



**Investor Presentation** 

**Dr Tom Duthy**Executive Director

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### A short video on Neurotech





# Corporate / Capital Summary



\$0.074

Share price (as at 8 Jul 2024)

\$75.2M

Market capitalisation

\$13.6M

Pro-Forma Cash 31 March '24\*

~2,450

No. of shareholders

1016.7M

**Share on issue** 

176.5M

Options^

\$6.5M

**FY23 R&D Exp.** (up from \$2.6M in FY22)

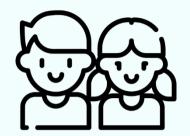
45.4%

**Top 20 Holders** 

<sup>• 31</sup> March cash balance of \$4.2 million + Equity Placement (net of fees of \$9.4m)

# Neurotech Four Core Strategies

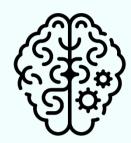




Focus on Paediatric Patients



Focus on Partnering with Key Opinion Leaders / Clinicians



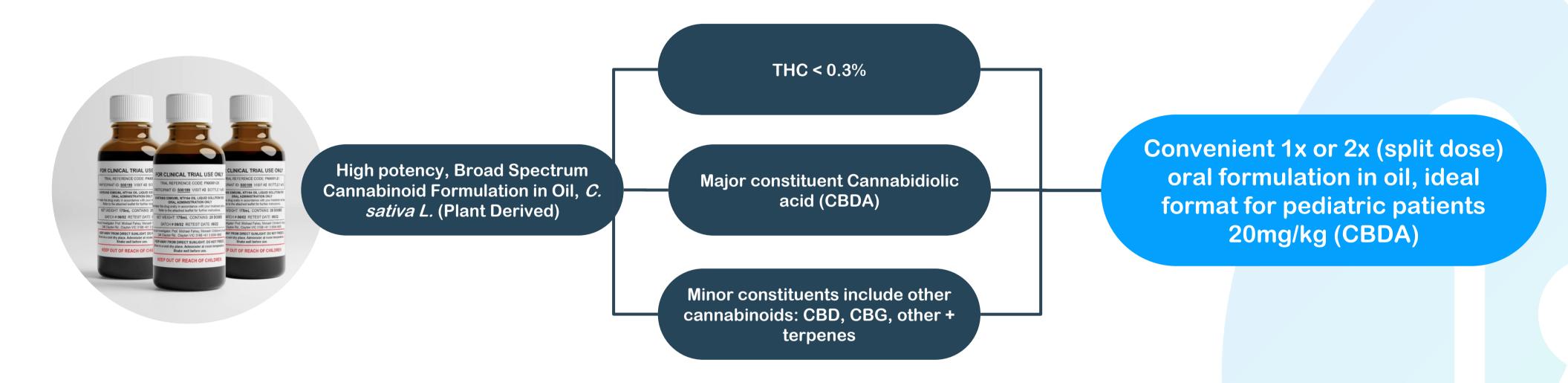
Focus On Rare Neurological Disorders with Neuroinflammation



