



Phase I/II ASD 20 Week Results & Capital Raise: Investor Presentation

Dr Tom Duthy Executive Director

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Presentation Contents



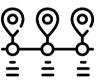
ASD Phase I/II Results



Neurotech Strategies



Pipeline & Milestones

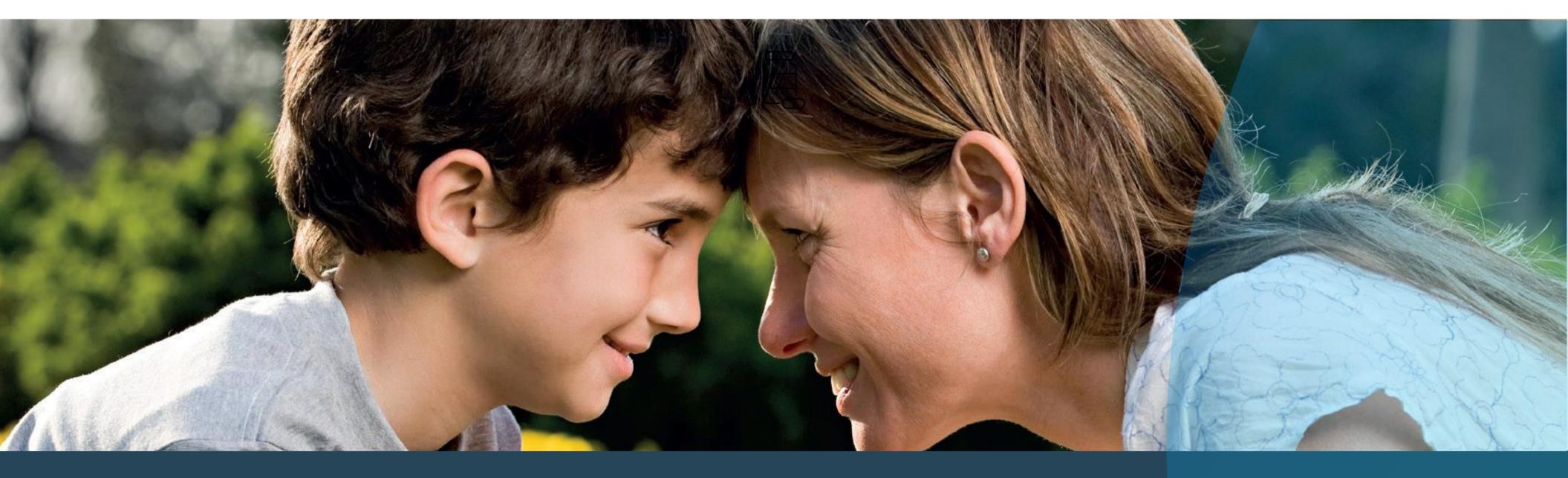


Summary & Outlook



Capital Raise





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



Autism Spectrum Disorder (ASD)



PREVALENCE OF ASD ~1 in 44 children in the US1

TREATMENT **MARKET SIZE** US\$1.85b²



RISPERIDONE

Approved 2006 (irritability label claim)



Clinical Trial



Market

ASD is a serious neuro inflammatory 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 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

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

2,250 Assessment points

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

Data Released 8 July 2022

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



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"

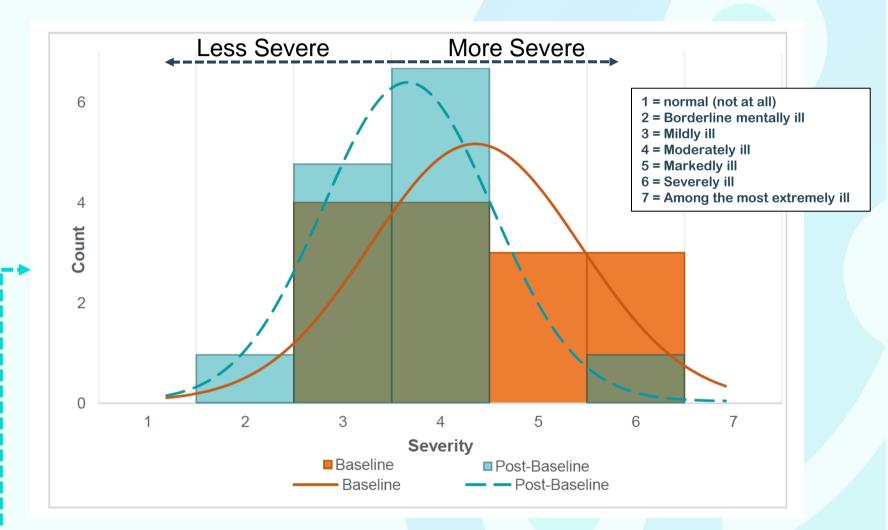
NTI164 reduced 'Severity of Illness' score by 0.8 (18%)

