Improving Lives

Neurotech International

Investor Presentation

Dr Tom Duthy
Executive Director

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FY23 – A Year of Significant Progress

Neurotech International

Governance & Strategy
- New Board & Executive Management
- New Clinical and Development Focus

Access to Capital
- New Bank/Broker Relationships
- Completed $9.0m Capital Raise

Operational Execution
- Launched/reported new clinical trials
- Manufacturing Scale Up

Corporate / Capital Summary

$0.056
Share price
(as at 20 Nov 2023)

$49.4M
Market capitalisation

$6.1M
Pro-Forma Cash as 30 Sept*

~1,900
No. of shareholders

882.3M
Share on issue

116.3M^
NTIOA (13.5c) +
Other Options

$6.5M
FY23 R&D Exp.
(up from $2.6M in FY22)

53%
Top 20 Holders

* 30 September cash balance of $2.9 million + R&D Tax Incentive of ~$3.2 million
^Options are comprised at various strike prices between $0.02 to $0.16 as at 20 November 2023

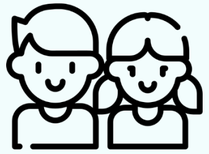
Neurotech is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders

Neurotech International

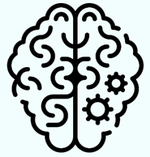
- NTI164 exclusive worldwide licence for neurological disorders
- Patents Pending – Use, Composition
- Novel oral biopharmaceutical cannabinoid platform (NTI164)
- Focus on Paediatric Patients
- Multiple Phase I/II and Phase II/III Clinical Trials
- Supportive Efficacy & Safety Data in Children

Neurotech Four Core Strategies

Neurotech International

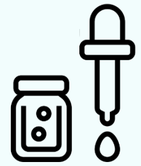


Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Drug Product Development

Clinical Pipeline – 2023

Neurotech International

Pre-Clinical

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

Other Licensed Strains

Phase I/II

NTI164
Cerebral Palsy

NTI164
PANDAS / PANS[1]

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

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

Therapeutic Agent: NTI164

High potency, Broad Spectrum Cannabinoid Formulation in Oil, *C. sativa L.* (Plant Derived)

- THC < 0.3%
- Major constituent Cannabidiolic acid (CBDA)
- Minor constituents include other cannabinoids: CBD, CBG, CBGA, other + terpenes

Convenient 1x or 2x (split dose) oral formulation in oil, ideal format for pediatric patients 20mg/kg (CBDA)

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

Entourage Effect

Neuroprotective

Anti- Neuroinflammatory

Developing NTI164 as a Therapeutic Agent

Neurotech International

- **NTI164 to be registered as a prescription-only medicine**
- **Neurotech investment into clinical trials to show safety and benefit**
- **Regulatory approval(s) will allow Neurotech to make a medical claim**
- **Significantly higher pricing and reimbursement + regulatory levers = strong competitive position**

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

CBD OTC Market - Australia

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

48
CBD Products Registered on the ARTG[1]

44/35
Domestic Manufacturers / Importers of Cannabis Products on ODC[2] Website

0
Number of over-the-counter (OTC) CBD products able to make a substantiated medical claim[3]

~$0.05
Average Cost per mg CBD

150mg
Max. amount of CBD per day allowed (sub-therapeutic)

101 / $1.3M
The number of infringements and total fines issued by TGA in FY23 (unlawful advertising)[4]

1. Australian Register of Therapeutic Goods (ARTG)
2. Office of Drug Control (ODC)
3. Approved by the Therapeutic Goods Administration (TGA) for one or more medical conditions via well-designed, valid clinical trials
4. Source: TGA

CBD as a Drug – Significant Long-Term Upside

TGA Approved Pharmaceutical Treatment – NTI164 Focus

1
TGA Approved CBD oil (Epidiolex®) – 3 rare diseases

1000mg
CBD for 50kg child at 20 mg/kg/day with Epidiolex®

A$24k
Epidiolex® cost per annum in Australia (US$33k in USA)

