### **ASX Announcement**

20 November 2024



# 2024 AGM Chairman Address and Investor Presentation

**Neurotech International Limited (ASX: NTI)** ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, herein provides the Chairman Address and Investor Presentation to the 2024 Annual General Meeting (AGM) of shareholders to be held today at the offices of BDO Australia - Melbourne, Collins Square, Tower 4, Level 18, 727 Collins St, Docklands VIC 3008 at 9:00am (AEDT).

#### Chairman Address to Shareholders

The agenda for the Meeting today will be as follows: I will start by providing a brief overview of Neurotech, our key highlights from the 2024 financial year (FY2024), including our clinical and financial developments and corporate governance. I will then outline the Meeting procedures and continue to the formal items of business.

Following the completion of the formal items, Executive Director Dr Tom Duthy will then give a presentation of Neurotech's core development platform, clinical trials, strategic initiatives and our outlook for the 2025 financial year.

FY2024 was one of substantial progress for Neurotech. Neurotech focussed its resources on the accelerated clinical development of our proprietary broad-spectrum cannabinoid drug therapy NTI164 across three difficult to treat paediatric neurological disorders, namely Autism Spectrum Disorder (ASD), Rett Syndrome and Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS. We are focused on developing NTI164 for neurological disorders where there is strong evidence of persistent or progressive neuroinflammation. All three opportunities represent a combined addressable market opportunity of approximately US\$7.2 billion per annum, with limited or no safe and effective therapies currently available.

During FY2024, our open-label Phase I/II clinical trials in Rett Syndrome and PANDAS/PANS met their respective primary endpoints and a number of key secondary endpoints, while our double-blind, placebo-controlled Phase II/III clinical trial in ASD also reported the primary endpoint had been met, along with all secondary endpoints available to date. Importantly, across all three clinical trials, NTI164 once again showed an excellent safety and tolerability profile, with just one serious adverse event recorded across all 94 patients to date (including into our long-term extensions). Adverse events were mild and included some nausea and vomiting in a small number of patients, which is most likely attributable to the oil-based carrier. These results represent a significant achievement for a small development company like Neurotech. All patients who have elected to do so, have received NTI164 for 52 weeks or longer under the extension phase of the trials. Our longest ASD patient has now received therapy for nearly 200 weeks, and our last Rett Syndrome patient will cross over 52 weeks of daily therapy in the first quarter of the next calendar year.

The execution of these trials has been exemplary. We would like to thank our three clinical investigators, Professor Michael Fahey, Professor Russell Dale and Associate Professor Carolyn Ellaway for their commitment to their patients in seeking safe and effective therapies like NTI164 for their patients, where safe and effective therapies are desperately needed.



In April, Neurotech announced the appointment of Mr Robert Maxwell Johnston as a Non-Executive Director. Prior to his non-executive director career, Mr Johnston held the position of President and Chief Executive officer of Johnson and Johnson Pacific, a division of the world's largest healthcare company for 11 years. In addition, the Company announced the resignation of Mr Winton Willesee as a Non-Executive Director. On behalf of the Board of Neurotech and its shareholders, we wish to thank Mr Willesee for his valuable contributions to the Company during his time in office since his appointment to the board in April 2019.

FY2024 saw the further development of Neurotech's manufacturing capabilities that it has established to produce NTI164. This allows the company to support the patients who continue on the extension phase of NTI's four clinical trials as well as the registration enabling toxicology programs. Neurotech through its strategic partner Fenix Innovation Group ("Fenix") has established three separate manufacturing sites in Australia to produce NTI164. All sites are unrelated to the Company's existing license/licensor for neurological disorders and are managed by Fenix. The Company intends to continue to develop this manufacturing capability as it moves towards a possible registration of NTI164 in the future.

During the year, we successfully raised capital via a share placement following our excellent Phase II/III ASD results, and top-line Phase I/II Rett Syndrome clinical data. Neurotech received \$10 million with support from existing and new institutional, professional and sophisticated Australian and overseas investors.

We are in the final stages of finalising our 2024 R&D tax incentive filing and anticipate receiving a rebate of at least \$2.5 million on eligible R&D spend during FY24. When coupled with our 30 September 2024 cash balance of \$8.7 million, our pro-forma cash position of \$11.2 million, will allow the company to complete all current IND-enabling studies including animal toxicology work and a human pharmacokinetic trial in preparation for planned regulatory meetings with the US FDA and Australian TGA during the 2025 calendar year.