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

(Note: A p-value < 0.05 is considered statistically significant)



All participants requested to continue for at least 54 weeks – progressive data collected including at 20 weeks

NTI164 ASD Phase I/II - Safety (20 week Data)



NTI164 Safety Effects Maintained Over 20 Weeks

No serious adverse events recorded

Across all doses

58% patients continued to tolerate maximum dose (20 mg/kg/day) over course of 20 weeks
Only 1 patient on Risperidone at enrollment (not considered a preferred standard of care)

Adverse events were tolerated and manageable i.e. mild nausea, abdominal pain



A total of 12 patients evaluable at 20 weeks

2 patients stopped treatment (not drug related)

Conclusion: NTI164 longer term (chronic) administration now established with an excellent safety profile and minimal patient-specific side-effects: safety data collected to 54 weeks ongoing

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



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

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



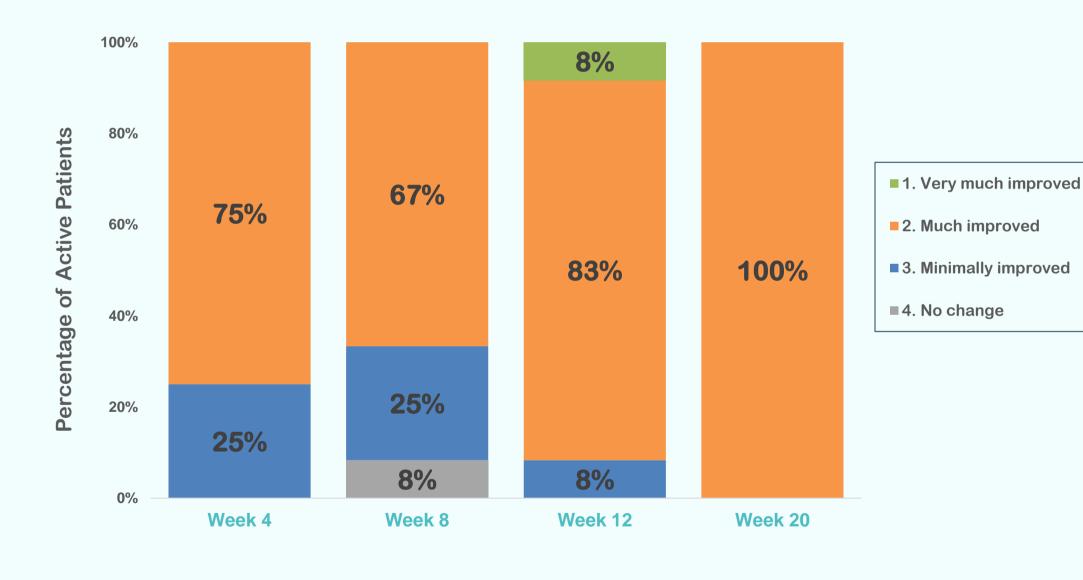


- Statistical significance (p<0.05):</p>
 - 20/27 measures assessed at 20 weeks
 - Study was <u>not</u> statistically powered for any efficacy measures (safety was primary endpoint)
- Highly significant results for the most clinically important measures:
 - Severity of illness
 - Adaptive behaviour
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