Focus On Drug Product
Development

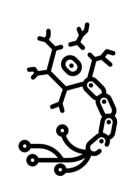
# Therapeutic Agent: NTI164





#### NTI164 is not a low dose CBD oil to be sold over-the-counter





Neuroprotective



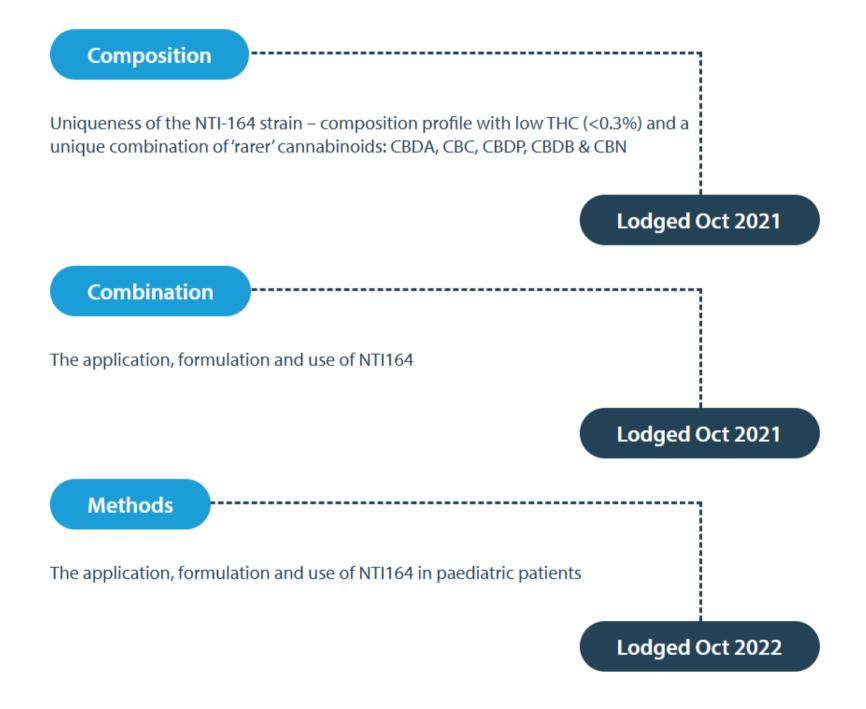
**Anti- Neuroinflammatory** 

# Intellectual Property – 2024



#### **Strong Patent Position**

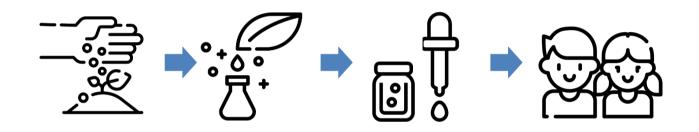
Neurotech has three patent families to underpin future worldwide commercialisation in neurological applications of NTI164. Two families have now entered the national phase and one family has entered the international (PCT) phase.



#### 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

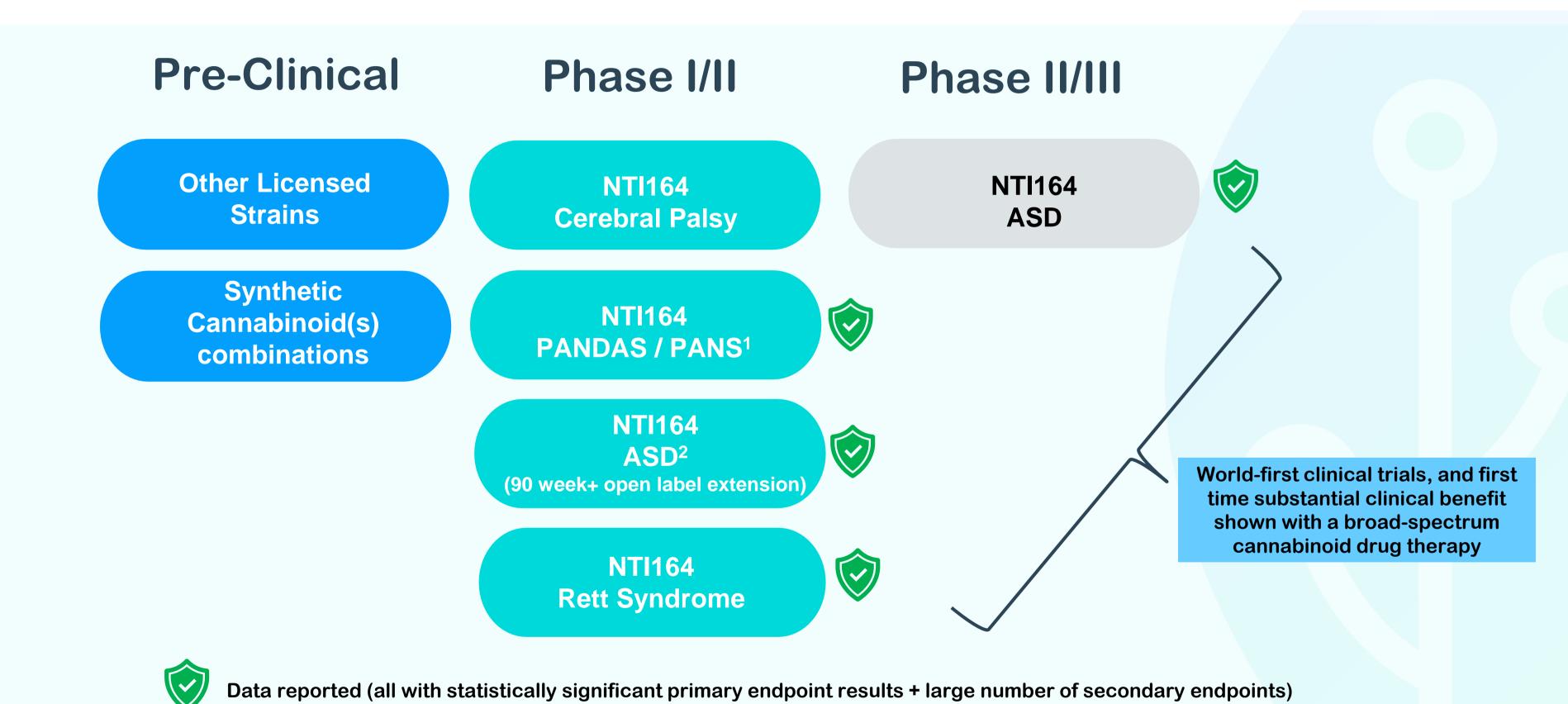
Market Exclusivity from Approval – Europe
Market Exclusivity from Approval – United States

