Improving Lives

Neurotech International

2022 Annual General Meeting

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Executive Director

30 November 2022

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Presentation Contents

Neurotech International

Neurotech Strategies & Clinical Focus

ASD Phase I/II Results + Update

Pipeline & Milestones

Financials

Summary & Outlook

Neurotech is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders

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- NTI164 exclusive worldwide licence for neurological disorders
- PCT patent applications lodged
- Novel oral biopharmaceutical cannabinoid platform (NTI164)
- Extensive pre-clinical studies completed (NTI164)
- World first Phase I/II trial in ASD completed
- Mente device & therapy for ASD

Neurotech Four Core Strategies

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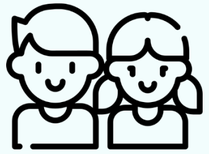
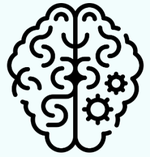
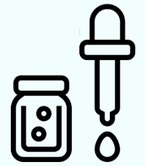


Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Drug Product Development

Strategic Focus Offers Significant Value Upside

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Focus on Paediatric Patients

- Often overlooked by big pharma
- Can be unencumbered drug therapy markets (no standard of care, no approved treatments)
- Lack of clinical trials that may compete for patients
- Ability to leverage significant regulatory levers at FDA & EMA: orphan designation, breakthrough status, fast-track, priority review

Focus On Rare Neurological Disorders with Neuroinflammation

- Literature well-established for cannabinoids / extracts on inflammatory processes
- NTI164 shown strong pre-clinical effects on inflammation, neuro-protection, neuro-modulation and neuro-regulation
- NTI164 shown efficacy in serious neuroinflammatory developmental disorder: Autism Spectrum Disorder
- Often chronic disorders requiring continued therapeutic intervention (higher lifetime patient value)

Focus on Partnering with Key Opinion Leaders / Clinicians

- Paediatric Neurology focus with supportive Human Research Ethics Committees (HRECs)
- Availability of patients / caregivers for clinical trials
- Decades of experience in paediatric clinical trials – sound trial design frameworks and outcomes
- Paediatric neurological disorders tend to have strong clinical networks / advocacy groups

Focus on Drug Product Development

- Regulated Drug Product via FDA, TGA, EMA (barrier to entry)
- Manufacture under Good Manufacturing Practice (GMP) & robust CMC (Chemistry, Manufacture, Controls)(barrier to entry)
- Premium Drug Pricing
- Reimbursement for “on-label” prescribing

Rapid Progress from Lab to Clinic Drives Strategy

- Reduction in brain cell inflammation (up to 60%)
- Increase in overall brain cell health and viability (in the absence of toxic insult up to 80%)
- Increase in mitochondrial viability and output (in the presence of toxic insult up to 60%)
- Significant suppression of neuro-markers linked to MS (GM-CSF < 40% and TNF-alpha < 30%)
- Multi-functional Mode of Action | neuro-protection, neuro-modulation and neuro-regulation

2020

Extraction of Drug Product (NTI164) & Pre-Clinical Data

2021

Manufacture Scale-Up & Analytical Methods Established

Patent Applications (Novel Composition & Methods)

2022

Phase I/II Clinical Trial (Safety) + Efficacy Shown in Autism Spectrum Disorder (ASD) Children

2023

Beach Head ASD Results Drives New Clinical Trials in Pediatric Neurological Disorders

- Phase I/II PANDAS/PANS[1]
- Phase I/II Cerebral Palsy
- Phase II/III ASD

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

Summary of Strategy

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Group Strategy

- Focus on Paediatric Patients
- Focus On Rare Neurological Disorders with Neuroinflammation
- Focus on Partnering with Key Opinion Leaders / Clinicians
- Focus On Drug Product Development

Implementation to Development

Current

- Phase I/II PANDAS/PANS
- Phase I/II Cerebral Palsy
- Phase II/III ASD

Potential

- ADHD
- Rett Syndrome
- Fragile-X
- Dravet
- Lennox-Gastaut

Neuroinflammation

Potential Regulatory Levers

FDA

Pre-IND Feedback
IND
Orphan Drug Designation
Priority Review
Breakthrough Therapy
Fast-Track
Rare Pediatric Priority Voucher

EUROPEAN MEDICINES AGENCY

Scientific Advice
Protocol Assistance
Orphan Drug Designation
Accelerated Assessment