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



CGI-Global improvement ¹



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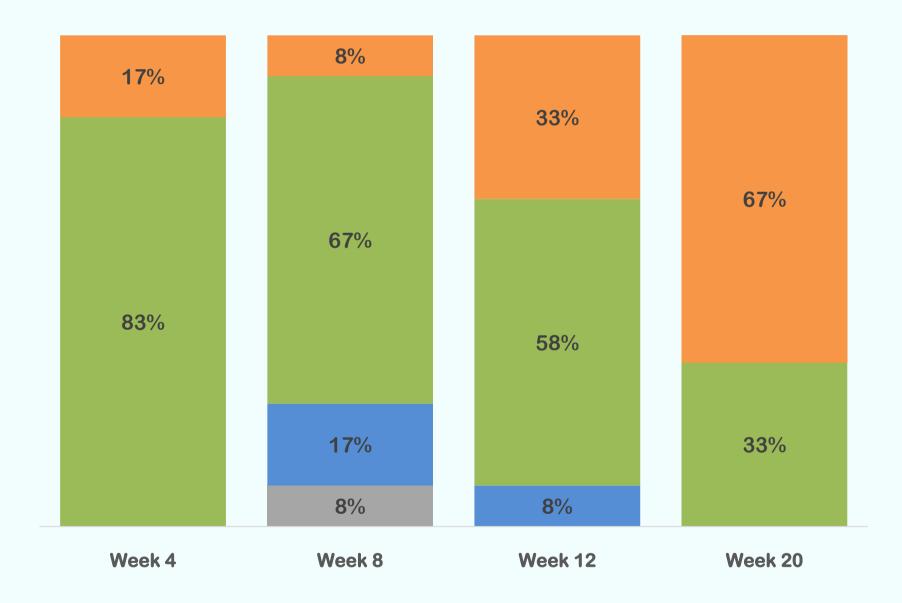


- 100% of active patients showed improvement after
 20 weeks of daily treatment with NTI164
- All patients had a global improvement of 2: Much improved

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



CGI-Therapeutic Effect¹



Therapeutic Effect (Efficacy Index)

1 = Marked - Vast improvement. Complete or nearly complete remission of all symptoms. No side effects.
 2 = Marked - Vast improvement. Complete or nearly complete remission of all symptoms. Side effects do not significantly interfere with patient's functioning.
 5 = Moderate - Decided improvement. Partial remission of symptoms. No side effects.
 6 = Moderate - Decided improvement. Partial remission of symptoms. Side effects do not significantly interfere with patient's functioning.
 7 = Moderate - Decided improvement. Partial remission of symptoms. Side effects significantly interfere with patient's functioning.
 9 = Minimal - Slight improvement. Doesn't alter status of care of patient. No side effects.
 10 = Minimal - Slight Improvement. Doesn't alter status of care for patient. Side effects do not significantly interfere with patient's functioning.
 13 = Unchanged or Worse. No side effects.



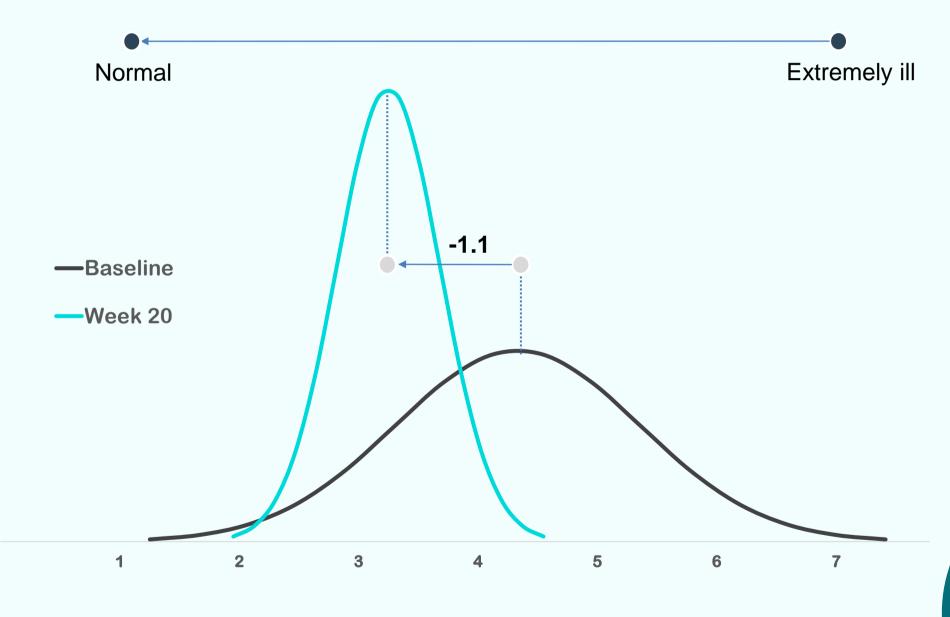


- 67% of active patients demonstrated the highest possible efficacy indexes of 1 and 2: Complete or nearly complete remission of all symptoms.
- 33% of patients were decidedly improved. Partial remission of symptoms
- Potential for further improvement to 54 weeks

NTI164 ASD Phase I/II - Efficacy (20 Week Data)



