#### **ASX Announcement**

13 August 2024



#### Neurotech to present at Investor Verse Biotech Workshop

**Neurotech International Limited (ASX: NTI)** ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today is pleased to announce that it will present at the Investor Verse Biotech Workshop to be held today.

Shareholders, investors and interested parties can register and join the live stream at the following link:

Join Zoom Meeting

https://us06web.zoom.us/j/86414258050?pwd=ilYKG1PpyATPAbbMeJ3MnYDNkMo3Aj.1

Meeting ID: 864 1425 8050

Passcode: Skillion

Executive Director Dr Thomas Duthy's presentation will be held from approximately 6.15pm AEST.

A copy of the presentation is attached.

#### **Authority**

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

#### **Further Information**

Dr Thomas Duthy
Executive Director
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#### **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, 20 weeks and 52 weeks of treatment with NTI164. The Company has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD, and completed a Phase I/II trial in Rett Syndrome and in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS. In addition, Neurotech has received human ethics committee clearance for a Phase I/II clinical trial in spastic cerebral palsy.

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





**Investor Verse Biotech Workshop Presentation** 

**Dr Tom Duthy**Executive Director

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## Corporate / Capital Summary



\$0.065
Share price

Share price (as at 9 Aug 2024)

\$66.1M

Market capitalisation

\$11.6M

Cash 30 June '24

~2,540

No. of shareholders

1017.3M

**Share on issue** 

176.5M

Options^

\$6.8M

FY24 cash R&D. (up from \$6.4M in FY23)

44.2%

**Top 20 Holders** 

## Neurotech Four Core Strategies

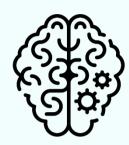




Focus on Paediatric Patients



Focus on Partnering with Key Opinion Leaders / Clinicians



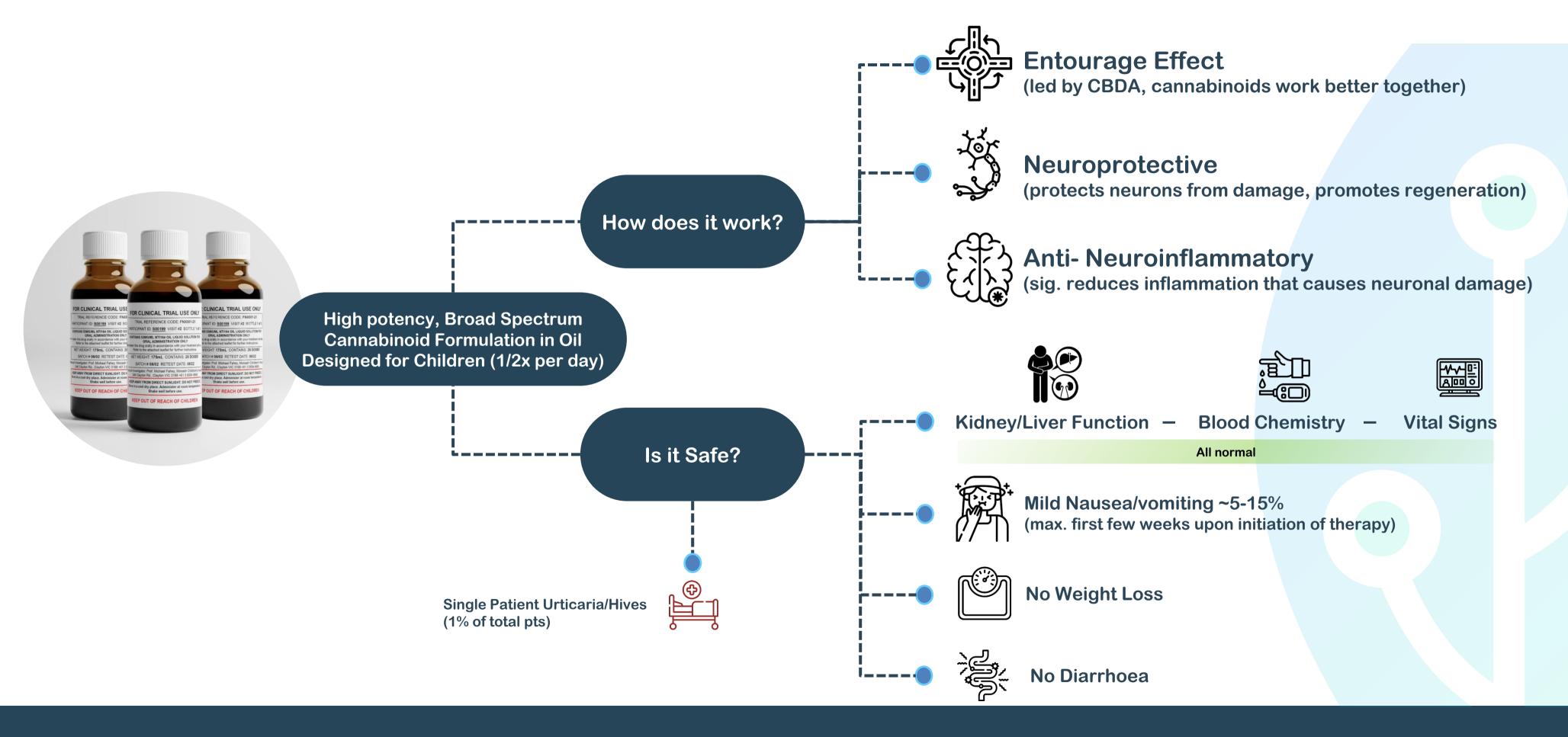
Focus On Rare Neurological Disorders with Neuroinflammation



