ASX Announcement

19 October 2022

Neurotech to Present at Upcoming South-West Connect ASX Showcase

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces an upcoming presentation by Executive Director Dr Thomas Duthy at the South-West Connect ASX Showcase to be held on 19-21 October 2022 in Busselton, WA.

The Canaccord Genuity South-West Connect ASX Showcase is designed to bring some of the ASX's most exciting companies to one of Western Australia's iconic and popular regions.

A copy of the presentation is attached.

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

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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 is currently conducting a world-first clinical trial to assess the potential application of NTI164 for the treatment of Autism Spectrum Disorder (ASD). Results of the Phase I/II clinical trial indicated that 93% of participants had notable improvements relating to the severity of illness with no serious side effects. The next step will be initiation of a Phase II/III clinical trial to further assess the long-term safety and efficacy of NTI164, with the potential to lead to drug registration. Neurotech is also commercialising Mente, the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

For more information about Neurotech please visit http://www.neurotechinternational.com.

Improving Lives

Neurotech International

South-West Connect ASX Showcase

Dr Tom Duthy
Executive Director

21 October 2022

Disclaimer

IMPORTANT INFORMATION

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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

Corporate / Capital Summary

$0.105
Share price
(as at 12 October 2022)

$75.1M
Market capitalisation

~$1.9M
Cash at bank*

~1,600
No. of shareholders

716.7M
Share on issue

124.1M^
Options/rights

~$2.6M
R&D Investment in FY22

57%
Top 20 Holders

*as at 30 June 2022
^Options are comprised at various strike prices between $0.005 to $0.16 as at 13 October 2022
In addition to the above issued capital the Company has agreed to issue 35 million adviser options, 30 million director options and 33 million licensor shares, subject to shareholder approval

Neurotech Four Core Strategies

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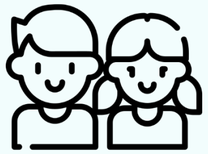
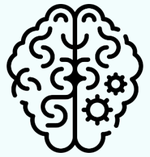
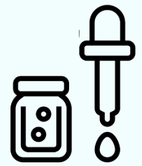


Focus on Paediatric Patients



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

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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 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)

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

"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.

Autism Spectrum Disorder (ASD)

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Market

PREVALENCE OF ASD
~1 in 44 children in the US[1]

Current Treatment

TREATMENT MARKET SIZE
US$1.85b[2]

RISPERIDONE
Approved 2006
(irritability label claim)

Clinical Trial

ASD is a serious <u>neuro inflammatory</u> developmental disorder that impairs the ability to communicate & interact

Common symptoms; behavioural issues, agitation, repetitive movements, inability to focus & compulsive neurological patterns

Huge unmet medical need - patients need better treatment

Current drugs have numerous side effects; weight gain, breast tissue development, nausea, dry mouth, anxiety, irritability, insomnia, stomach pain & movement disorders

Initial Focus of NTI164 – A full spectrum, oral cannabinoid biopharmaceutical product

Strong Scientific Rationale

- Anti-inflammatory effects + safety
- Clinician support
- High Patient/Caregiver interest
- Risperidone not a clinical standard

1. www.cdc.gov/ncbddd/autism/addm.html
2. https://www.fortunebusinessinsights.com/industry-reports/autism-spectrum-disorder-therapeutics-market-101207-CAGR-of-7-4.html

NTI164 ASD Phase I/II - Trial Design

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The Program

First in human Phase I/II ASD paediatric study (S8)

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

Data Released 8 July 2022

Dose regime assessments

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

2,250 Assessment points

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

NTI164 ASD Phase I/II – Safety/Efficacy (28 Day Recap)

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NTI164 was Safe

No serious adverse events recorded

Across all doses

93% of patients showed improvement

CGI - Global Improvement

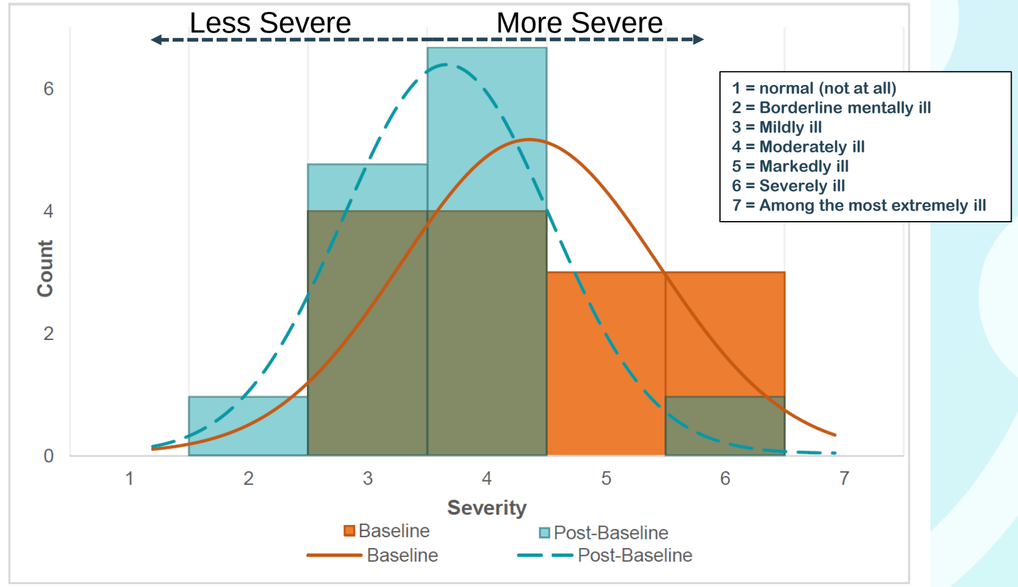
64% of patients "much improved"
29% of patients "minimally improved
7% of patients "no change"

