coming out of what is called the Liggins Institute, which is a center for research on human growth and development. The people in that center, including Professor Peter Gluckman who was the head of the Liggins at that time, were working on IGF-1 which is the effector molecule for growth hormone. As it turns out, IGF-1 not only plays a significant role in human growth, but it also plays a sig-

nificant role in the function of the brain, both in natural development as well as in the response to injury or degeneration. Peter Gluckman and his colleagues were among the first to recognize that IGF-1 plays an important role in the CNS, publishing one of the first papers on the topic in 1992. In the intervening twenty years, he and other folks have continued to explore the role of IGF-1 in the brain and that is the core logic for starting the company and our primary focus.

CEOCFO: What are you trying to understand and where are you in the process?

Mr. Glass: When the brain is injured or when there is a neurodegenerative process like Alzheimer's or Parkinson's disease, IGF-1 in the brain is up-regulated and the amount that is expressed is increased. There is a piece on the end – technically called the n-terminal tripeptide or (1-3)IGF-1. We have called it Glypromate®, which is just Glycine-Proline-Glutamate stuck together. What we have done with our lead molecule, which is NNZ-2566, is to produce a synthetic version of (1-3)IGF-1 that has been modified slightly to make it look and act more like a drug. It is resistant to degradation in the body, it is orally available and more and more we have confirmed just how safe and effective it is. With NNZ-2566,the first therapeutic target was identified through a collaboration with the US Army. It is focused on traumatic brain injury. There is growing evidence that IGF-1 is up-regulated following a brain injury and that the tripeptide I mentioned falls off and plays a significant role in helping the brain restore and repair itself, particularly by controlling inflammation. We began working with the Army in 2004 to elaborate the effectiveness of the molecule in animal models with traumatic brain injury and to determine specifically what its molecular mechanisms are. While the Army was doing that research, Neuren was busy figuring out how to manufacture it cost-effectively and putting it through the stages that are required by the FDA regulations to put it into humans. That process has now reached the point that we are part way through a Phase II trial in patients with moderate to severe traumatic brain injury where the drug is infused into the patients for three days following brain injury. That trial is ongoing at eleven level one and level two trauma centers in the US. It is predominantly paid for via grants from the Army with a total of about $23 million worth of funding that helps support that trial. We also discovered that because of the modifications we made to the native molecule in creating NNZ-2566 that the molecule is also orally available whereas the native tripeptide and the native parent molecule, IGF-1, are not orally available. That means that potentially NNZ-2566 could be used as a therapy not just for severe injuries or diseases that either require or justify the use of intravenous administration but also in a few doses or on a chronic basis for diseases where an oral formulation is suitable. We're getting ready to start a trial in mild traumatic brain injury or concussion where it is suitable or reasonable to administer the drug by mouth rather than intravenously.

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We are also working on a program in a very severe neurodevelopmental disorder that was previously linked to autism spectrum disorder called Rett Syndrome. Rett Syndrome is a genetic condition that occurs almost exclusively in girls because it is lethal in males. Kids develop normally from anywhere from six to eighteen months and then there is a very rapid period of decline such that, by the time they're three or four years old, many of the kids are wheelchair bound, the vast majority of them are incapable of language, they have stereotypical hand movement that makes it difficult for them to use their hands purposively and they have a pretty significant range of autonomic problems including seizures and breathing and cardiac irregularities. It is a fairly rare disorder but after Downs syndrome it is the second most common cause of severe intellectual disability in girls. A group at MIT, several years ago, published a paper resulting from an ambitious research product where they had shown that IGF-1 and particularly the tripeptide were very effective at reducing the severity of symptoms and in fact reversing some of the symptoms in a mouse model of Rett Syndrome. On the basis of that research they are actually running a Phase II trial at Boston Children's Hospital with the full length IGF-1 molecule. IGF-1 or mecasermin, which is branded Increlex®, is a recombinant human product approved for IGF-1 deficiency in children which results in very short stature. It was developed by a company called Tercica, which was actually created by Neurens' first chief scientific officer and is now owned by a company called Ipsen. Based on their work, we started looking at whether NNZ-2566 could be a potential therapy for Rett syndrome and we believe it is. It recapitulates mechanisms of the native tripeptide or Glypromate®, and it has certain clinical advantages over IGF-1. For one thing, it can be orally administered whereas IGF-1 is administered by injection. And, as far as we know, it can be given to adults and older children whose bone growth is finished, whereas full length IGF-1 can not because it induces rapid bone growth. That is the basic rationale for pursuing Rett Syndrome with NNZ-2566 without going into all kinds of detail on the molecular mechanisms. We have announced that we are working with the Bluebird Circle Rett

Center at Baylor College of Medicine and Texas Children's Hospital in Houston, which is one of the world's leading centers on Rett research. Baylor has now been awarded a grant from the International Rett Syndrome Foundation which will pay for a good part of the cost for the first trial.