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

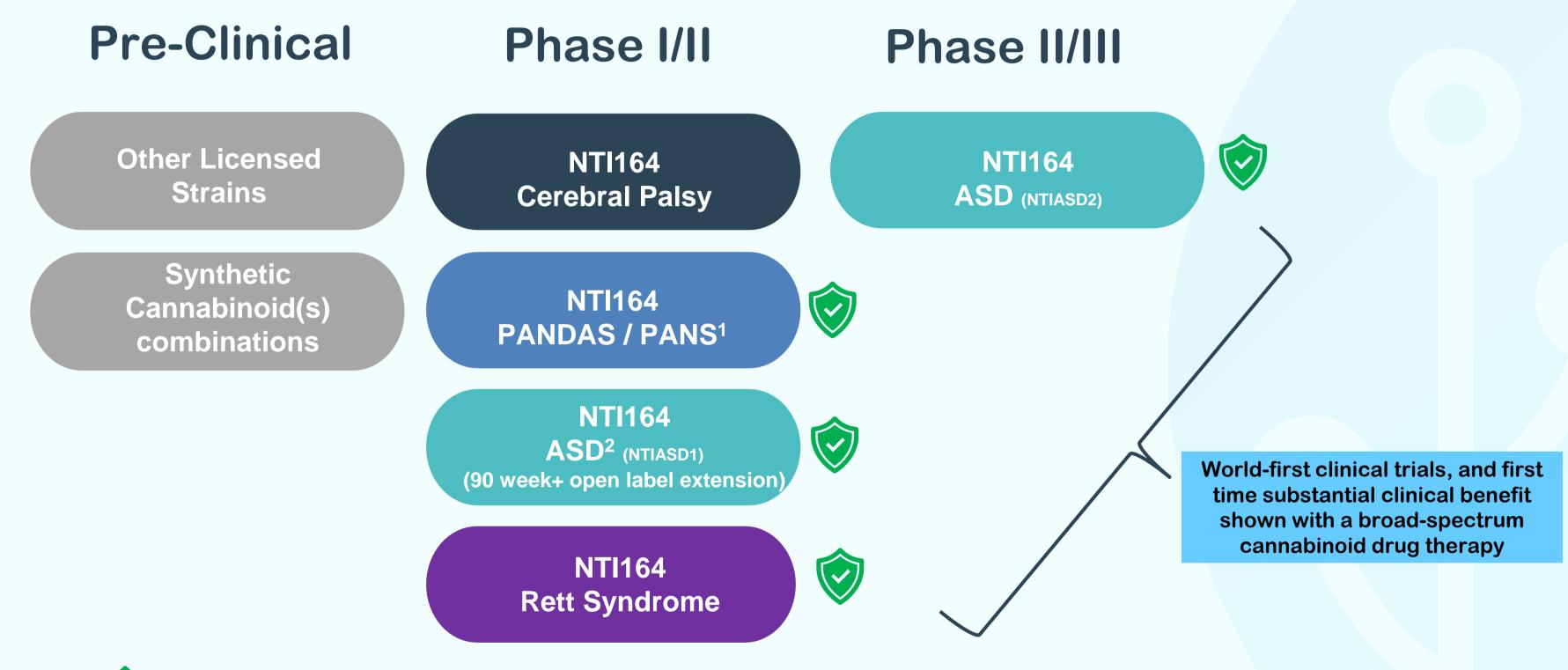
<sup>2. &</sup>lt;a href="https://www.lgsfoundation.org/">https://www.lgsfoundation.org/</a>

