NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

ASX ANNOUNCEMENT
28 February 2022

KEY ACTIVITY HIGHLIGHTS 1HY22

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) is pleased to announce the release of its financial report for the half year ended 31 December 2021.

KEY HIGHLIGHTS

- **NeuroScientific significantly progressed the Neurology Safety Program with the reporting of successful completion of GLP Safety Pharmacology studies and Off-Target Safety studies.**
- **The completion of pivotal safety studies for the Ophthalmology Safety Program were reported and undertaken in the leading gold standard model for ocular toxicity.**
- **Positive biomarker data indicates EmtinB™ has a significant effect on inflammation associated with Multiple sclerosis. NeuroScientific has partnered with leading research organisations BioSpective and Imeka to accelerate development of EmtinB™ as a treatment for Multiple sclerosis.**
- **The Scientific Advisory Team was expanded to including key international experts, ophthalmologist Dr Peter Hnik and toxicologist Dr Frank Bonner.**
- **Positive preclinical outcomes were reported for the Exploratory Pulmonary Fibrosis Program, in which EmtinB™ significantly reduced inflammatory markers associate with COVID-19 infections by >50%.**
- **1HY2022 Financial Results include a loss of $5,731,040 compared to $1,224,848 loss 1HY2021.**
- **NeuroScientific expects to report on a number of significant milestone and de-risking events in the lead up to commencing the first-in-human Phase I study during 2HY2022. The transition from preclinical to clinical development is an incredibly exciting period in the drug development process and the NeuroScientific Team are acutely focused on achieving this goal during the second half of FY2022.**

During the first half of the 2022 financial year NeuroScientific achieved significant progress across its research and development (R&D) programs involving lead drug candidate EmtinB™. In addition to completing a number of pivotal safety studies for both neurology and ophthalmology preclinical programs, the Company accelerated its Multiple sclerosis R&D Program by undertaking biomarker studies and partnering with industry leading research organisations and expanded its scientific advisory team to include international experts in toxicology and ophthalmology. NeuroScientific also reported positive outcomes from its exploratory preclinical Pulmonary Fibrosis studies.

NEUROLOGY R&D SAFETY PROGRAM

During this period NeuroScientific achieved important progress with the Neurology Safety Program, reporting the successful completion of pivotal GLP Safety Pharmacology studies and positive outcomes from a comprehensive *in vitro* Off-target Safety Assessment. Nonclinical GLP Safety

Pharmacology studies evaluate the potential for a drug to cause adverse effects on the central nervous, cardiovascular, and respiratory systems, and form a key component of the safety package to support regulatory approval to start clinical hastudies. The off-target Safety Assessment of EmtinB™ involved screening across 173 known targets of human toxicities, demonstrating the low potential for EmtinB™to cause major adverse events in humans.

Key GLP Toxicity studies were also undertaken in first half of FY2022 and the Company remains on-track to report this data during 2HY2022 and finalise the safety data package to support a first-in-human Phase I study.

OPHTHALMOLOGY R&D SAFETY PROGRAM

NeuroScientific significantly progressed its Ophthalmology Safety Program with the completion of a pivotal 4-week Ocular Safety and Tolerance study in non-human primates (NHPs) and completion of the dosing phase of a GLP 13-week Ocular Toxicity study in NHPs. Both studies assessed multiple doses of EmtinB™up to 3x the estimated effective dose in humans and were undertaken in the leading gold-standard model for ocular toxicity, with the 4-week Ocular Tolerance study reporting no abnormal adverse effects and safety outcomes from the 13-week Ocular Toxicity study due to report in 2HY2022.

The safety data from the GLP 13-week Ocular Toxicity study represents a major de-risking event for EmtinB™and the Ophthalmology Safety Program due to the duration of the study being the longest to be undertaken by the Company to date in assessing safe dosing of EmtinB™.

MULTIPLE SCLEROSIS R&D PROGRAM

NeuroScientific reported positive biomarker data that indicated significant reductions in the dysfunctional immune responses associated with Multiple sclerosis (MS). MS is a chronic neurodegenerative disease in which abnormal immune responses attack the central nervous system. In preclinical assays of T Cell inflammation, EmtinB™reduced important MS-related biomarkers Interferon-gamma-inducible protein-10 (CXCL10/IP-10), Matrix Metalloproteinase-9 (MMP-9), Immunoglobulin G (IgG), and decreased Th1-mediated cell proliferation. Of notable significance, the biomarker results indicate that EmtinB™has the potential to treat the early-phase of MS (relapse-remitting MS) and the previously demonstrated positive effect of EmtinB™on the process of remyelination is relevant to the more advance phases of the disease. Currently available drugs for the treatment of MS are only effective in the early phase relapse-remitting type of MS, positioning EmtinB™as a potential first-in-class disease modifying drug for the treatment of MS.