CGI-Severity of illness 1 (p = 0.005)



- 1. Normal, not at all ill
- 2. Borderline mentally ill
- 3. Mildly ill
- 4. Moderately ill

- 5. Markedly ill
- 6. Severely ill
- 7. Among the most extremely ill patients

Mean Severity of Illness (n=12)





- NTI164 treatment is associated with a significant reduction in disease severity (1.1 scale change, 26% improvement)
- ~40% of subjects markedly or severely ill at baseline 0% from week 4 onwards
- Potential for further improvement to 54 weeks

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



Vineland™-3¹

Standardised measure of adaptive behaviour (3 month+ measure)

Norm-based: adaptive functioning compared to others of same age

Excellent test, re-test reliability & between rater (clinician, parent)

Vineland-3 Domain	P-value (Paired T-Test)
Adaptive behaviour composite	0.0005
Communication	0.002
Daily living skills	0.019
Socialisation	0.014





- Adaptive behaviour improvement is a treatment goal in ASD
- Highly significant improvements in composite outcome <u>AND</u> individual domains of communication, daily living, socialisation at 20 weeks

^{1.} Vineland™-3 is internationally recognised as a leading instrument for supporting the diagnosis of intellectual and developmental disabilities in ASD; specifically adaptive behaviour. 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. The adaptive behaviour composite consists of (a) communication, (b) daily living skills & (c) socialisation. Baseline 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 - Efficacy (20 week Data)



SRSTM-21

Children with autism spectrum disorder have difficulty with social interaction behaviours, including establishing and maintaining relationships, reciprocating social interaction, and communicating with others. SRS-2 is a validated measurement tool of assessing these factors

SRS-2 Domain	P-value (Paired T-Test)
Total	0.012
Social awareness	0.596
Social cognition	0.028
Social communication	0.019
Social motivation	0.118
Restricted interest and repetitive behaviour	0.009
Social communication and interaction	0.029





- Achieved strong overall statistical significance for social responsiveness (p=0.012)
- NTI164 targets social skills: beneficial for social functioning and social anxiety symptoms
- Social communication differences are one of the core features of ASD

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



Anxiety (Parent/Child)

Anxiety Scale	Baseline Mean	Week 20 Mean	Mean Difference	P Value (Paired T-test)
Parent Version (ASC-ASD-P) <i>n=10</i>	29.4	22.2	-7.2	0.034
Child Version (ASC-ASD-C) <i>n=11</i>	29.5	18.2	-11.2	0.025

40% of young people with ASD have clinically elevated levels of anxiety or at least one anxiety disorder. It is particularly important to recognize and treat anxiety in ASD since it has a great impact on the course and the core aspects of the disorder, exacerbating social withdrawal as well as repetitive behaviours. ¹





Clinical Interpretation

- Statistically significant and clinically meaningful 24% improvement in anxiety scale (parent, p=0.034) and 38% improvement in child version (p=0.025)
- Improvements in anxiety, adaptive behaviour and social responsiveness: important benefits for child

1. Anxiety and Depression Association of America

Data Comparison & Context - Risperidone







CGI-Severity of illness

(n=96): -1.0 from baseline at 12 months¹ (n=38): -0.7 from baseline at 48 weeks²

- -1.1 change at 20 weeks (p=0.005), 26% improvement
- ~40% of subjects markedly or severely ill at baseline 0% from week 4 onwards
- At 20 weeks, mean result: 100% mildly ill

CGI-Improvement

- (n=15): CGI-I changes after 8 weeks from baseline³
 - 27% very much improved
 - 47% much improved
 - 20% minimal improved
 - 6.6% no change

- 100% of active patients showed improvement after 20 weeks of daily treatment with NTI164
- All patients had a global improvement of '2. Much improved'

Vineland™-3

- Near absence of RCTs examining Vineland noted in the medical literature No impact on social interaction and communication⁴
- Adaptive behaviour composite score (p=0.001)
- Highly significant improvement
- Highly significant improvements also in domains of communication, daily living, socialisation at 20 weeks

Safety

- Significant weight gain Increase in BMI by 0.621
- Weight gain²
- Increase in appetite, sedation³

- No change to weight
- No change to appetite
- Mild nausea, stomach pain

"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."