Recently, we announced the appointment of Dr Anthony Filippis as Managing Director and CEO of Neurotech International. Anthony will bring to Neurotech a significant amount of experience across the life sciences sector, with an outstanding track record of partnering success and capital markets expertise. On behalf of the Board, we welcome Anthony to the role and look forward to his contribution in executing our NTI164 strategy once he commences on 1 February 2025.

In September and November, Neurotech announced the results of the proteomic and genomic analysis on PANDAS/PANS patients, that participated in the Company's Phase I/II clinical trial, which confirmed that NTI164 normalises immune system gene expression and protein production. This significant finding has led to two further patent applications by the Company. Neurotech has now developed a strong Intellectual Property position and directly owns a portfolio of patent applications associated with the composition of different cannabinoids, their use in neurological disorders and modification of proteomic and genomic pathways in humans.

Finally, on behalf of the Board of Directors, we once again would like to thank our paediatric patients, their caregivers, our clinicians and our committed shareholders for their support of Neurotech over the last year. As a Board we certainly believe our current share price does not reflect the significant progress we have made, and the sound financial position of the Company as we embark on an exciting year ahead.

We look forward to updating our various stakeholders throughout the year ahead, which holds great promise for Neurotech International.

#### Authority

This announcement has been authorised for release by the Board of Neurotech International Limited.



#### **Further Information**

Dr Thomas Duthy Executive Director td@neurotechinternational.com +61 (0)402 493 727

#### **About Neurotech**

**Neurotech International Limited (ASX:NTI)** is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. Neurotech has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days and 20 weeks of treatment with NTI164. The Company has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD during Q4 CY2022. Neurotech plans to conduct additional Phase I/II trials in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with cerebral palsy during CY2023. Neurotech is also commercialising Mente, the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

For more information about Neurotech please visit <a href="http://www.neurotechinternational.com">http://www.neurotechinternational.com</a>.

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**Investor Presentation 2024 Annual General Meeting** 

**Dr Tom Duthy**Executive Director

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## **Neurotech Four Core Strategies**





Focus on Paediatric Patients



Focus on Partnering with Key Opinion Leaders / Clinicians



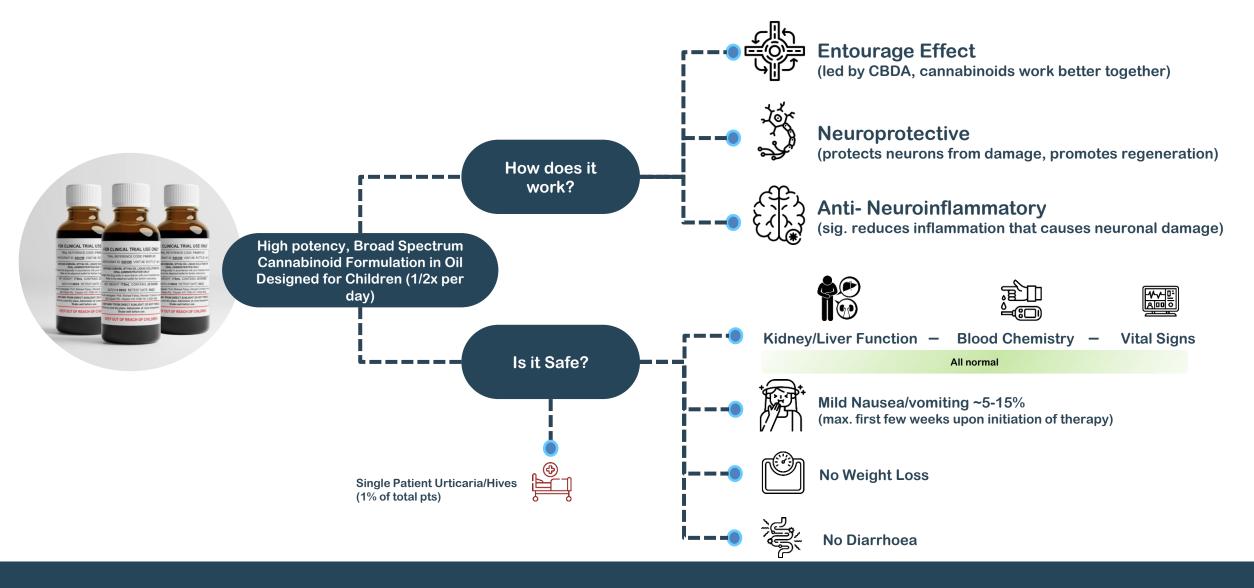
Focus On Rare Neurological Disorders with Neuroinflammation