PANDAS/PANS Rett Syndrome

Pending

## Clinical Pipeline – 2024





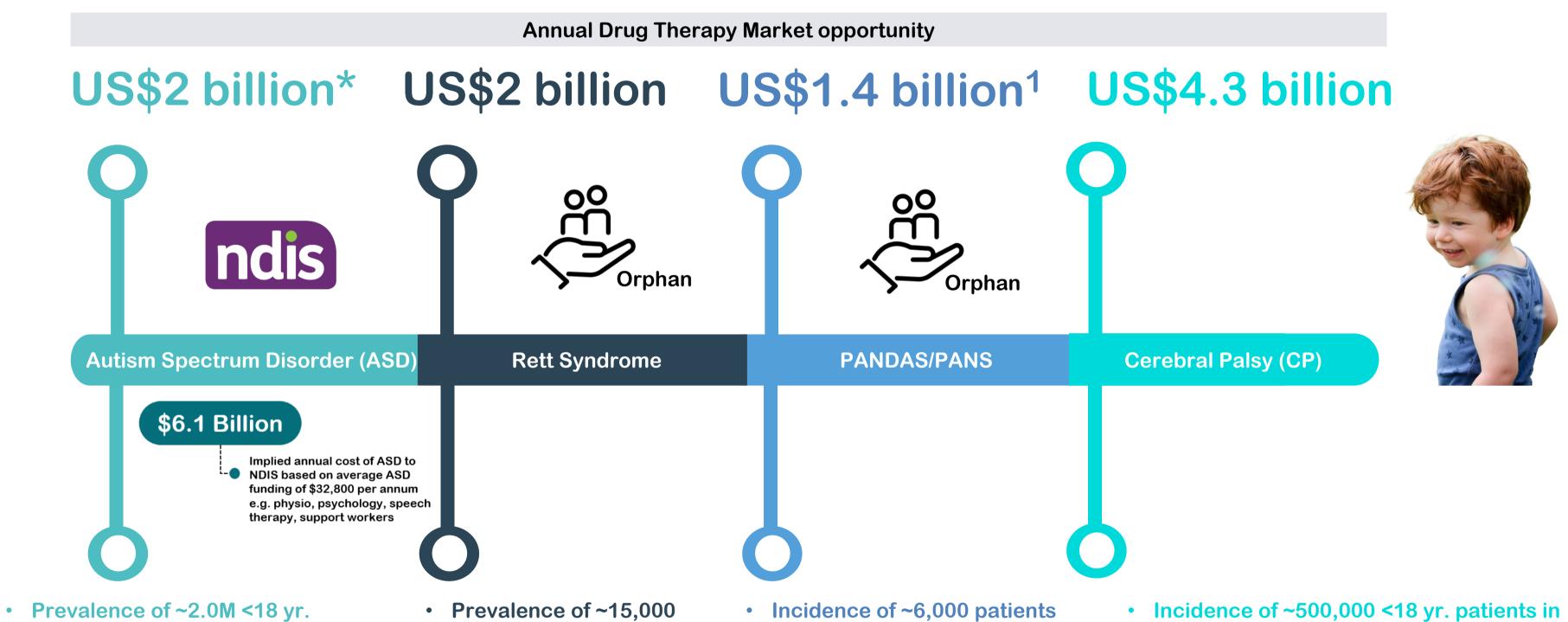
8

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

# **Our Target Markets**



#### Lack of effective therapies, significant unmet medical need



- patients in the US
- 2 Approved Drugs (\* limited use)
- Risperidone, Aripiprazole

