Improving Lives

Neurotech International

Investor Presentation

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Executive Director

20 March 2023

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Presentation Contents

- Financials
- Neurotech Strategies & Clinical Focus
- ASD Phase I/II Results
- Milestones
- Summary & Outlook

Corporate / Capital Summary

$0.057
Share price
(as at 15 March 2023)

$49.8M
Market capitalisation

$8.1M
Cash at bank*

~1,700
No. of shareholders

873.9M
Share on issue

156.9M^
NTIOA (13.5c) +
Other Options

~$2.6M
R&D Investment in FY22

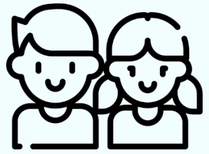
55%
Top 20 Holders

*as at 31 December 2022
^Options are comprised at various strike prices between $0.02 to $0.16 as at 14 March 2023

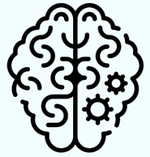
Neurotech is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders

- 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

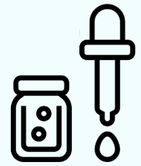


Focus on Paediatric Patients



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

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- 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 Paediatric Neurological Disorders

- Phase II Rett Syndrome
- 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)

Clinical Pipeline – 2023

Pre-Clinical

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

Other Licensed Strains

Phase I/II

NTI164
Cerebral Palsy

NTI164
PANDAS / PANS

NTI164
ASD
(54 week open label extension)

NTI164
Rett Syndrome
(Expected 1H CY23)

Phase II/III

NTI164
ASD

Pipeline (2020/1)

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

NTI164
Neuronal Cell Assays

Other Licensed Strains

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

Neuroinflammation

Implementation to Development

Current

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

Potential

- ADHD
- Rett Syndrome — Announced 20 March
- Fragile-X
- Dravet
- Lennox-Gastaut

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

FDA approval
EMA approval

FDA,EMA Orphan Designations, Fast-Track Status


Magazine Article | April 1, 2016

GW Pharmaceuticals Changes Its Focus To Rare Diseases

Source: Life Science Leader

By Suzanne Elvidge, Contributing Writer

Follow Me On Twitter @suzannewriter

Jazz Pharmaceuticals

US$7.2 Billion acquisition of GW[1]

2022 Epidiolex® Sales: US$736 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 approved with FDA for Rett (10 March 2023)

neuren pharmaceuticals

NEU Market Cap: $1.5Bn

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

Clinical Focus

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Strong Scientific Rationale for NTI164

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

ASD

PANDAS/PANS

Cerebral Palsy

Rett Syndrome

Neurological & Neuroinflammation

Lack of effective treatments

Paediatric Onset

Rare / Orphan

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, 25 October, 2022- https://www.afr.com/politics/federal/how-the-ndis-will-blow-out-to-50b-in-four-charts-20221019-p5br1c
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
5. Australian Bureau of Statistics. (2018). Autism in Australia. Retrieved from https://www.abs.gov.au/ausstats/abs@.nsf/mf/4428.0

About PANDAS / PANS

About

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

About Cerebral Palsy

Interventions ideally seek to: improve gross motor function, to increase participation at a social role level, to improve comfort, to improve the ease of care by others or to improve the overall quality of life of the individual

About

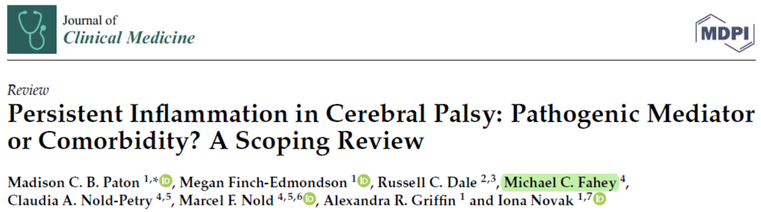
- Most common motor disability in childhood, abnormal brain development or damage to the developing brain
- Stratified by: Spastic CP (80% of cases), Dyskinetic CP (6% of cases), Ataxic CP (6% of cases) and Mixed CP (balance of cases)

Lacking Treatments

- Primary treatment options for cerebral palsy are medication, therapy, and surgery. The goal of cerebral palsy treatment is to manage symptoms – specifically, spasticity and/or dystonia
  - Botulinum A : no improvement in motor function(s)
  - Baclofen – unwanted side-effects, weak evidence for quality of life benefits

Neuroinflammation

- Available evidence supports the pathogenic role of inflammation and its ongoing role as a comorbidity of CP – Advantages for NTI164