Focus On Drug Product
Development

## **Therapeutic Agent: NTI164**





## NTI164 – Ideal Target Product Profile







**Prescription Only Medicine** 



FDA, EMA, TGA Approved



**Multiple Paediatric Neurological Disorders** 



**Premium Pricing Reflecting Clinical Investment** 



Reimbursed



**Orphan Designations + Other Regulatory Levers** 

<sup>1.</sup> Based on 73m children with 1/15,700 living with disease

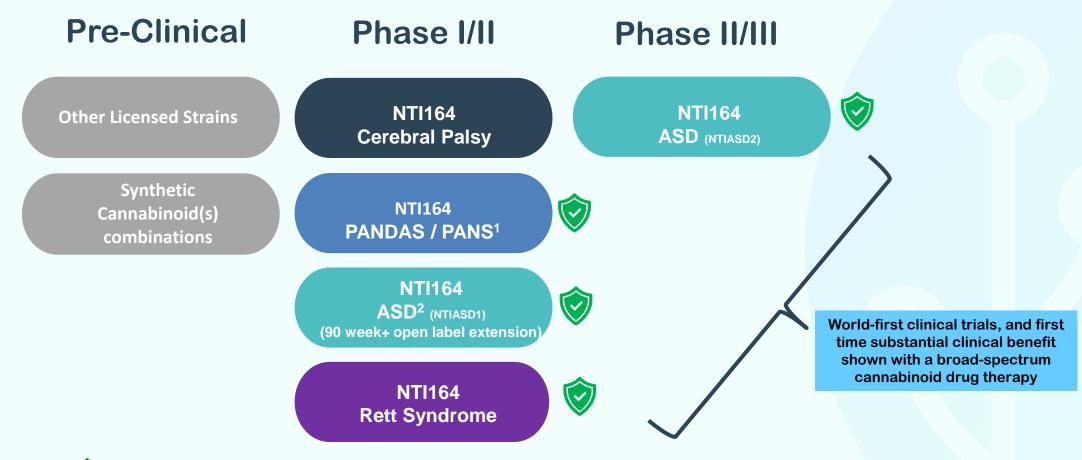
<sup>2. &</sup>lt;a href="https://www.lgsfoundation.org/">https://www.lgsfoundation.org/</a>

<sup>3.</sup> Tuberous Sclerosis Complex (TSC)

<sup>4.</sup> Jazz Pharmaceuticals

## Clinical Pipeline – 2024







Data reported (all with statistically significant primary endpoint results + large number of secondary endpoints)

<sup>1.</sup> Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)

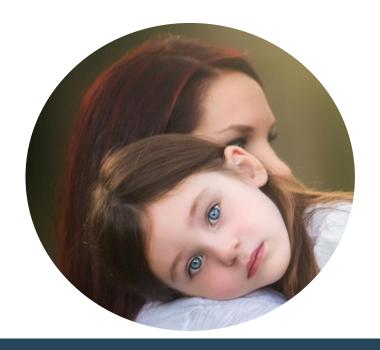
## Autism Rett PANDAS/PANS

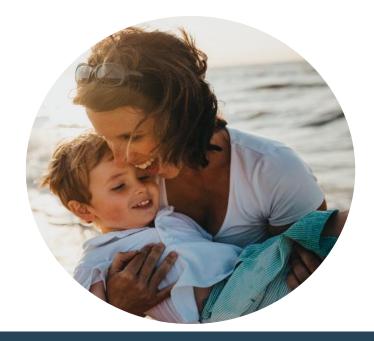


"The goals of treatment for Autism are to improve core deficits in social communication and social interactions and minimize the impact of restricted behaviours, with an overarching goal to help children develop greater functional skills and independence." 1

"Caregivers of children with **Rett** experience the illness as being like an "obstacle course", where they must continuously overcome hurdles. These include hindrances for finding responses to their symptoms and achieving a diagnosis, for managing the treatment and daily care, and for finding the essential financial resources to meet all the expenses generated by the illness."<sup>2</sup>

"We encourage clinicians, teachers, providers, extended family, and friends to understand the human aspects of PANDAS/PANS as symptoms are often so distressing, causing high levels of caregiver burden." 3







<sup>1.</sup> Weitlauf AS, McPheeters ML, Peters B, et al. Therapies for Children With Autism Spectrum Disorder: Behavioural Interventions Update. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Aug. (Comparative Effectiveness Review, No. 137.) Introduction.