<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)

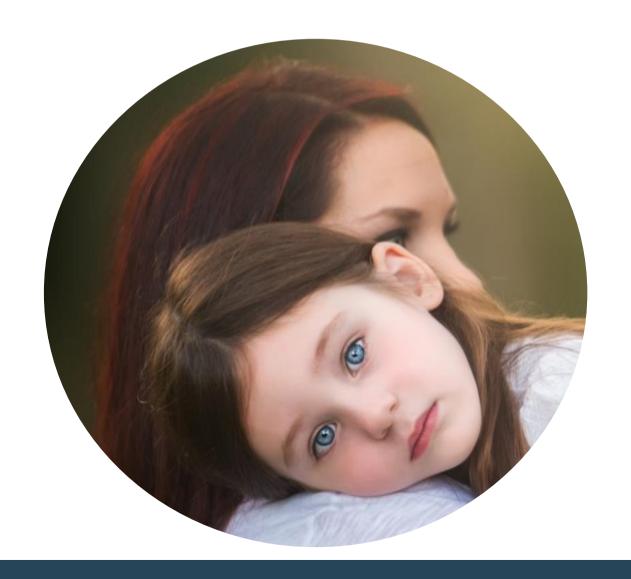
# Autism Rett PANDAS/PANS

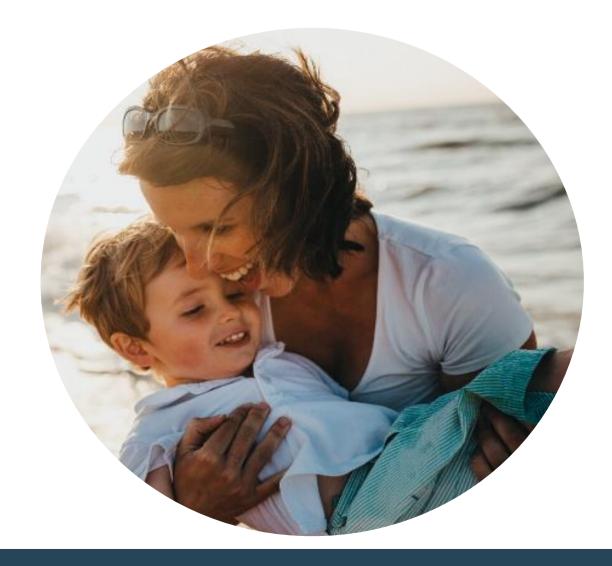


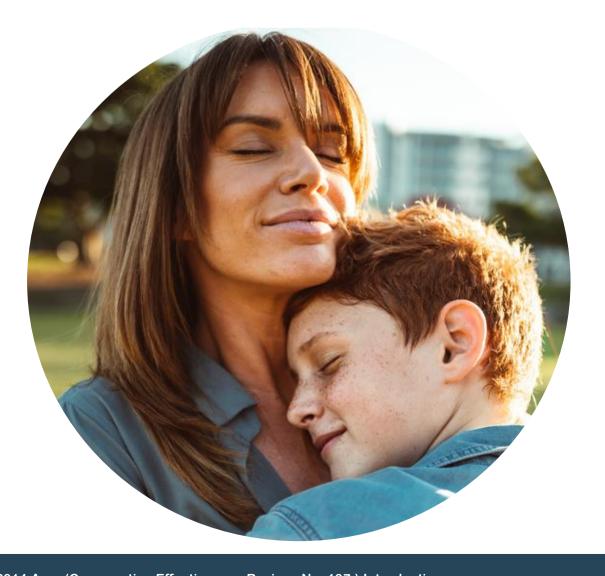
"The goals of treatment for Autism are to improve core deficits in social communication and social interactions and minimize the impact of restricted behaviours, with an overarching goal to help children develop greater functional skills and independence." 1

"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>2.</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