RCT- randomised controlled trial; BMI – Body Mass index

^{1.} Kent, et al. Risperidone Dosing in Children and Adolescents with Autistic Disorder: A Double-Blind, Placebo-Controlled Study. Journal of autism and developmental disorders. 2012. 43. 10.1007

^{2.} A Study to Evaluate the Efficacy and Safety of Risperidone (R064766) in Children and Adolescents With Irritability Associated With Autistic Disorder, 2015

^{3.} Ghaeli P et al. Effects of risperidone on core symptoms of autistic disorder based on childhood autism rating scale: an open label study. Indian J Psychol Med. 2014 Jan;36(1):66-70.

^{4.} McDougle CJ, et al.. Risperidone for the core symptom domains of autism: results from the study by the autism network of the research units on pediatric psychopharmacology. Am J Psychiatry. 2005 Jun;162(6):1142-8

NTI164 ASD Phase I/II - Conclusions



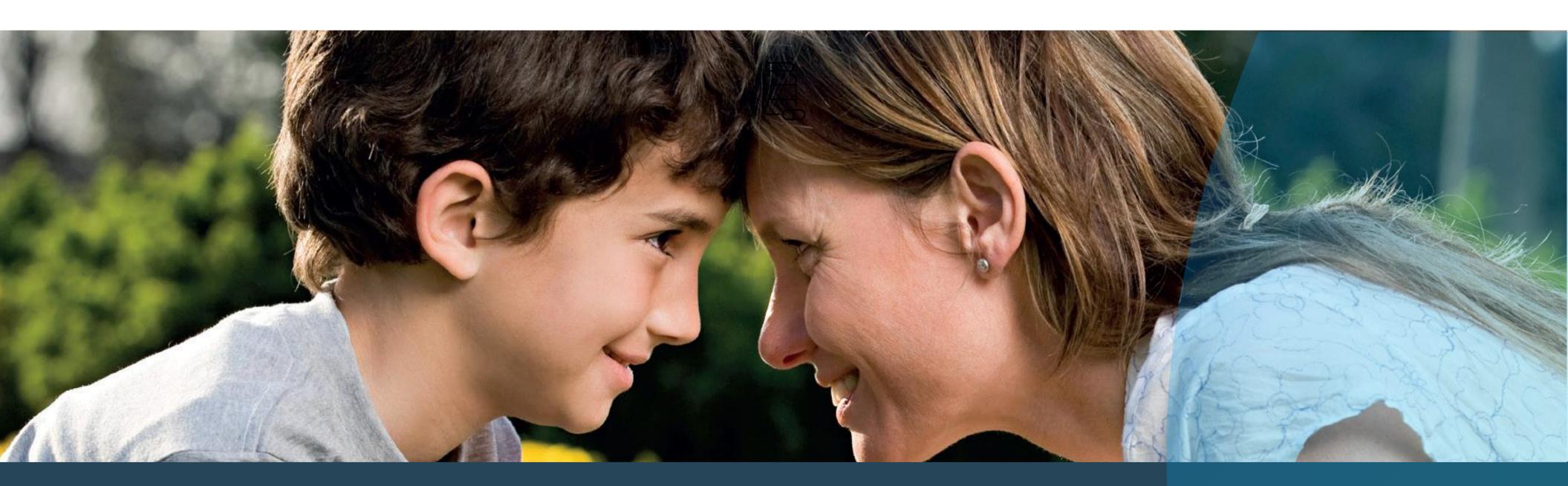
- Any significant change over time for measures of CGI-S, Vineland™-3 and SRS™-2 are considered clinically meaningful: NTI164 showed sig. improvement for all measures at 20 weeks v baseline
- NTI164 is a patient 'enabling' drug with non-drug behavioural therapies, by improving daily living and allowing children to integrate into society via significant improvements in socialisation & anxiety versus 'restrictive' prescription of Risperidone (prevention of aggression, irritability)
- Approximately 6,300 assessment points now collected at 20 weeks. Trial continues to 54 weeks, with data to form part of FDA IND submission
- Data strongly supports progression to randomised, double-blind, placebo-controlled ASD Phase II/III clinical trial: expected to commence in Q4 CY2022 – HREC has been submitted

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."