Journal of Clinical Medicine

MDPI

Review

Persistent Inflammation in Cerebral Palsy: Pathogenic Mediator or Comorbidity? A Scoping Review

Madison C. B. Paton [1,*], Megan Finch-Edmondson [1], Russell C. Dale [2,3], Michael C. Fahey [4], Claudia A. Nold-Petry [4,5], Marcel F. Nold [4,5,6], Alexandra R. Griffin [1] and Iona Novak [1,7]

Significant Market

- 500,000 children under age of 18 currently have Cerebral Palsy (USA)[1]
- 8,000-10,000 babies born each year with CP
- US$4.3 billion treatment market (mostly spastic CP) by 2030[2]

1. www.cerebralpalsy.org
2. https://www.emergenresearch.com/industry-report/cerebral-palsy-treatment-market

About Rett Syndrome

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About

- Rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome: **impaired brain development and function**

First Ever Approval[1]

Daybue™ (trofinetide)

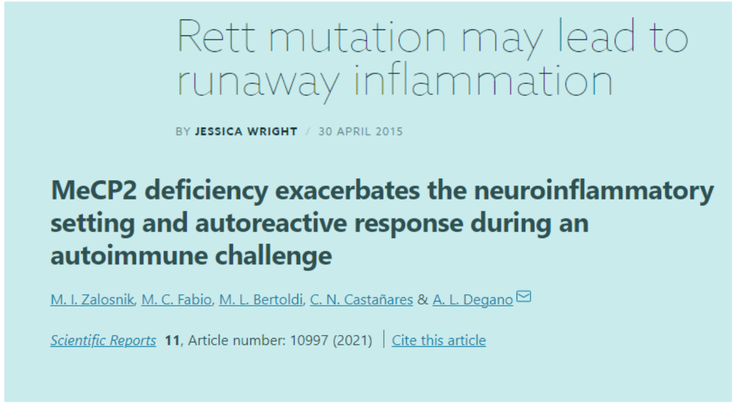
US annual average net realized cost of DAYBUE expected to be ~US$375,000

Before the approval, David Hoang SMBC Nikko Securities analyst estimated a list price at launch of $450,000 annually. He forecast peak U.S. trofinetide sales of $487.2 million by 2035. RBC Capital Markets analyst Gregory Renza, also writing before the approval, predicted peak U.S. sales to exceed $500 million by 2032 and an average annual launch price of about $425,000.

- Neuren Pharmaceuticals (ASX:NEU) / Acadia Pharmaceuticals (NASDAQ:ACAD): FDA Approval **10 March 2023**
- Sets benchmark for FDA accepted clinical endpoints, safety tolerance

Neuroinflammation

- Numerous scientific reports support neuroinflammatory effects in Rett
- NTI164 also shown to exhibit neuroprotective effects *in vitro*


Rett mutation may lead to runaway inflammation

BY JESSICA WRIGHT / 30 APRIL 2015

MeCP2 deficiency exacerbates the neuroinflammatory setting and autoreactive response during an autoimmune challenge

M. I. Zalosnik, M. C. Fabio, M. L. Bertoldi, C. N. Castañares & A. L. Degano

Scientific Reports **11**, Article number: 10997 (2021) | Cite this article

Significant Market

- Annual Market Opportunity of over US$2 billion[2]
- Incidence 1/10,000 live births | Prevalence ~15,000 girls and women in the US and ~350,000 globally[3]

1. https://www.neurenpharma.com/pdf/c309dbf9-f3dd-44de-9a5e-bf56b1d247d8/Investor-Presentation-14-March-2023.pdf
2. https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside
3. https://reverserett.org/about-rett-syndrome/

Phase I/II Clinical Results:
Autism Spectrum Disorder (ASD) – 52 weeks

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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

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 of NTI164 (initial 4 weeks)

Maximum tolerated dose daily through to 52 weeks

~7,000 Assessment points over 52 weeks, daily oral treatment

- 28 Day Data Released 8 July 2022
- 20 Week Data Released 26 October 2022
- 52 Week Data Released 17 March 2023

NTI164 ASD Phase I/II – Safety (52 week Data)

NTI164 Safety Effects Maintained Over 52 Weeks

No serious adverse events recorded

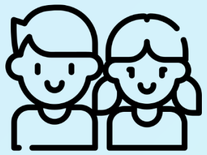
Across all doses

Only 1 patient on Risperidone at enrollment (not considered a pref. standard of care)

