



**NeuroScientific**  
BIOPHARMACEUTICALS

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## **Research and Development Program Update, 18 November 2019**

### **Commencement of study “Protective effects of intravitreal EmtinB in a pig model of raised IOP” with data expected by the end of the CY2019**

The Company recently commenced a pivotal pre-clinical efficacy study in the NeuroScientific Biopharmaceuticals’ (“NSB”) ophthalmology program. The study is conducted by the research team at the Lions Eye Institute and is investigating the ability of EmtinB to protect the retinal ganglion cells (RGCs, specialized projection neurons that relay an immense amount of visual information from the retina to the brain), nerve fibers, glial cells and other retinal neurons in a porcine model of elevated intraocular pressure. In this model, the short-term elevation of intraocular pressure has been shown to produce neuronal and astrocyte damage after only a few hours in this model.

By looking at changes in astrocyte morphology and evidence of reduced apoptosis within the optic nerve head of these eyes, the Company will be able to determine whether EmtinB is able to rescue this Glaucoma model (revert pathology of Glaucoma to a healthy state). Success in this regard would be a major outcome in ophthalmology and would present a major potential commercial opportunity in the Glaucoma field. The initial protocol of the study required eight pigs and we currently have finished the experimental procedures in half of the animals with final data expected by the end of the calendar year. Positive data in this study will allow the Company to progress into testing of EmtinB in human Glaucoma patients early next year.

### **CVN Alzheimer’s mouse model study results to be released this month**

The Board and the management of NeuroScientific Biopharmaceuticals believe that the turning point in Alzheimer’s pathology is when the brain accumulates enough plaques and tangles to prompt the microglia inflammatory response.

Under normal conditions, the microglia inflammatory response represents the brain’s “housekeeping squad” cleaning away damaged neurons and their components to keep the brain healthy. However, under pathological conditions such as Alzheimer’s, this response can overreact to accumulation of protein plaques and launch an all-out inflammatory attack on both harmful and healthy cells. This type of microglia is now classified by scientists as disease associated microglia.

EmtinB’s ability to modulate microglia induced neuroinflammation in Alzheimer’s Disease and its ability to activate neuronal pro-survival pathways leading to axonal regeneration could be a game-changing approach towards Alzheimer’s Disease.

To provide additional evidence for this unique approach, NSB is currently completing a preclinical efficacy study in one of the most comprehensive animal models of Alzheimer’s disease (CVN mouse model).

One of the biggest issues identified as negatively impacting the translation of preclinical Alzheimer’s research into effective drug treatments is the lack of animal models that replicate the disease as it occurs in humans.

The previous “gold standard” animal models do not fully replicate the progression of the disease in an age-related manner, are mainly based around plaque production in the brain and do not show significant neuronal loss.

In contrast, CVN mice develop both amyloid and tau pathologies, the hallmarks most commonly associated with Alzheimer’s disease, and demonstrate significant neuronal loss and inflammation resulting in significantly reduced performance in learning and memory tasks.

We are particularly interested in changes in biochemical and immunological markers in the CVN model, as well as cognitive endpoints:

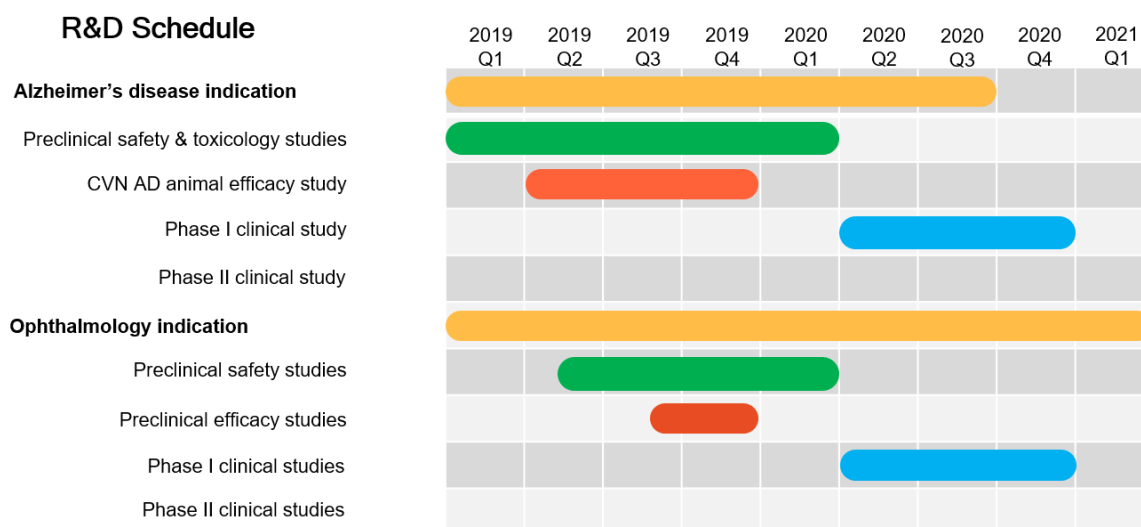
- The CVN study is using proton magnetic resonance spectroscopy (MRS) to provide a window into the biochemical changes associated with the loss of neuronal integrity and other neurodegenerative pathology that involve the brain. MRS allows regional measurement of metabolites including myo-Inositol (ml), choline (Cho), N-acetyl aspartate (NAA), Gamma-Aminobutyric acid (GABA) and creatine (Cr). Changes in these biomarkers have been described as early indicators of Alzheimer’s Disease manifestation and the Company is investigating the ability of EmtinB to return the biomarker signatures to a healthy state.
- The pathology in CVN mice is driven by local immune suppression and areas of neuronal death are associated with the presence of immunosuppressive microglia. In the final part of the CVN study, the Company will evaluate the ability of EmtinB to modulate microglia activity in the brain.

If both endpoints demonstrate positive outcomes, EmtinB will be the first drug in development to have these unique traits. We expect full set of data from CVN study to be available this month.

### Preclinical safety and toxicology program to complete early CY2020

The safety and toxicology program conducted by Covance is progressing towards the important Good Laboratory Practice (GLP) studies and the Company estimates that the program is 75% complete. On the basis that there are no further delays to any aspects of the program that are within the control of Covance and / or Neuroscientific Biopharmaceuticals, the Company expects a final report with full data on pre-clinical safety and toxicology program to be available early next year. This data will allow the Company to progress into a Phase 1 study in humans early next year.

### Company’s Updated R&D schedule provided below



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## **About NeuroScientific Biopharmaceuticals Ltd**

NSB (ASX:NSB) is a drug development company focused on developing peptide-based pharmaceutical drugs for the treatment of neurodegenerative conditions with high unmet medical need. The Company's product portfolio includes EmtinB, a novel therapeutic peptide most advanced as a treatment for Alzheimer's disease; and other related peptides (EmtinAc, EmtinAn, and EmtinBn) which have demonstrated similar therapeutic potential as EmtinB. For more information, please visit [www.neuroscientific.com](http://www.neuroscientific.com)

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