NTI164 Reduced 'Severity of Illness' score by 0.8 (18%)

Average rating for the severity of illness at baseline: **4.4**

Average rating for the severity of illness at 28 Days of treatment with NTI164 was **3.6**

p= 0.027



All participants requested to continue for at least 54 weeks – progressive data collected including at 20 weeks (data early Q4 CY22)

Note: Baseline and 28 day data reported above (ASX Announcement 8 July 2022) represents 14 patients having completed daily treatment with NTI164 to 28 days per study protocol

Rapid Pipeline Progression

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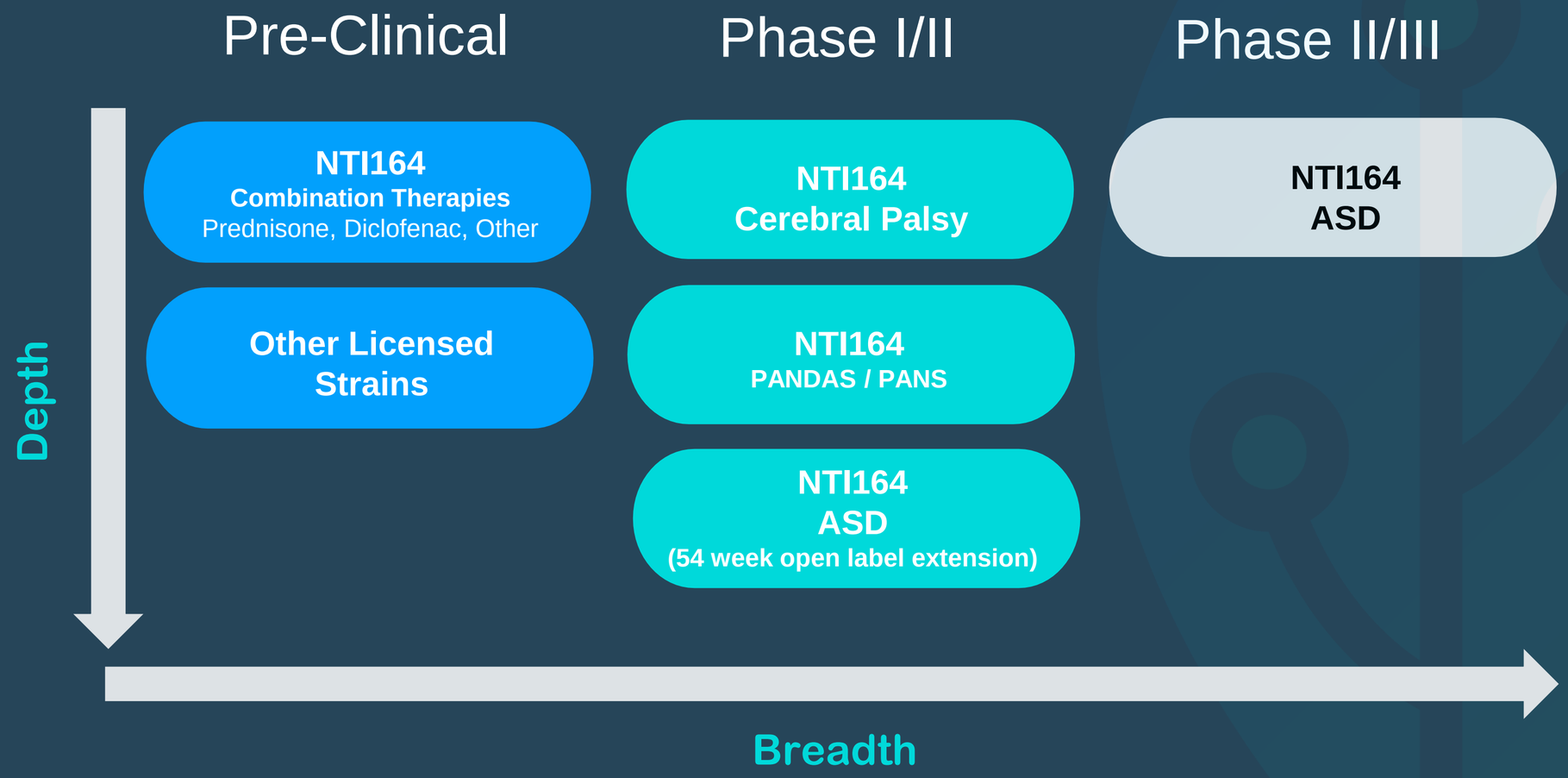
Pipeline (2020/1)

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

Pipeline (Pro-Forma 1 Jan 2023)



Key 12 Month Milestones – NTI164

Q4 CY2022

- Results of ASD 20 week Phase I/II Clinical Trial
- Human Research Ethics Committee (HREC) Clearance 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

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

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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

Outlook

- Focus on rare paediatric neurological disorders
- Initial safety & efficacy of NTI164 now established in a predominant paediatric neurological disorder with strong neuroinflammatory effects (ASD) – **20 week data imminent**
- 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

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

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