Adverse events were tolerated and manageable

mild nausea, abdominal pain

Normal blood chemistry, normal kidney and liver function and vital signs



A total of 11 patients evaluable at 52 weeks
(12 pts. at 20 weeks)

Conclusion: NTI164 longer term (chronic) administration now established with an excellent safety profile and minimal patient-specific side-effects: safety data will be collected beyond 52 weeks for at least six additional months

NTI164 ASD Phase I/II – Efficacy (52 week Data)

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Summary Outcome Measures

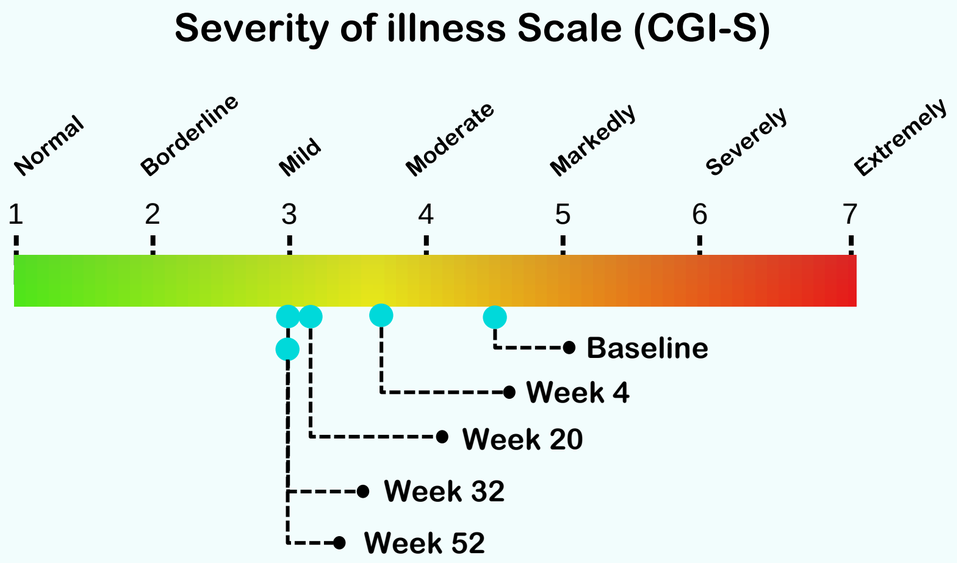
Sub-Domain	Scale	20 Weeks P-value (Paired T-Test)	52 Weeks P-value (Paired T-Test)
Severity of illness	**CGI-S**	**0.005**	**0.032**
Global improvement	**CGI-I**	**n/a***	**n/a***
Therapeutic effect	**CGI**	**n/a***	**n/a***
Adaptive behaviour composite (Total)	**Vineland-3**	**0.0005**	**0.028**
Communication	Vineland-3	0.002	0.0001
Daily living skills	Vineland-3	0.019	0.005
Socialisation	Vineland-3	0.014	0.118
Social responsive scale – Total	**SRS-2**	**0.012**	**0.049**
Social awareness	SRS-2	0.596	0.421
Social cognition	SRS-2	0.028	0.105
Social communication	SRS-2	0.019	0.216
Social motivation	SRS-2	0.118	0.005
Restricted interest and repetitive behaviour	SRS-2	0.009	0.109
Social communication and interaction	SRS-2	0.029	0.081
Anxiety scale for children - Child's total	**ASC-ASD-C**	**0.025**	**NM**
Performance anxiety	ASC-ASD-C	0.364	NM
Anxious arousal	ASC-ASD-C	0.12	NM
Separation anxiety	ASC-ASD-C	0.025	NM
Uncertainty	ASC-ASD-C	0.033	NM
Anxiety scale for children - Parent's total	**ASC-ASD-P**	**0.034**	NM
Performance anxiety	ASC-ASD-P	0.07	NM
Anxious arousal	ASC-ASD-P	0.333	NM
Separation anxiety	ASC-ASD-P	0.025	NM
Uncertainty	ASC-ASD-P	0.066	NM
Sleep disturbances scale for children - Total	**SDSC**	**0.016**	NM
Disorders of initiating and maintaining sleep	SDSC	0.01	NM
Sleep breathing disorders	SDSC	0.047	NM
Sleep-wake transition disorders	SDSC	0.094	NM
Anxiety, depression and mood scale – Total	**ADAMS**	**0.001**	NM