- Strong Market Position
- Therapeutic Dosing
- High Price + Reimbursement

Epidiolex® Small Markets by Number Patients, Large by $ Value – NTI164 Focus

- **4,700** Children with Dravet Syndrome in the USA[1]
- **13,400** Children with Lennox-Gastaut Syndrome in the USA[2]
- **13,000** Children with TSC in the USA[3]
- **US$731M** 2022 Sales
- **US$1Bn**[4] Jazz Pharmaceuticals sales expectations
- **253%** Sales CAGR 2018-2022

1. Based on 73m children with 1/15,700 living with disease
2. https://www.lgsfoundation.org/
3. Tuberous Sclerosis Complex (TSC)
4. Jazz Pharmaceuticals

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
- Phase I/II Rett Syndrome

Potential

- Fragile-X
- ADHD
- 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

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 → 2023

neuren pharmaceuticals

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

ACADIA® Pharmaceuticals

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

ACADIA® Pharmaceuticals

FDA Approval for Rett
ROW licence for US$527M[2]

neuren pharmaceuticals

NEU Market Cap: $1.8Bn

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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ASD

PANDAS/PANS

Cerebral Palsy

Rett Syndrome

Strong Scientific Rationale for NTI164

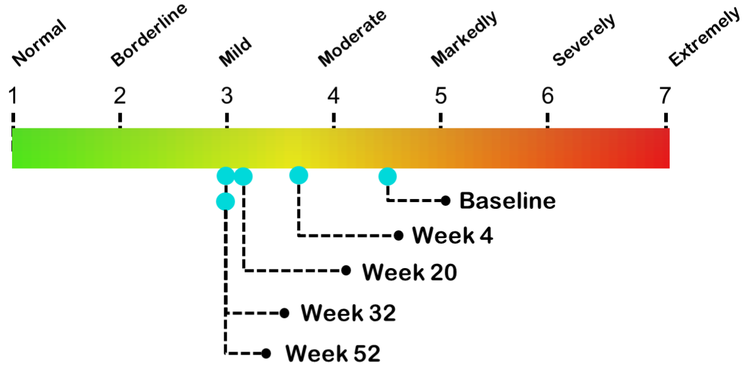
- Anti-inflammatory effects + safety
- Clinician support
- High Patient/Caregiver interest

Neurological & Neuroinflammation | Lack of effective treatments | Rare / Orphan | Paediatric Onset

Austism Spectrum Disorder

- Phase I/II Clinical Trial reported data out to 52 weeks of treatment

Severity of illness Scale (CGI-S)



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

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

Federal government set to cut NDIS funding for autism

21 hours ago · sky news .com.au

Vineland-3 Domain	P-value *(Paired T-Test) 20 weeks*	P-value *(Paired T-Test) 52 weeks*
Adaptive behaviour composite	0.0005	0.0278
Communication	0.002	0.0001
Daily living skills	0.019	0.0050
Socialisation	0.014	0.118

Adaptive functioning, which are skills people need to function independently at home, at school and in the community is an important factor in predicting long-term outcomes for people with ASD.

Improving adaptive abilities in patients is therefore a desirable treatment goal

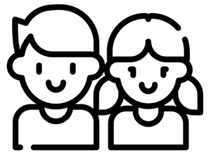
- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years[5]

- World first trial of broad-spectrum cannabinoid therapy
- 11 children continue treatment under Special Access > 52 weeks
- NTI164 is a patient ‘enabling’ drug with non-drug behavioural therapies
- Chronic administration required to maintain effects
- No serious adverse events over 52 weeks of daily oral treatment
- About to complete larger Phase II/III trial

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. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.