Neurotech: Strategies, Pipeline, Milestones, Outlook





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)



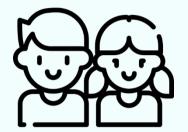
World first Phase I/II trial in ASD completed



Mente device & therapy for ASD

Neurotech Four Core Strategies

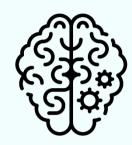




Focus on Paediatric Patients



Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Rare Neurological Disorders with Neuroinflammation



Focus On Drug Product
Development

Strategic Focus Offers Significant Value Upside





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

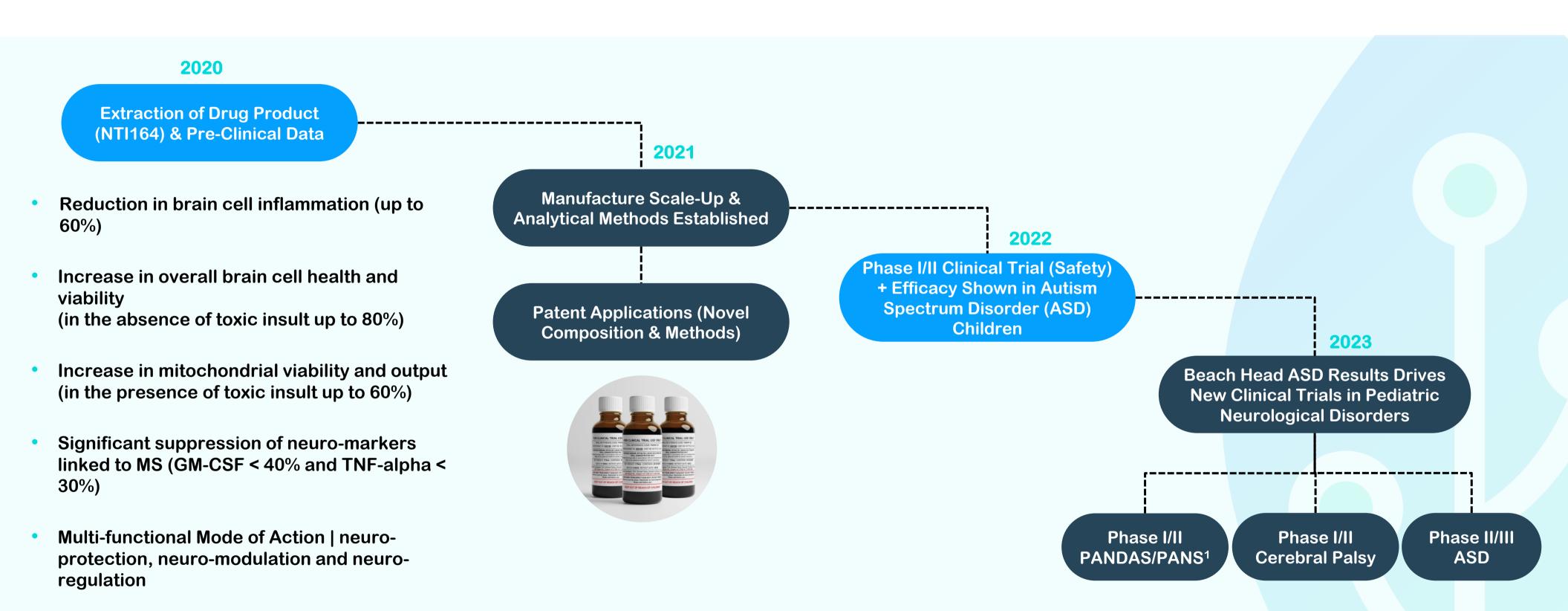


Focus on Drug Product Development

- 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





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

Rapid Pipeline Progression



Pipeline (Pro-Forma 1 Jan 2023)

Pipeline (2020/1)

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

NTI164
Neuronal Cell Assays

Other Licensed Strains

Pre-Clinical Phase I/II Phase II/III **NTI164 NTI164 NTI164 Combination Therapies Cerebral Palsy ASD** Prednisone, Diclofenac, Other **Other Licensed NTI164** Depth **PANDAS / PANS Strains NTI164 ASD** (54 week open label extension)