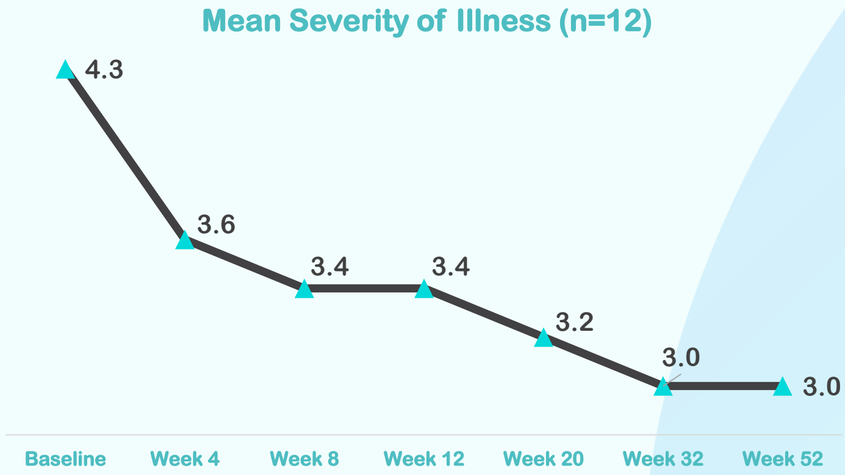
** t-test cannot be performed due to different measurement scale used at baseline; NM – not measured*

Clinical Interpretation

- **Statistical significance ($p<0.05$):**
  - **Study was <u>never</u> statistically powered for any efficacy measures (safety was primary endpoint)**
- **Highly significant results for the most clinically important measures:**
  - **Severity of illness**
  - **Adaptive behaviour**
  - **Social responsiveness**
- **Consistent improvements across multiple standard clinical measures at 52 weeks versus baseline do not support a placebo effect**

NTI164 ASD Phase I/II – Efficacy (52 Week Data)





CGI-Severity of illness[1] (p = 0.03)

Clinical Interpretation

- NTI164 treatment is associated with a significant reduction in disease severity (1.3 scale change, 30% improvement)
- ~40% of subjects markedly or severely ill at baseline – 0% from week 4 onwards

1. Clinical Global Impression (CGI)- is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders. 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 and one patient at 52 weeks. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.

NTI164 ASD Phase I/II – Conclusions

- **Continued excellent durability of results at 52 weeks, with clinical benefits showing a significant improvement across a large number of clinically validated assessments versus baseline (Day 0)**
- **Any significant change over time for measures of CGI-S, Vineland™-3 and SRS™-2 are considered clinically meaningful: NTI164 showed sig. improvement for all measures at 52 weeks v baseline**
- **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)**

Professor Michael Fahey – Lead Investigator

"We continue to see benefits in these ASD patients through daily oral treatment with NTI164 over 52 weeks. Our standardised ASD scales relating to global improvement, severity of illness, socialisation and adaptive behaviour, continued to show a clinically meaningful and statistically significant difference from baseline measures with no serious adverse events recorded and clean pathology results. Importantly, there was no evidence that prolonged use of NTI164 in these patients can lead to any form of therapeutic tolerance as measured by a slow reversion of symptoms through extended use. This is particularly pleasing and highlights chronic administration of NTI164 is required to achieve significant improvements in clinical outcome measures. We certainly look forward to the next phase of this exciting development opportunity in ASD."

Key 12 Month Milestones – NTI164

1H CY2023

- Final results of ASD Phase I/II Clinical Trial (52 weeks)
- Commencement of Patient Recruitment PANDAS/PANS Phase I/II Clinical Trial
- HREC/TGA Extension of ASD Phase I/II Clinical Trial – 6 months
- FDA Pre-IND Meeting
- Launch Rett Syndrome Clinical Trial Initiative
- HREC/TGA Approval Rett Syndrome Phase II Clinical Trial
- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment PANDAS/ PANS Phase I/II Clinical Trial

2H CY2023

- Results of PANDAS/PANS Phase I/II Clinical Trial
- Commencement of Patient Recruitment Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment ASD Phase II/III Clinical Trial
- US FDA IND submission
- Completion of initial recruitment of Rett Syndrome Phase II Clinical Trial
- Commence Phase II Clinical Trial in Rett Syndrome

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 & Rett)
- Strong clinician engagement
- Access to numerous regulatory levers from the FDA and EMA
- Fully funded to complete all current clinical trials and pathway with the US FDA – significant valuation upside if met

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