Given the impressive body of early-stage evidence to support the disease modifying potential of EmtinB™in MS, NeuroScientific partnered with leading Canadian-based research companies BioSpective, Inc. (BioSpective) and Imeka to support its MS R&D program. BioSpective were engaged to undertake animal studies at their state-of-the-art facilities during 2HY2022, which will incorporate Imeka's powerful diffusion MRI imaging technology to assess different aspects of activity in the brain and evaluate the disease modifying effects of EmtinB™in MS.

EXPANSION OF SCIENTIFIC ADVISORY TEAM

The Company reported the addition of two key drug development experts to its scientific advisory team with the appointments of highly experienced clinical ophthalmologist Dr Peter Hnik MD MHSc and internationally recognised toxicologist Dr Frank Bonner PhD FBTS.

Both Dr Hnik and Dr Bonner bring considerable drug development experience to NeuroScientific and continue to provide invaluable supporting guidance for the Company's R&D programs and the advancement of EmtinB™into clinical development.

EXPLORATORY PULMONARY FIBROSIS STUDIES

NeuroScientific successfully completed its exploratory Pulmonary Fibrosis program during the first half FY2022, with the reporting of significant reductions of >50% in inflammatory markers associated with COVID-19 infections. Significant reductions were demonstrated in inflammatory markers Serum Amyloid A (SAA), Interferon-gamma-inducible protein-10 (CXCL10/IP-10), and Eotaxin 3 (Eot3). Safety studies undertaken by the Institute for Respiratory Health also confirmed that EmtinB™ was safe and well tolerated in lung tissue.

Further studies for this program may be undertaken in the future, however the Company will focus on its core R&D programs and the transition into clinical development during 2HY2022.

FINANCIAL RESULTS 1HY22

The financial results for 1HY2022 reflect the continued advancement of the Company's lead drug candidate EmtinB™ from preclinical to clinical development as a potential treatment for Alzheimer's disease, Multiple sclerosis, and glaucoma.

NeuroScientific reports a net after-tax loss for the half year ended 31 December 2021 of $5,731,040 (31 December 2020: $1,224,848). Research and development expenditure was significantly higher during the period at $3,795,238 (31 December 2020: $583,296) predominantly driven by preclinical studies and manufacturing activities to support the commencement of clinical trials during 2HY2022.

At 31 December 2021 the Company had a cash and cash equivalents balance of $9,498,909 (30 June 2021: $14,162,247) and Net Assets of $9,844,223 (30 June 2021: $14,604,031).

OUTLOOK FOR 2HY2022

During 2HY2022 NeuroScientific expects to report a number of significant milestone and major de-risking events for EmtinB™ associated with the transition from preclinical development to clinical development:

- Reporting of the final safety data for the Neurology Safety Program
- Submission of the Neurology Safety Data Package for review by Human Research Ethics Committee (HREC) for approval to commence the Phase I clinical study
- Patient recruitment and commencement of a first-in-human Phase I study

This announcement is authorised by the Board of NeuroScientific Biopharmaceuticals Ltd.

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About NeuroScientific Biopharmaceuticals Ltd

NeuroScientific Biopharmaceuticals Limited (ASX: NSB) is a company developing peptide-based pharmaceutical drugs that target a number of neurodegenerative conditions with high unmet medical demand. The company's product portfolio includes EmtinB™, a therapeutic peptide initially targeting Alzheimer's disease and glaucoma, as well as other Emtin peptides (EmtinAc, EmtinAn, and EmtinBn) which have demonstrated similar therapeutic potential as EmtinB™. For more information, please visit www.neuroscientific.com

About EmtinB™

EmtinB™ is a peptide-based compound that binds to surface-based cell receptors from the LDLR family, activating intracellular signalling pathways that stimulate neuroprotection, neuroregeneration and modulate neuroinflammation. EmtinB™ is modelled on a specific active domain of the complex human protein called Metallothionein-IIA, which is produced as part of the human body's innate immune response to cell injury.

Our preclinical research has established that EmtinB™ is highly specific and selective for its target receptor, safe and well tolerated at high concentrations, and is able to penetrate the blood brain barrier. A series of Phase I clinical studies will be conducted to establish the safety profile of EmtinB™ in humans.