Commercialisation Examples*

2016 → 2018/9 → 2021

GW pharmaceuticals

Phase III Trials

Dravet

Lennox-Gastaut


Magazine Article | April 1, 2016

GW Pharmaceuticals Changes Its Focus To Rare Diseases

Source: Life Science Leader

By Suzanne Elvidge, Contributing Writer

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FDA approval
EMA approval

FDA,EMA Orphan Designations, Fast-Track Status

Jazz Pharmaceuticals

US$7.2 Billion acquisition of GW[1]

2021 Epidiolex® Sales: US$464 Million[1]

2016 → 2018 → 2022

neuren pharmaceuticals

Pipeline focus on rare neurodevelopmental disorders
ASX:NEU Market Cap: $200M

ACADIA Pharmaceuticals

US$455 Million Licence for Trofinetide in Rett[2]

ACADIA Pharmaceuticals

NDA filed with FDA for Rett

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NEU Market Cap: $900M

Multiple FDA,EMA Orphan Designations, Fast-Track Status in Rett, Fragile-X, Angelman, Phelan-McDermid, Pitt Hopkins, Prader-Will

1. Jazz Pharmaceuticals 2. Neuren Pharmaceuticals

* For illustrative purposes only highlighting transactions in the rare paediatric neurological disorder field

Rapid Pipeline Progression

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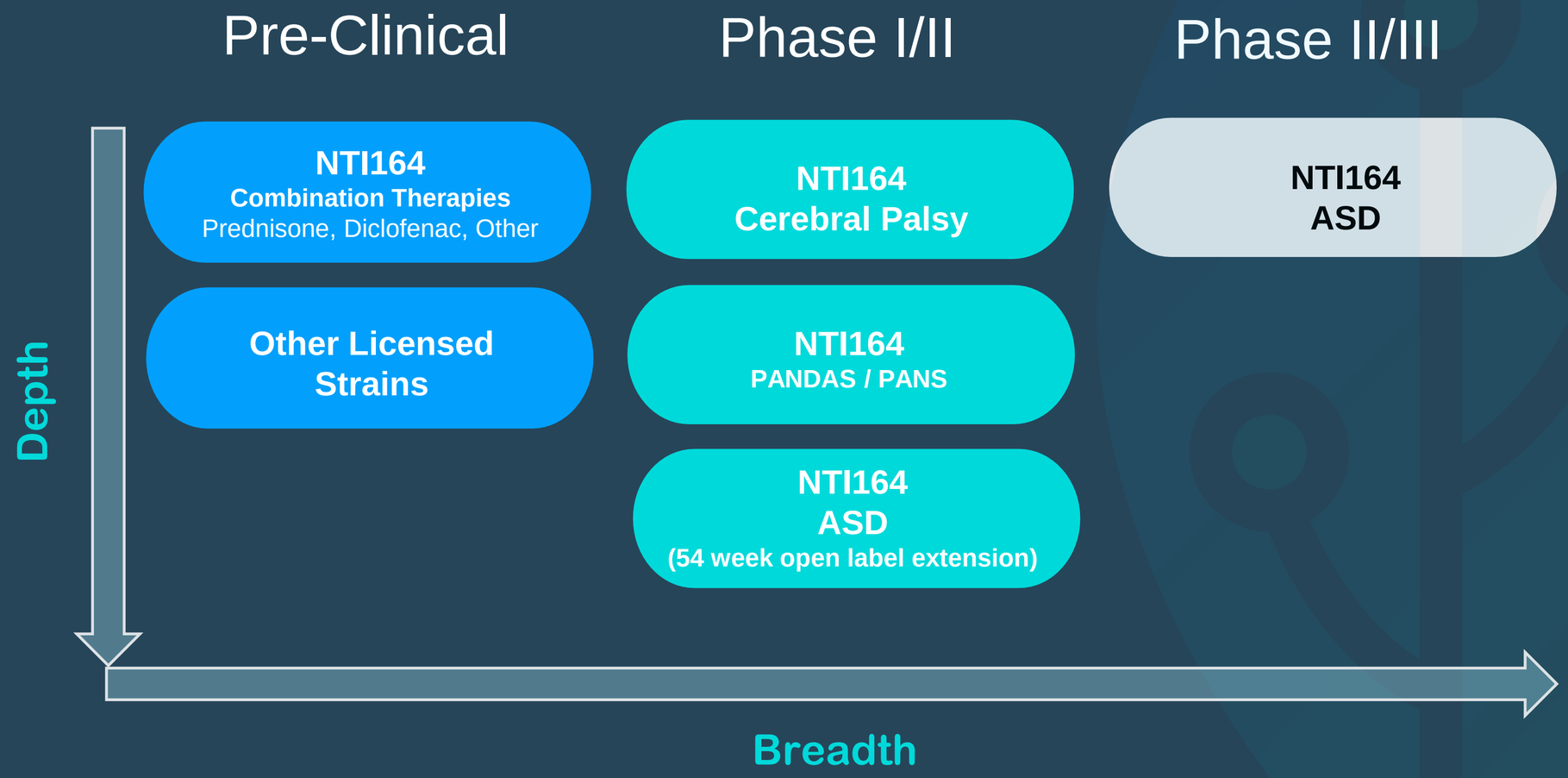
Pipeline (2020/1)