- patients in the US
- 1 Approved Drug
- Trofinetide (DAYBUE™)
- <18 yr. in the US<sup>1</sup>
- No FDA/EMA Approved Drug
- the US
- 2 Approved Drugs for spastic CP
- Baclofen, Botox

### **CBD OTC Market - Australia**



Highly Competitive, Low Margin, Low Price, Lack of Differentiation, Stringent Regulatory Oversight – Not the Market for NTI164

**CBD Products Registered on the** ARTG<sup>1</sup>

44/35

**Domestic Manufacturers / Importers** of Cannabis Products on ODC<sup>2</sup> Website

Number of over-the-counter (OTC) CBD products able to make a substantiated medical claim<sup>3</sup>

**Average Cost per mg CBD** (↓↓ 76% since 2018)

150mg

Max. amount of pure CBD per day allowed under Schedule 3 (pharmacist-only medicine) (sub-therapeutic)

165 / \$2.3M

The number of infringements and total fines issued by TGA in last two years (unlawful advertising)4

Australian Register of Therapeutic Goods (ARTG)

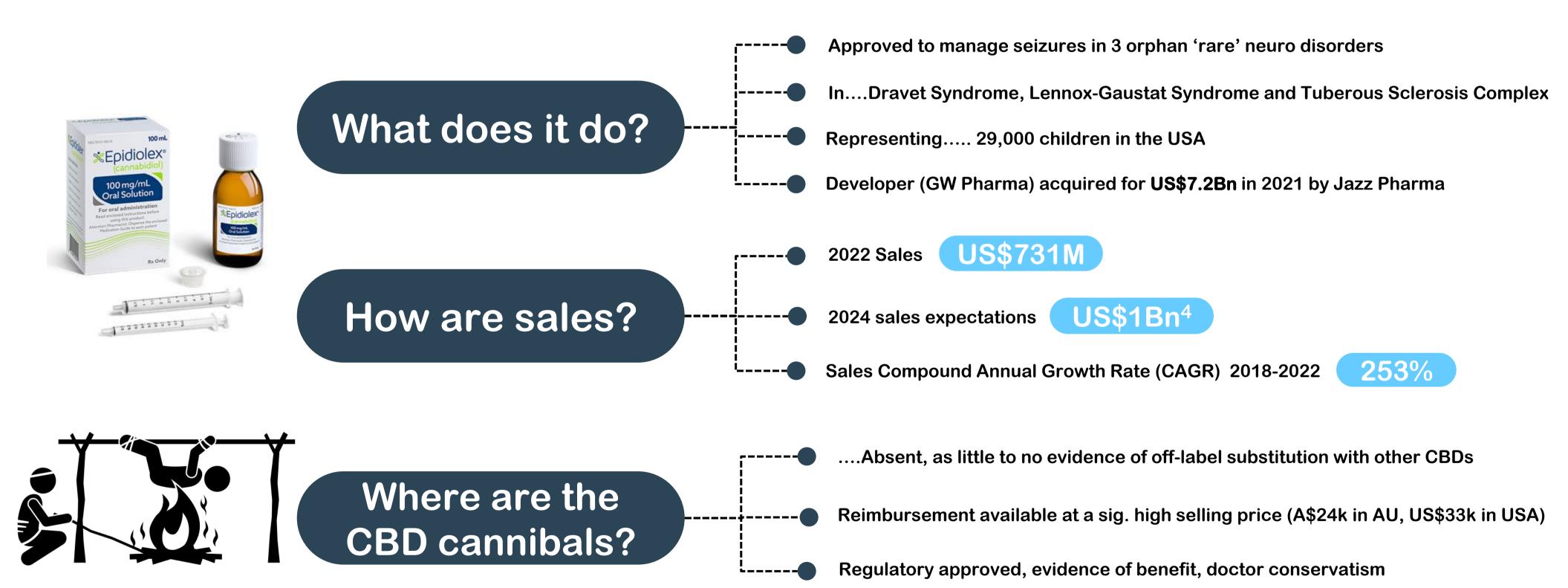
Office of Drug Control (ODC)

Approved by the Therapeutic Goods Administration (TGA) for one or more medical conditions via well-designed, valid clinical trials

# Why a Prescription Medicine Pathway for NTI164?



Epidiolex®: The only FDA, TGA, EMA approved high potency CBD-only oil (Schedule 4)