<sup>.</sup> Palacios-Ceña D, Famoso-Pérez P, Salom-Moreno J, Carrasco-Garrido P, Pérez-Corrales J, Paras-Bravo P, Güeita-Rodriguez J. "Living an Obstacle Course": A Qualitative Study Examining the Experiences of Caregivers of Children with Rett Syndrome. International Journal of Environmental Research and Public Health. 2019: 16(1):41

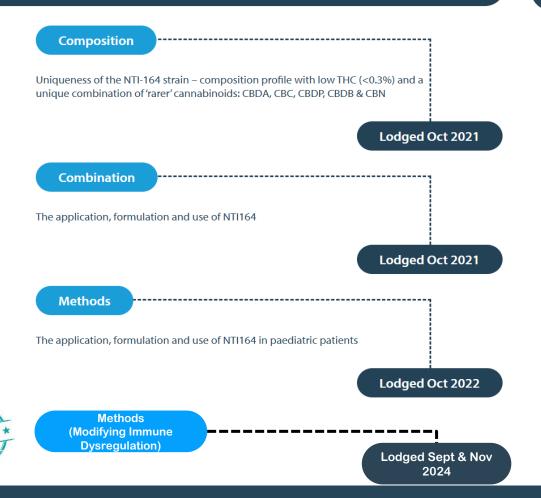
<sup>3.</sup> https://aspire.care/what-is-pans/caregiver-experience/

## **Intellectual Property – 2024**



#### **Strong Patent Position**

Neurotech has three patent families to underpin future worldwide commercialisation in neurological applications of NTI164. Two families have now entered the national phase and one family has entered the international (PCT) phase.



#### Other IP & Barriers to Entry

#### **Vertically Integrated: Seed to Patient Controlled**

(Trade Secret: continuity of production to SOP, extraction(s))



#### **Orphan Drug Designation(s)**

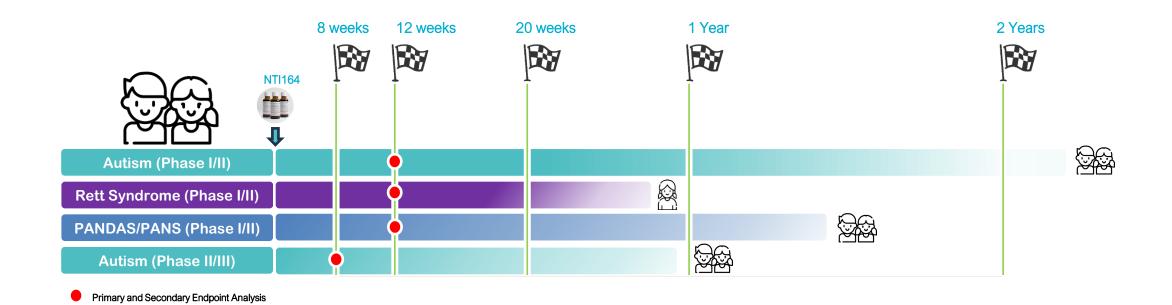
10 Years 7 Years Market Exclusivity from Approval – Europe
Market Exclusivity from Approval – United States

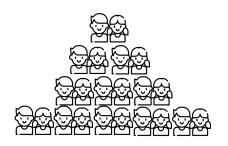
Rett Syndrome (US, EU)

### **Clinical Trials, Treatment Durations**



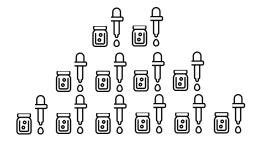
All patients can continue on NTI164 'extension' – additional long-term safety and efficacy collected





94
Children treated with NTI164 in a clinical trial and extension studies

2+
Years of daily oral treatment with NTI164 and counting

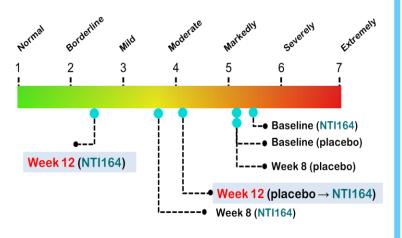


### NT1164 Efficacy is Strong, Durable and Consistent



### Autism (Phase II/III)

56% Improvement in Severity of illness at 12 weeks

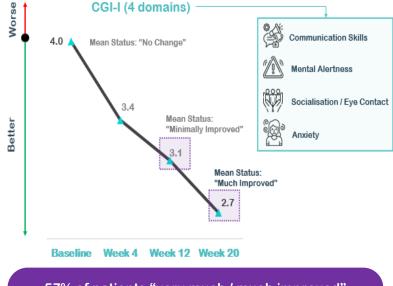


46% Patients much Improved / improved at 8 weeks

**Significant Improvements in Adaptive Behaviours** 

### Rett

100% of patients improved by week 20

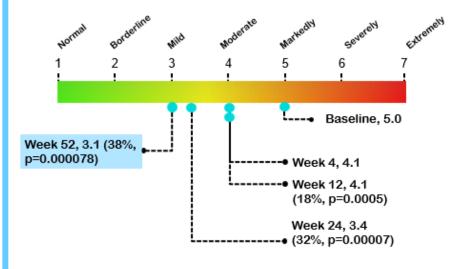


57% of patients "very much / much improved"