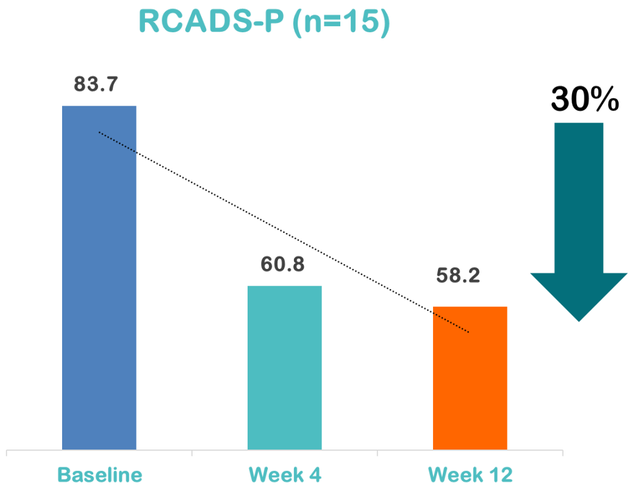
PANDAS/PANS

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



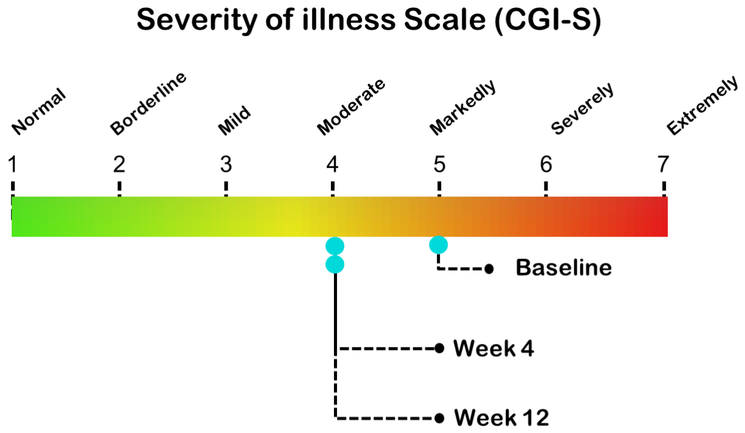
Phase I/II reported: 15 patients with moderate-severe PANDAS/PANS recruited,12-week data

Significant Improvement in anxiety / depression



RCADS-P[1] (p = 0.016)

Significant Improvement in Disease Severity



CGI-Severity of illness[1] (p = 0.0005)

Attractive Clinical and Market Dynamics

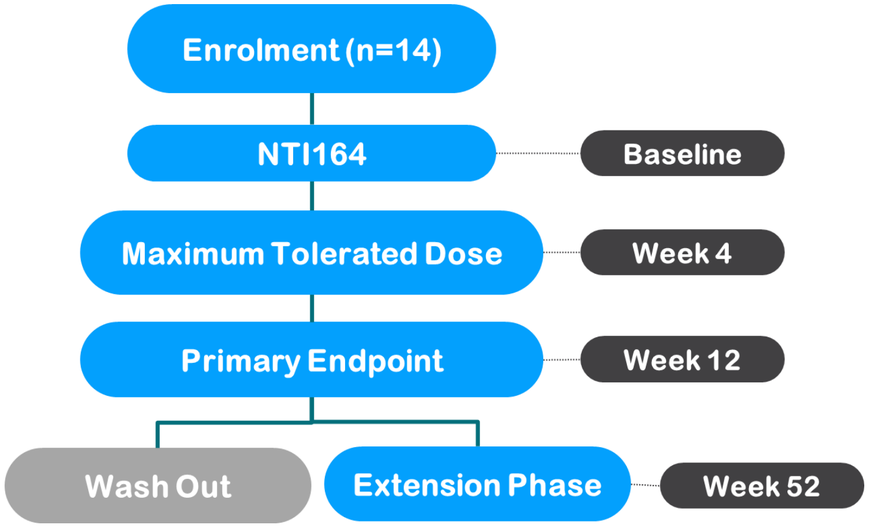
- Rare, paediatric onset with **NO** Approved treatments
- Diagnostic and Treatment Criteria now accepted
- Strong correlation to brain inflammation
- World first trial of broad-spectrum cannabinoid therapy
- All patients continue treatment > 12 weeks, some now adults
- Seeking orphan drug designations (ODDs) in US, EU

1. Revised Child Anxiety and Depression Scale – Parent Version (RCADS-P) - is a 47-item parent-report questionnaire of youth anxiety and depression (a scale of anxiety, social phobia, panic disorder, OCD, and low mood, a score below 65 represents low severity, scores between 65-70 represent medium severity and are on the borderline clinical threshold, and scores above 70 represent high severity and are above the clinical threshold). This test is completed at the site.
2. 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. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.