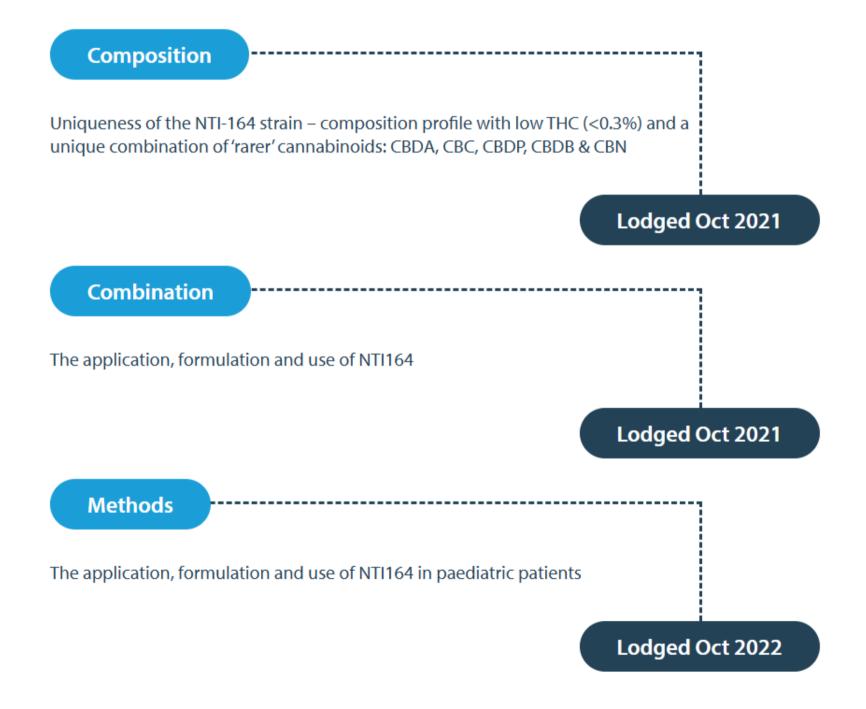
<sup>3.</sup> https://aspire.care/what-is-pans/caregiver-experience/

# 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

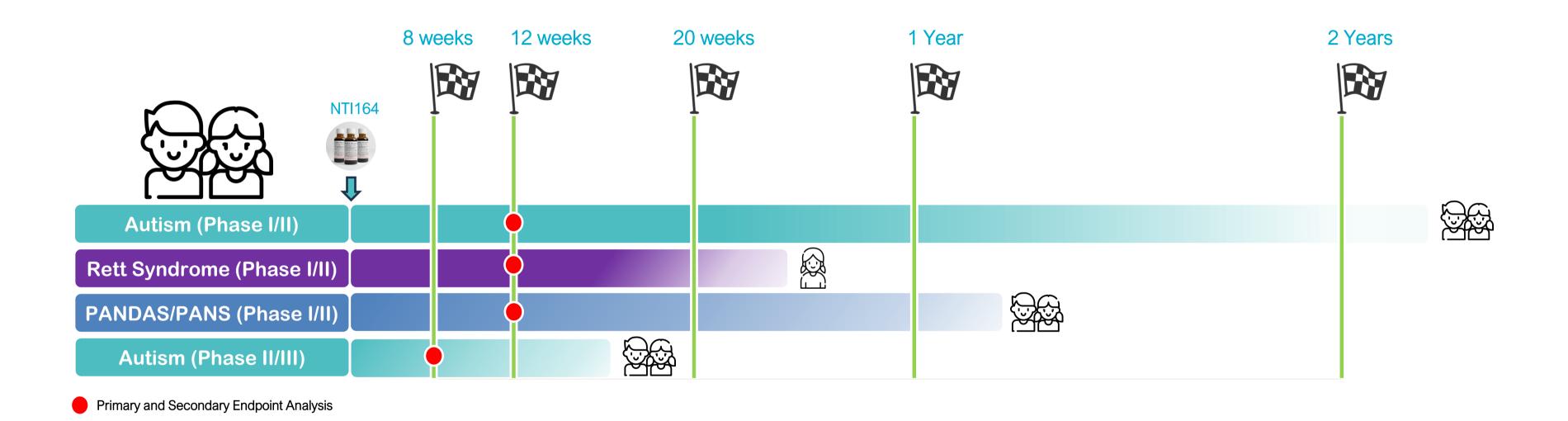
PANDAS/PANS Rett Syndrome

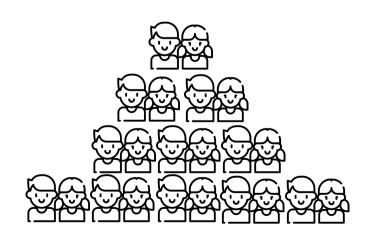
Pending

## Clinical Trials, Treatment Durations



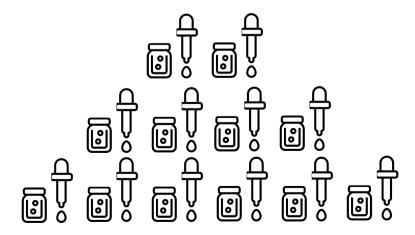
All patients can continue on NTI164 'extension' – additional long-term safety and efficacy collected