- **NTI164**
  Combination Therapies
  Prednisone, Diclofenac, Other
- **NTI164**
  Neuronal Cell Assays
- **Other Licensed Strains**

Pipeline (Pro-Forma 1 Jan 2023)



Clinical Focus

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ASD

PANDAS/PANS

Cerebral Palsy

Neurological & Neuroinflammation

Lack of effective treatments

Paediatric Onset

Rare / Orphan

Strong Scientific Rationale for NTI164

- Anti-inflammatory effects + safety
- Clinician support
- High Patient/Caregiver interest

1. 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.

ASD and the NDIS

The National Disability Insurance Scheme (NDIS) provides assistance to people with a disability, as well as their families and carers

- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years

$35.5 Billion

Cost of NDIS in 2022, to increase to $52 billion by 2026, $100 billion by 2033[1]

34% ASD

34% of the 550,000 NDIS participants have ASD, 40% ≤ 14 years old (860,000 by 2030)[2]

$6.1 Billion

Implied annual cost of ASD to NDIS based on average ASD funding of $32,800 per annum e.g. physio, psychology, speech therapy, support workers[3]

TREATMENT MARKET SIZE

US$1.85b[4]

RISPERIDONE

Approved 2006
(irritability label claim)

Current Treatment

There is a strong market need for an effective therapeutic intervention such as NTI164 to improve ASD symptoms & reduce healthcare costs

1. The Australian
2. https://www.uwa.edu.au/news/Article/2022/August/An-autism-minister-may-boost-support-and-coordination-But-governments-that-follow-SAs-lead-should-be-cautious
3. https://disabilityplanservices.com.au/blog/how-much-is-ndis-funding-for-autism/#:~:text=At%20Disability%20Plan%20Services%2C%20we,per%20year%20under%20the%20NDIS.
4. https://www.fortunebusinessinsights.com/industry-reports/autism-spectrum-disorder-therapeutics-market-101207-CAGR-of-7-4.html

About PANDAS / PANS

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About

PANDAS Network.org
ADVOCACY, SUPPORT & RESEARCH FOR PANDAS, PANS, AE

PANDAS Physicians Network
PPN
A Division of The Foundation for Brain Science and Immunology

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)

No Treatments

No FDA or EMA approved treatments: Intravenous immunoglobulin (IVIG) off-label: not proven, v. high cost

Rare, Neuroinflammation

Considered a rare paediatric orphan disorder, with strong neuroinflammatory effects – ideally suited for NTI164 clinical trial

2015 | 2017 | 2022

Release of PANDAS/PANS Diagnostic Criteria (2015) and Treatment Guidelines (2017) and the World Health Organisation recognition within the International Classification of Diseases (ICD-11) for the first time (2022)

Source: PACE Foundation

Phase I/II Clinical Results: Autism Spectrum Disorder (ASD)

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"The goals of treatment for ASD 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]

1. 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.