### 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> https://www.lgsfoundation.org/

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

<sup>4.</sup> Jazz Pharmaceuticals

# **Epidiolex® – Actual Target Product Profile**















Orphan Designations + Other Regulatory Levers

NTI164.....not re-inventing the wheel, simply aligning to a proven model

Based on 73m children with 1/15,700 living with disease

<sup>2. &</sup>lt;u>https://www.lgsfoundation.org/</u>

Tuberous Sclerosis Complex (TSC)

<sup>4</sup> lazz Pharmacoutical

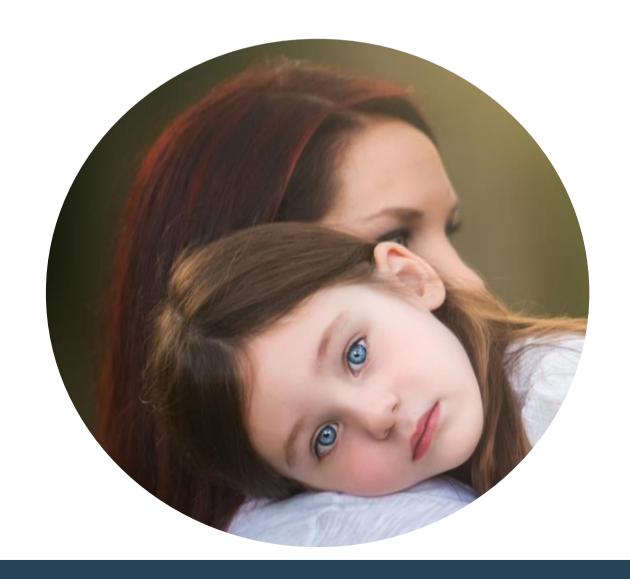
# Autism Rett PANDAS/PANS

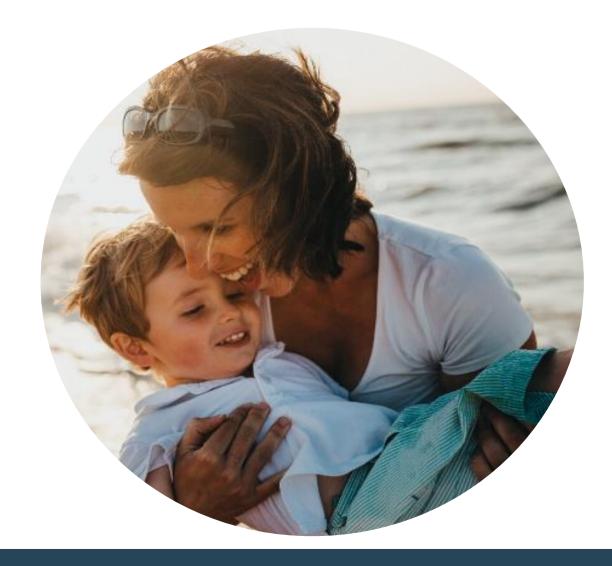


"The goals of treatment for **Autism** are to improve core deficits in social communication and social interactions and minimize the impact of restricted behaviours, with an overarching goal to help children develop greater functional skills and independence." 1

"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







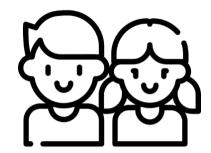
<sup>1.</sup> Weitlauf AS, McPheeters ML, Peters B, et al. Therapies for Children With Autism Spectrum Disorder: Behavioural Interventions Update. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Aug. (Comparative Effectiveness Review, No. 137.) Introduction.

<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/

### No Safety concerns – across all trials to date





94 children across all trials (inc. extensions reported to date, max 2 years)

Autism | Rett | PANDAS/PANS

# **Minor Adverse Events Normal** Mild Nausea/vomiting ~5-15% **Kidney/Liver Function Vital Signs** No diarrhoea **Blood Chemistry** No weight loss



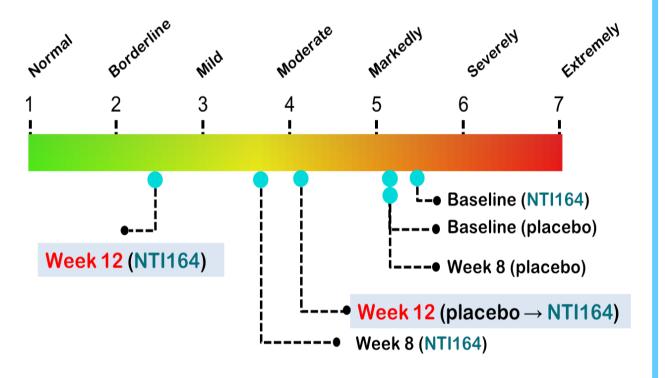
One single Serious Adverse Event (SAE) recorded across all trials – hives (Rett). Incidence of ~1% (1/94)