G4
Children treated with NTI164 in a clinical trial and extension studies

2+
Years of daily oral treatment with NTI164 and counting

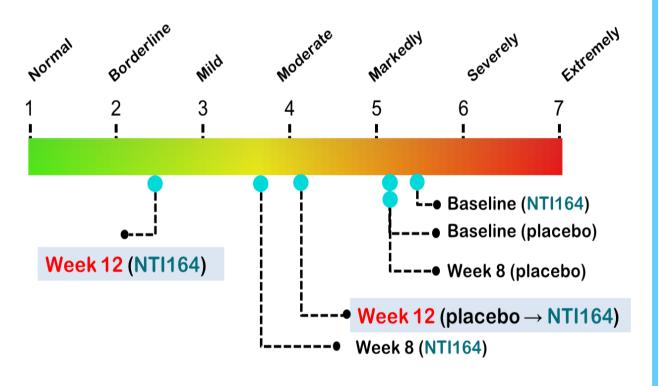


### NT1164 Efficacy is Strong, Durable and Consistent



## Autism (Phase II/III)

56% Improvement in Severity of illness at 12 weeks

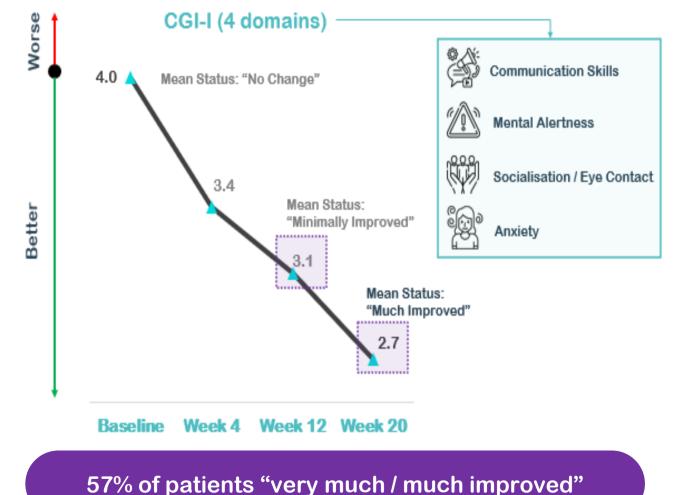


46% Patients Much Improved / Improved at 8 weeks

Significant Improvements in Adaptive Behaviours

### Rett

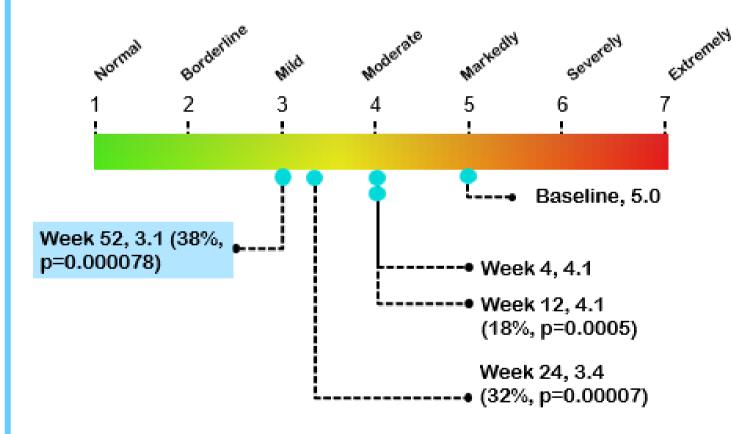
#### 100% of patients improved by week 20



60% Improvement in patient/caregiver quality of life

### PANDAS/PANS

38% Improvement in Disease Severity 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**