NTI164 ASD Phase I/II - Trial Design

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The Program

First in human Phase I/II ASD paediatric study

Commenced in May 2021 at Monash Children's Hospital led by A/Prof. Michael Fahey

Open label – single group

14 patients from 8 to 17yo, Level II and III Autism Spectrum Disorder

Dose regime assessments

5mg/kg, 10mg/kg, 15mg/kg and 20mg/kg

Thousands of assessment points & growing

Parameters Anxiety, Participation, Irritability, Hyperactivity, Mood and Self-stimulation

Data Released
8 July 2022 (28 day)
26 October (20 week)

NTI164 ASD Phase I/II – Efficacy (20 week Data)

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A total of 12 patients evaluable at 20 weeks

2 patients stopped treatment (not drug related)

Summary Outcome Measures

Sub-Domain	Scale	P-value (Paired T-Test)	Wilcoxon Signed-Rank Test
Severity of illness	**CGI-S**	**0.005**	**0.010**
Global improvement	**CGI-S**	**n/a***	**n/a***
Therapeutic effect	**CGI-S**	**n/a***	**n/a***
Adaptive behaviour composite (Total)	**Vineland-3**	**0.0005**	**0.003**
Communication	Vineland-3	0.002	0.004
Daily living skills	Vineland-3	0.019	0.025
Socialisation	Vineland-3	0.014	0.012
Social responsive scale – Total	**SRS-2**	**0.012**	**0.013**
Social awareness	SRS-2	0.596	0.439
Social cognition	SRS-2	0.028	0.036
Social communication	SRS-2	0.019	0.018
Social motivation	SRS-2	0.118	0.138
Restricted interest and repetitive behaviour	SRS-2	0.009	0.014
Social communication and interaction	SRS-2	0.029	0.021
Anxiety scale for children - Child's total	**ASC-ASD-C**	**0.025**	**0.012**
Performance anxiety	ASC-ASD-C	0.364	0.474
Anxious arousal	ASC-ASD-C	0.12	0.089
Separation anxiety	ASC-ASD-C	0.025	0.035
Uncertainty	ASC-ASD-C	0.033	0.035
Anxiety scale for children - Parent's total	**ASC-ASD-P**	**0.034**	**0.053**
Performance anxiety	ASC-ASD-P	0.07	0.096
Anxious arousal	ASC-ASD-P	0.333	0.229
Separation anxiety	ASC-ASD-P	0.025	0.033
Uncertainty	ASC-ASD-P	0.066	0.084
Sleep disturbances scale for children - Total	**SDSC**	**0.016**	**0.018**
Disorders of initiating and maintaining sleep	SDSC	0.01	0.026
Sleep breathing disorders	SDSC	0.047	0.042
Sleep-wake transition disorders	SDSC	0.094	0.072
Anxiety, depression and mood scale – Total	**ADAMS**	**0.001**	**0.009**

NTI164 Safety Effects Maintained Over 20 Weeks

** t-test cannot be performed due to different measurement scale used at baseline*

Clinical Interpretation

- Statistical significance ($p<0.05$):
  - 20/27 measures assessed at 20 weeks
  - Study was **not** statistically powered for any efficacy measures (safety was primary endpoint)
- Highly significant results for the most clinically important measures:
  - Severity of illness
  - Adaptive behaviour
  - Anxiety, depression and mood
  - Social responsiveness
- Consistent improvements across multiple standard clinical measures at 20 weeks versus baseline do not support a placebo effect

Note: Baseline and 28 day data as previously reported has been normalised to exclude those two patients who did not complete 20 weeks of daily NTI164 treatment.