60% Improvement in patient/caregiver quality of life

### PANDAS/PANS

38% Improvement in Severity of illness at 52 weeks



45% Improvement in anxiety / depression at 52 weeks

### **2024 Corporate Strategy**





Secure one or more strategic partnerships for NTI164 in the United States, Europe and certain Asian territories to support clinical, regulatory development, manufacturing and future market launches

In 2023, at least 49 deals were announced involving rare neurological diseases, with disclosed values totalling US\$13.2 billion



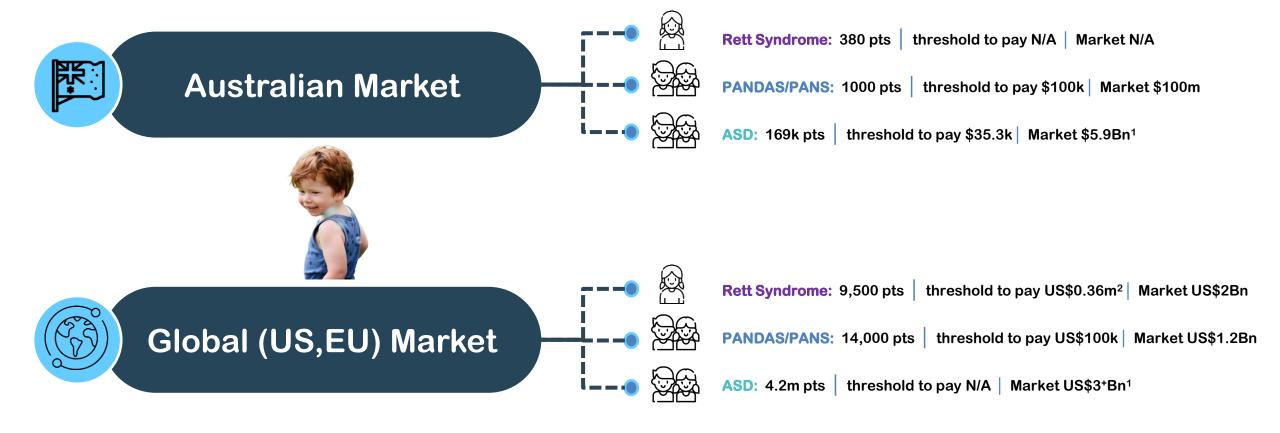
Seek provisional registration pathway for NTI164 initially for either PANDAS/PANS or Rett Syndrome (i.e. the orphan disease franchise)

Provisional registration(s) can save up to two years of development and a provisionally registered prescription medicine may be able to receive reimbursement. Follow with ASD (large market in AU)

### 2024 Corporate Strategy







## **Key Milestones – NTI164**



### 1H CY2024



HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial



24-week PANDAS/PANS Phase I/II Clinical Trial Data



Rett Syndrome Phase I/II 52-week Extension HREC Approval



Results of ASD Phase II/III Clinical Trial



Top-line Rett Syndrome Phase I/II Clinical Trial data



Results of Rett Syndrome Phase I/II Clinical Trial – full data



Meeting outcome – TGA¹ Regulatory Advice

### 2H CY2024



Appointment of A/Prof Carolyn Ellaway as CMO



Filing of Orphan Drug Designation USA – PANDAS/PANS + Rett Syndrome



Additional Phase II/III 12 Week Cross-Over Results – ASD



Metabologenomic data from Phase I/II PANDAS/PANS Clinical Trial

HREC approval human pharmacokinetic (PK) Phase I clinical trial

Orphan Drug Designation USA – Rett Syndrome

Continuation of FDA IND / EMA<sup>2</sup> enabling toxicology program

Commencement of the Phase I human PK trial

Orphan Drug Designation Europe – Rett Syndrome (Q1 CY2025)



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\*This presentation has been authorised by the Board of Neurotech International Limited