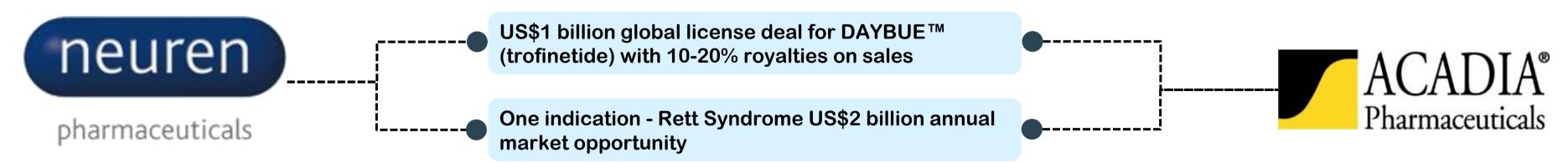


Partnering Example – Plant Derived High Dose Cannabinoid (CBD) Drug



Partnering Example –Rare Paediatric Neurological Disorders

(ASX:NEU), Market Cap: \$2Bn

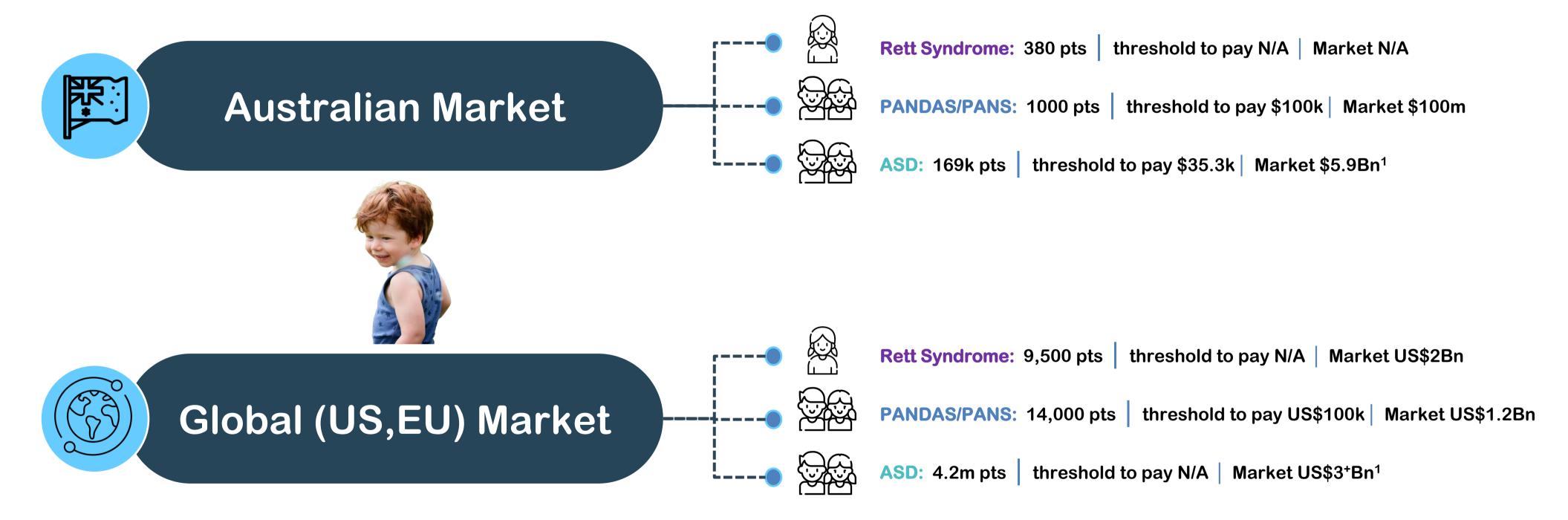


(NASDAQ:ACAD), Market Cap: US\$6.8Bn

### 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 TGA<sup>1</sup> Regulatory Advice
- Metabologenomic data from Phase I/II PANDAS/PANS Clinical Trial

Pending final analysis by Prof. Dale team (Q3)

### 2H CY2024



Appointment of A/Prof Carolyn Ellaway as CMO



Filing of Orphan Drug Designation USA – PANDAS/PANS



- Additional Phase II/III 12 Week Cross-Over Results ASD
- Orphan Drug Designation USA Rett Syndrome
- Orphan Drug Designation USA PANDAS/PANS
- Orphan Drug Designation Europe Rett Syndrome
- Orphan Drug Designation Europe PANDAS/PANS
- Presentation of Phase I/II Rett Syndrome data at international Rett meeting
- FDA IND / EMA<sup>2</sup> toxicology
- Commence Phase I/II Cerebral Palsy Clinical Trial
- Publications for ASD Phase I/II + pre-clinical NTI164 results (was 1H)



### **Contact Details**

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