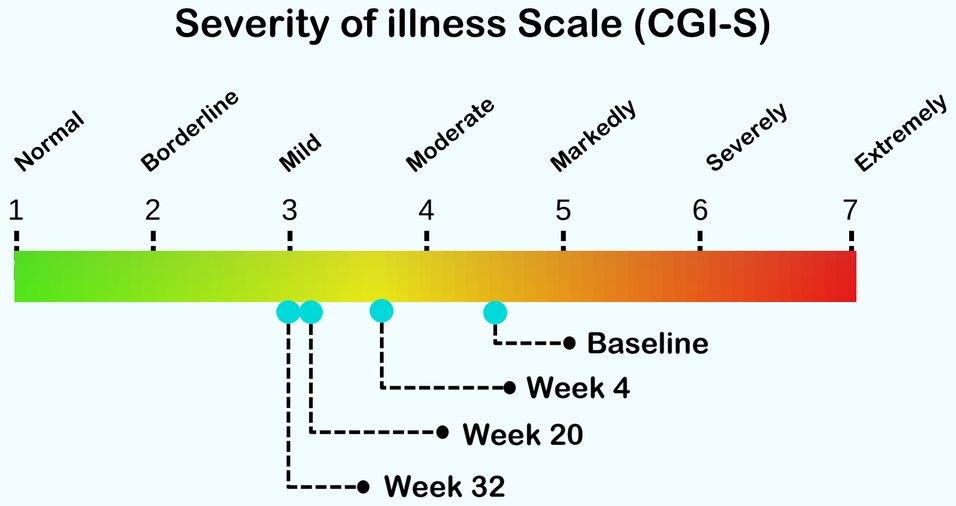
NTI164 ASD Phase I/II – Conclusions

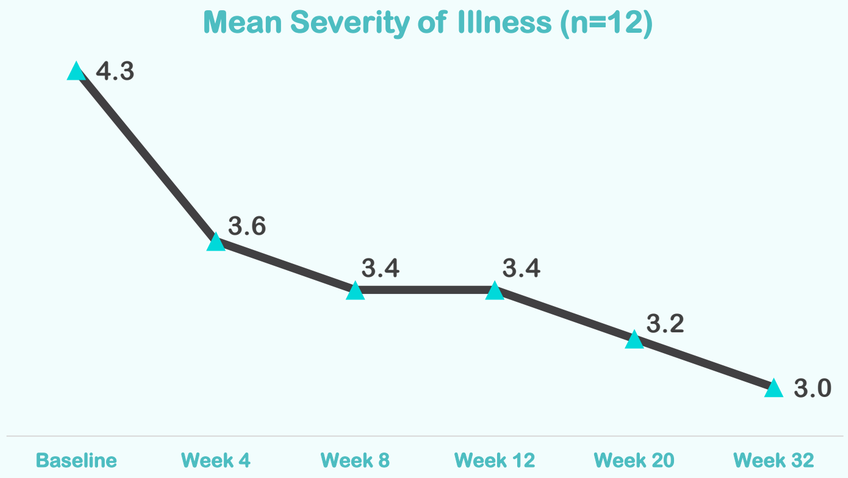
- **NTI164 is a patient ‘enabling’ drug with non-drug behavioural therapies, by improving daily living and allowing children to integrate into society via significant improvements in socialisation & anxiety versus ‘restrictive’ prescription of Risperidone (prevention of aggression, irritability)**
- **Data strongly supports progression to randomised, double-blind, placebo-controlled ASD Phase II/III clinical trial: expected to commence in Q4 CY2022**

Professor Michael Fahey – Lead Investigator

“I am extremely encouraged by the 20-week results and the clinical improvements in troubling symptoms we have seen to date. These benefits, as measured by standardised scales, relate to global improvement, severity of illness, socialisation, adaptive behaviour, communication and reduction in anxiety. These results provide positive momentum as we move to the commencement of the next phase of clinical development. This is a strong indication that NTI164 has the potential to be an enabling treatment for some of the symptoms that cause people with Autism Spectrum Disorder distress.”

32 Week Data - Preliminary





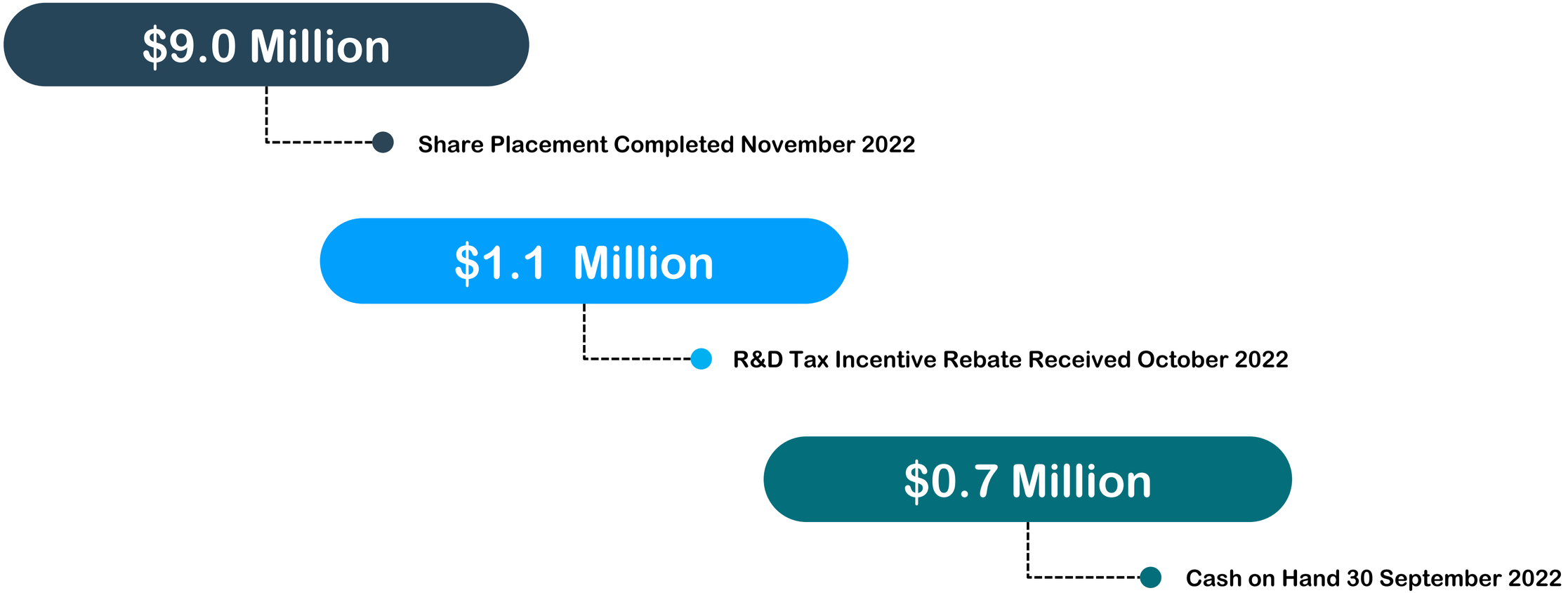
Severity of illness (CGI-S) Improvements Continue to Week 32