Breadth

Key 12 Month Milestones – NTI164



Q4 CY2022

- 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

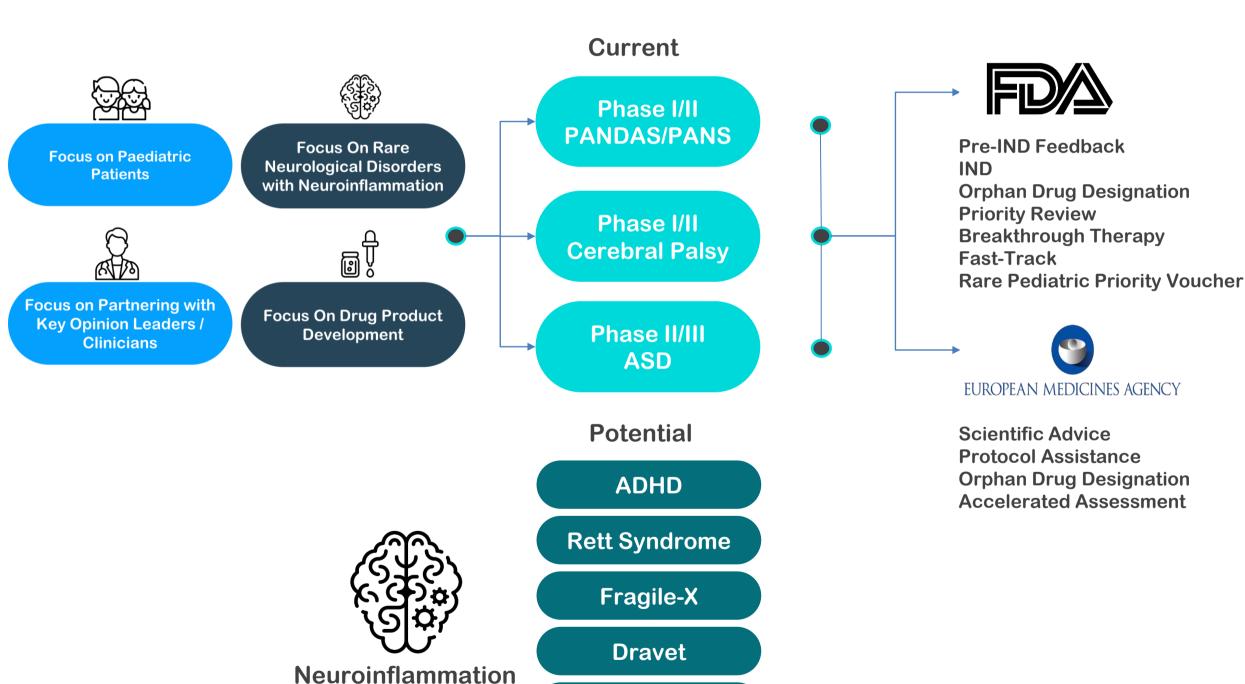


Group Strategy

Implementation to Development

Potential Regulatory Levers





Lennox-Gastaut





Track Status in Rett, Fragile-X, Angelman,

Phelan-McDermid, Pitt Hopkins, Prader-Will

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



Highly Experienced Executive Team and Board





Mark Davies
Non-Executive Director

More than 20 years' experience in trading, investment banking & providing corporate advice

Specialises in providing corporate advice & capital raising services to emerging companies seeking business development opportunities and funding from the Australian market

Managing Director of 1861 Capital and cofounder of investment banking firm, Cygnet Capital

BCom



Dr Thomas Duthy Executive Director

Dr Duthy has over 18 years of direct financial market and executive level/ Board experience with ASX listed companies.

Director of Nemean Group -corporate advisory and investor relations services in the Life Sciences and Technology sectors.

PhD Molecular Microbiology, MBA, MAICD



Prof. Allan Cripps AO
Non-Executive Director
Chief Scientist

Distinguished academic, clinical scientist and health services leader

Independent Chair of the Children's Health Research Alliance Board and Non- Executive Director at Bard1 (BD1)

Formerly the Pro Vice Chancellor (Health) at Griffith University and currently professor emeritus at Griffith University

PhD, BSc (Hons), FAHSM, FASM, FAIMS, FIBMS, FCHSM. MACID



Winton Willesse
Non-Executive Director

Experienced company director with over 20 years experience in various roles within the Australian capital markets

Core expertise in strategy, company development, corporate governance, company public listings, merger and acquisition transactions and corporate finance

MCom, FFin, CPA, GAICD, FGIA/FCG



Gerald Quigley
Non-Executive Director

Pharmacist and consumer health commentator.

Leading media health commentator heard each week on television and radio stations across Australia.

Extensive knowledge relating to pharmaceutical/nutraceutica I product development, dispensing & marketing in addition to product positioning within the relevant regulatory landscapes (eg. TGA, FDA).