Rett Syndrome

Neurotech International

Phase I/II reported: 14 patients with Rett Syndrome,12-week data, fully recruited



Improvement was seen by doctors in nearly 4 out of 10 patients (38%) taking DAYBUE at 12 weeks, compared with less than 2 out of 10 (15%) of those taking the placebo.

	1 Very much improved	2 Much improved	3 Minimally improved	4 No change	5 Minimally worse	6 Much worse	7 Very much worse
DAYBUE	0%	13%	24.7%	61%	1.3%	0%	0%
Placebo	0%	4.7%	10.5%	81.4%	3.5%	0%	0%

Individual results may vary.

Significant Market

Daybue™ (trofinetide)

- One FDA approved therapy
- Neuren (ASX:NEU) license deal with Arcadia (NASDAQ:ACAD) close to US$1 billion, multiple ODDs
- US$2.0 billion annual market, drug cost to patient ~US$1,000 per day
- US$67 million in Q3 CY2023 net sales, 800 patient starts
- 15,000 patients in US (5,000 registered)

NTI164 Advantages

- Dual targeting both neuroprotection and neuroinflammation
- Trofinetide sets FDA (+other) benchmarks for safety and efficacy
- NTI164 has exhibited excellent safety/efficacy in ASD and PANDAS/PANS
- Orphan Drug Designations planned for US and Europe
- Results in Q1 CY2024, anticipate good treatment durability

Of the 154 patients who enrolled in LILAC, 84 (54.5%) completed the study[3]

- 35.7% of patients discontinued due to adverse events[3]
- 3.2% of patients discontinued due to lack of efficacy[3]

Types of adverse events reported in the OLE study were comparable to those observed in LAVENDER.

Our Target Markets

Lack of effective therapies, significant unmet medical need

Annual Drug Therapy Market opportunity

Autism Spectrum Disorder (ASD)	Rett Syndrome	PANDAS/PANS	Cerebral Palsy (CP)
US$2 billion*	US$2 billion	US$1.4 billion[1]	US$4.3 billion
ndis	Orphan	Orphan	
$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			
• Prevalence of ~2.0M <18 yr. patients in the US • 2 Approved Drugs (* limited use) • Risperidone, Aripiprazole	• Prevalence of ~15,000 patients in the US • 1 Approved Drug • Trofinetide	• Incidence of ~6,000 patients <18 yr. in the US[1] • No FDA/EMA Approved Drug	• Incidence of ~500,000 <18 yr. patients in the US • 2 Approved Drugs for spastic CP • Baclofen, Botox

1. Neurotech Estimate based on: Wald ER, et al. Estimate of the incidence of PANDAS and PANS in 3 primary care populations. Front Pediatr. 2023 Sep 21; EU/UK: 8,000 pts / US: 6,000 pts <18 years based on annual intravenous immunoglobulin (IVIG) cost of ~US$100k (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8019941/)

Key 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 I/II Clinical Trial *
- Completion of Patient Recruitment PANDAS/ PANS Phase I/II Clinical Trial

2H CY2023

- Commence Phase II Clinical Trial in Rett Syndrome
- Results of PANDAS/PANS Phase I/II Clinical Trial
- Completion of patient recruitment of Rett Syndrome Phase I/II Clinical Trial
- Completion of Patient recruitment ASD Phase II/III Clinical Trial (Q4)
- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial (Q4)
- Publication(s) of ASD Phase I/II data (through to 52 weeks)(Q4)

Q1 CY2024

- Results of Rett Syndrome Phase I/II Clinical Trial
- Results of ASD Phase II/III Clinical Trial

* 10 July 2023

Outlook

- Focus on rare paediatric neurological disorders
- Accelerated clinical development via rapid & cost-effective proof of concept Phase I/II clinical trials in Australia for new paediatric neurological disorders (PANDAS/PANS, Rett and CP)
- Two further clinical trial read-outs in Q1 CY2024
- Access to numerous regulatory levers from the FDA and EMA – initial focus on Orphan Drug Designations for PANDAS/PANS and Rett Syndrome in Europe and the US
- Planned meetings with TGA and FDA to refine regulatory process in 2024
- Fully funded to complete all current clinical trials

Neurotech International

Contact Details

Dr Tom Duthy
Executive Director
td@neurotechinternational.com
+61 402 493 727

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