CEOCFO: Has the medical community been paying attention to Neuren?
Mr. Glass: The medical community, particularly in the neurotrauma area and, not just Rett Syndrome but also some of the other genetically determined forms of autism or pervasive neurodevelopmental disorders, are definitely paying attention, especially in areas where public awareness is really growing. I'm sure you've heard all the stories lately about concussion in football, soccer and other sports and at the moment there is no treatment for concussion. Yet, just a few years ago we used to say "well it's just a concussion". More and more, we are realizing that the long-term consequences of concussion can be really devastating. Therefore, yes, the medical and research and biopharmaceutical communities are definitely sitting up and paying attention.

CEOCFO: You recently added to your team as far as clinical development and medical affairs; why now?
Mr. Glass: Right now, we are running one Phase II clinical trial in moderate to severe traumatic brain injury and that is a collaboration with the army. In partnership with the army, we put together a stellar advisory group to help guide that program. By the end of this year, we will be running two more Phase II clinical trials which are in very different areas that have more of a neuropsychiatric focus. The expertise that Dr. Joe Horrigan brings in psychiatry, pediatric drug development for neurosciences, neurology and across the board in clinical development, is a most welcome and needed addition to the intellectual capital that Neuren brings to the project. Joe is a well-recognized expert in clinical trials, design and execution in neurology and psychiatry particularly in pediatric groups.

CEOCFO: Would you tell us about the psychiatric aspects being considered at Neuren Pharma?
Mr. Glass: With concussion, the effects that last a few days or a few months in some people and in others can last a lifetime are actually neuropsychiatric, caused by damage to the brain particularly the white matter or axons which connect the neurons and maintain communication between them. Irritability, memory problems, attention problems, sleeping problems, problems with self-control can all be very much a part of the post-concussion syndrome. For lack of a more precise term, those would fall generally under the area of psychiatry or neuropsychiatry. In concussion, you do not see the kinds of effects that you do from more severe traumatic brain injury where people can be profoundly impacted in terms of their physical ability and in terms of their ability to function on a day-to-day basis. It looks more like a severe stroke than it does a concussion, whereas concussions tend to be milder and symptoms tend to be more clustered in the neuropsychiatric domains. Rett Syndrome and the more severe autism spectrum disorders have a range of both psychiatric and neurological symptoms. However, it is the neuropsychiatric symptoms that are in some ways the most important in terms of quality of life and we believe that these potentially are amenable to effective therapy. Dr Horrigan does not just work in psychiatry; when he was at Glaxo SmithKline he did a lot of work in other areas including multiple sclerosis and Alzheimer's and attention deficit hyperactivity disorder. He works and we work in that broad area of neurosciences which includes parts of neurology and parts of psychiatry which is why we tend to use the term neuropsychiatry.

CEOCFO: Why should Neuren stand out to the medical and investment communities?
Mr. Glass: We stand out in part because of the superior science and development strategies and because we are targeting indications or diseases and conditions that very few other companies have the nerve to target. For every indication we are chasing right now, such as brain injury, concussion, Rett Syndrome and potentially other autism spectrum disorders there are no approved drugs at all. There is a huge unmet medical need and that translates into a huge market opportunity for us and for our shareholders. We also have obtained $23 to $24 million worth of non-dilutive capital which has kept our internal costs down and allows us to do bigger more expensive, more elaborate trials than we would be able to do if we were a typical struggling biotech dependent on raising venture capital. We think it is a great opportunity, it is well funded, we have cash in the bank right now enough to get through next year. We are listed on the Australian Securities Exchange which is a fairly easy exchange to invest in either from here or Europe as well as from Australia and New Zealand. We are a very open, transparent company. Our phone number is on the website and investors can call me up and ask me whatever they want, any time they want. We are what we are. We believe that Neuren represents an unusual investment opportunity - not that it doesn't carry the same kind of risk that any other biotech company carries, but we think we have gone a long way down the track towards de-risking the assets. We will not know until the end of the trials if they work or not. However, if they do, then from the market cap that we are seeing right now we would expect a pretty substantial jump. Of course, as bigger pharmaceutical and biotech companies increase their targeting of orphan and rare diseases and particularly in the autism space, there are substantial opportunities for partnering with bigger companies as well. That would mean we retain some of the value of what we have built and the cost of taking it through to approval and marketing.

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