Mean CGI-S of 12 Children now at intersection of "Borderline mentally ill" to "Mild" from "Moderate" at Baseline

"The goals of treatment for ASD 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."

Financials

- **Pro-Forma[1] Cash and Cash Equivalents of $10.3 million**



1. Cash as at 30 September 2022 of $0.7 million, $8.5 million (net of fees) from share placement and $1.1 million R&D Tax Incentive Rebate

Deployment of $9M Nov Share Placement

$4.0 Million

- NTI164 Clinical Trial Programs

$1.0 Million

- Regulatory Development (Europe – EMA; US – FDA)

$3.5 Million

- Manufacturing scale-Up & NTI164 production
- Working Capital
- New Indication Development

EVENT	ALLOCATION OF FUNDS (PLACEMENT)
Phase II/III ASD Trial	$3.0M
Phase I/II PANS/PANDAS Trial	$0.5M
Phase I/II CP Trial	$0.5M
Regulatory / FDA IND	$1.0M
Manufacturing / Production	$0.5M
Working Capital	$3.0M
Offer Costs / Other	$0.5M
TOTAL	$9.0M

Key 12 Month Milestones – NTI164

Q4 CY2022

- Human Research Ethics Committee (HREC) Approval ASD Phase II/III
- HREC/TGA Approval PANDAS/PANS Phase I/II Clinical Trial
- Completion of FDA Pre-IND Package
- Commencement of Patient Recruitment ASD Phase II/III Clinical Trial
- HREC Submission Cerebral Palsy Phase I/II Clinical Trial

1H CY2023

- Commencement of Patient Recruitment PANDAS/PANS Phase I/II Clinical Trial
- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial
- Commencement of Patient Recruitment Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment PANDAS/PANS Phase I/II Clinical Trial
- FDA Pre-IND Meeting
- Additional paediatric neurological disorder clinical trial launch

2H CY2023

- Results of PANDAS/PANS Phase I/II Clinical Trial
- Completion of Patient Recruitment Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment ASD Phase II/III Clinical Trial
- US FDA IND submission
- Results of Cerebral Palsy Phase I/II Clinical Trial

Outlook

- Focus on rare paediatric neurological disorders
- Longer term safety and solid efficacy of NTI164 now established in a predominant paediatric neurological disorder with strong neuroinflammatory effects (ASD)
- Accelerated clinical development via rapid & cost-effective proof of concept Phase I/II clinical trials in Australia for new paediatric neurological disorders (PANDAS/PANS & CP)
- Strong clinician engagement
- Access to numerous regulatory levers from the FDA and EMA
- Additional funding provides sufficient runway to complete all current clinical trials and pathway with the US FDA – significant valuation upside if met

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*This presentation has been authorised by Thomas Duthy, Executive Director of Neurotech International Limited

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