### NT1164 Efficacy is Strong and Durable



### **Autism**

56% Improvement in Severity of illness at 12 weeks

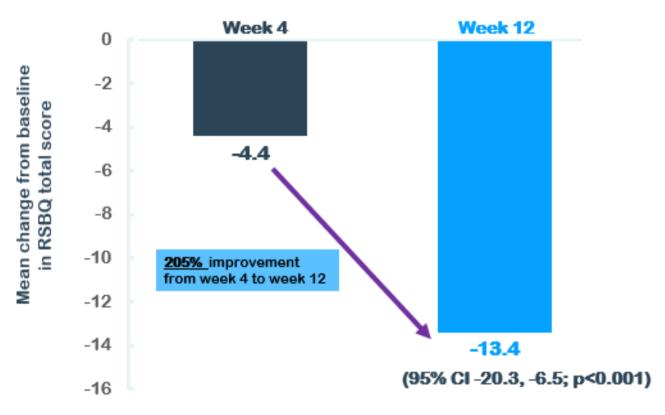


46% Patients Much Improved / Improved at 8 weeks

Significant Improvements in Adaptive Behaviours

### Rett

30% Improvement in RSBQ, 205% from 4-12 weeks

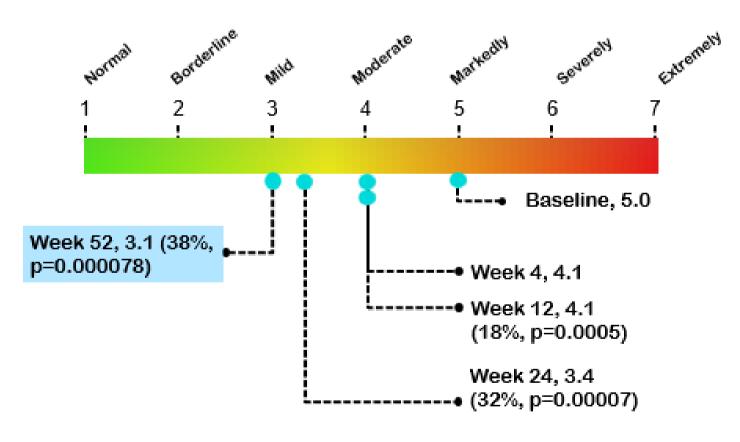


60% Improvement in patient/caregiver quality of life

93% of patients improved on 4 core Rett symptoms

### PANDAS/PANS

38% Improvement in Disease Severity at 52 weeks



45% Improvement in anxiety / depression at 52 weeks

### Recent Clinician Developments





#### A/Prof Carolyn Ellaway Appointed Chief Medical Officer (CMO)

- Internationally recognised clinical geneticist and was the lead Investigator on the Company's successful Phase I/II Rett Syndrome clinical trial
- Key opinion leader engagement along with overseeing the development and execution of regulatory and clinical trial strategies
- ".....I was the Principal Investigator on the trial and observed significant improvements in my patients after just 12 weeks of treatment"



### International PANDAS/PANS Expert Panel Established

- International panel of leading PANDAS/PANS clinicians to build expert global consensus and drive awareness, led by Professor Russell Dale (Principal Investigator on Neurotech Phase I/II trial
- Professor Jennifer Frankovich, Department of Pediatrics Division of Allergy, Immunology & Rheumatology, Stanford Medicine
- Adj Assoc Prof Terrence Thomas, Head Neurology Service & Senior Consultant Head at KK's Women's and Children's Hospital and Singapore General Hospital, Singapore

## 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)

### Outlook



- Completed \$10.0 million capital raise in April, \$13.6 million in available pro-forma funds: well-funded to accelerate development activities in Australia and US, EU
- Continued safety/efficacy data releases across 3 indications (ASD, PANDAS/PANS, Rett) as patients enter or are maintained in open-label extensions
- Clinical, regulatory, commercial strategies in development anticipate finalisation early Q3
   CY2024
- Strong focus on expedited path(s) to market given NTI164 efficacy and safety in very serious neurological disorders in children lacking effective therapies



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

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