B(Pharm)



Dr Alexandra AndrewsCOO

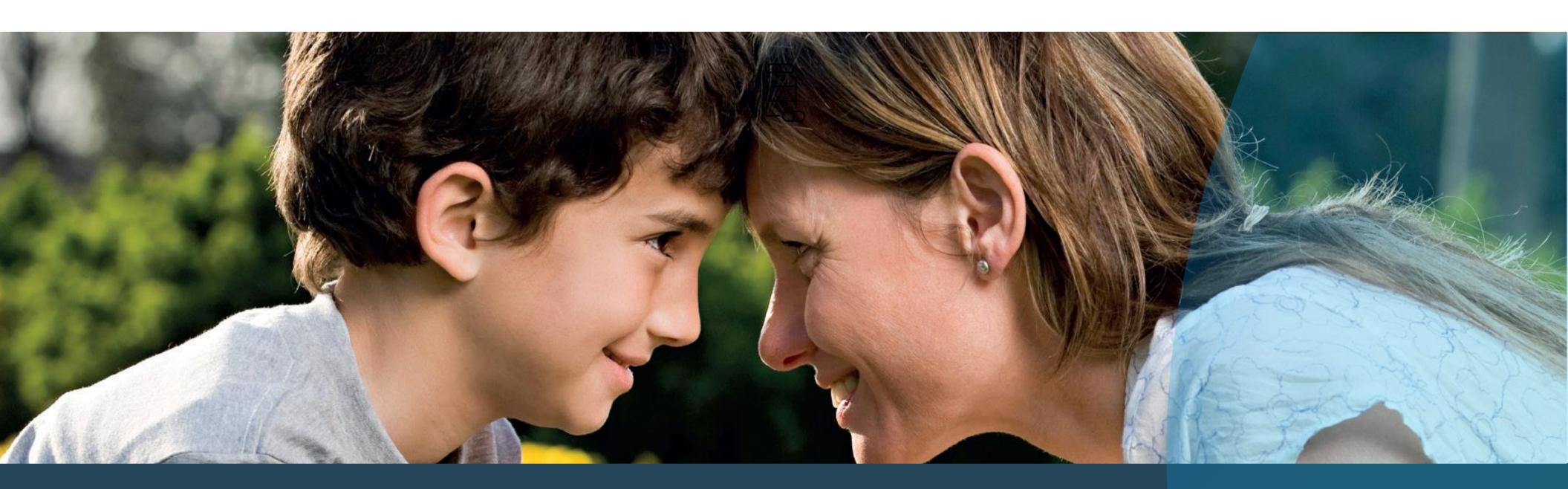
Expertise in corporate development, investor engagement, product development and commercialisation, clinical trials and regulatory environments.

Former Director of Operations at NeuroScientific Biopharmaceuticals Ltd.

PhD Neuroscience, BBMed Sci (Hons1st)

Capital Raise





Structure



PRO-FORMA CAPITAL STRUCTURE - \$9 Million Placement		
Current Shares on Issue	717.7M	
Current Options Outstanding	123.1M	
New Shares	90.0M	
New Options ¹	55.0M	
Pro-Forma Shares on Issue (fully diluted)	985.8M	
Pro-Forma Cash ²	\$10.4M	
Pro-Forma Enterprise Value ³	\$88.2M	

^{1.} New Options include 45,000,000 issued to shareholders under the Transaction as well as an additional 10,000,000 issued to the JLMs on the same terms

^{2.} Cash at 30 June 2022 - \$1.9 million, Placement of \$9.0 million minimum, transaction costs of \$(0.5) million

^{3.} Assumes \$0.10 share price

^{4.} The Company has also agreed to issue 35 million adviser options, 30 million director options and 33 million licensor shares, subject to shareholder approval

Timetable*



Event	Date
Trading Halt (For Clinical Trial results + Transaction)	Tuesday 25 October 2022
Placement Bookbuild Commences	Tuesday 25 October 2022
Allocations and Signed Acceptances	Thursday 27 October 2022
ASX Announcement – Transaction, Investor Presentation, Trading Halt Lifted	Friday 28 October 2022
Settlement of Placement Shares	Thursday 3 November 2022
Allotment of Placement Shares on ASX & Commencement of Trading	Friday 4 November 2022
Allotment of Placement Options	Friday 3 December 2022

^{*} Timetable is indicative and subject to change

Use of Funds



EVENT	ALLOCATION OF FUNDS (PLACEMENT)
Phase II/III ASD Trial	\$3.0M
Phase I/II PANS/PANDAS Trial	\$0.5 M
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



Contact Details

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

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