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# **Unique Value Proposition**



Neurotech is focussed on the development & commercialisation of neurological solutions that improve quality of life



Neurotech has completed extensive preclinical studies with human clinical trials underway



Neurotech has exclusive worldwide licence to utilise proprietary cannabis strains from Dolce Cann Global Pty Ltd ('Dolce') for all neurological disorders



Commencement of world's first whole plant extract cannabis clinical study in autistic children with little to no THC and unique cannabinoids



Dolce Cann Global cannabis strains contain naturally low levels (<0.3%) THC. High levels of CBD-A, CBG, CBN, CBD-B, CBD-P



Neurotech's Mente device & therapy is clinically proven to increase engagement & improve relaxation in autistic children with elevated delta band brain activity



Potential for the NTI/Dolce cannabis strains to treat neurological disorders including autism, epilepsy, MS & ADHD



Mente continues to gain recognition as a therapeutic tool with parents and carers of those with autism spectrum disorder



# **Corporate Overview**

CAPITAL STRUCTURE	
Share price (as at 4 August 2021)	\$0.05
Shares on issue	696m
Options	113m^
Cash at bank*	~\$4.83m
Market capitalisation	~\$35m

<sup>^</sup>Options have various strike prices between \$0.005 to \$0.09

#### **12-Month Share Price Performance**



<sup>\*</sup>As at 30 June 2021

# **Highly Experienced Board**



**Brian Leedman**Chairman

- More than 15 years' experience in the biotechnology sector
- Founder / co-founder of five ASX listed healthcare/ biotechnology companies including: RAP, NGS, NSB, OSL, IMU
- Former Chairman of Ausbiotech (WA)
- BEc, MBA (UWA)



Krista Bates Non-Executive Director

- Experienced director of ASX and LSX companies
- More than 20 years' experience in legal practice
- Former Partner at leading law firm, Lavan Legal – Head of the Medical Cannabis Group
- BA(Hons), Grad Dip (Law), PostGrad Dip (Law), GAIDC



Prof. Allan Cripps AO
Non-Executive
Director

- 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



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 co-founder of investment banking firm, Cygnet Capital
- BCom



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

## Medicinal Cannabis industry is only just getting started

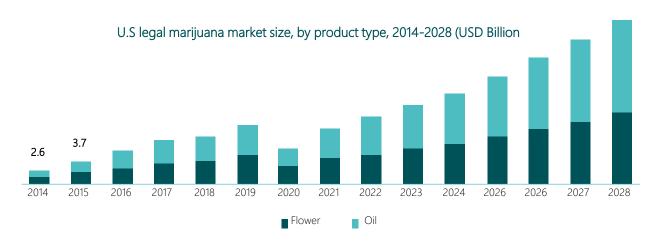
There are only four approved cannabis based drugs

#### **FDA**

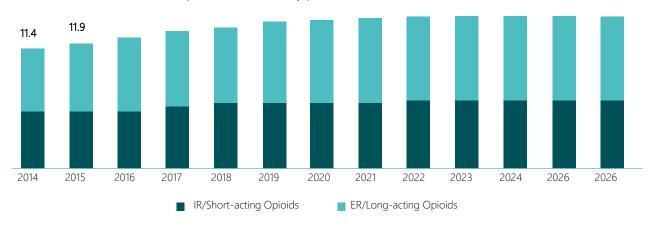
- Marinol® (dronabinol) synthetically manufactured (CBD | THC) and registered in the US by the Food and Drug Administration (FDA) for the treatment of anorexia in patients with AIDS and for the management of chemotherapy-induced nausea and vomiting where standard anti-nausea treatments have failed.
- Cesamet® (nabilone) synthetically manufactured (CBD | THC), and registered in the US by the FDA for the management of chemotherapy-induced nausea and vomiting.

#### **TGA**

- Epidyolex® is approved for adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older.
- Sativex® is approved for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

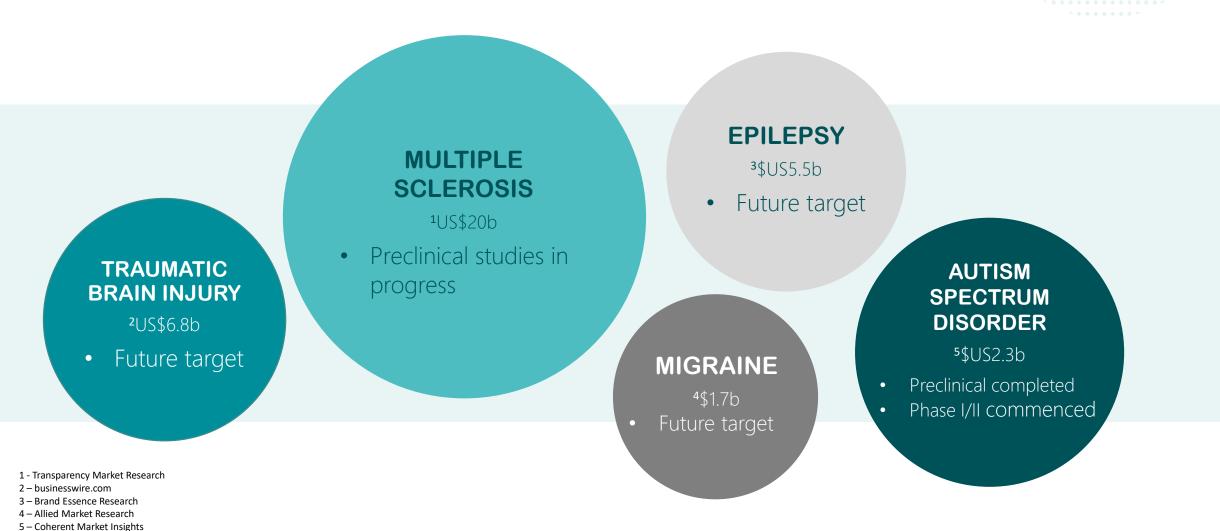






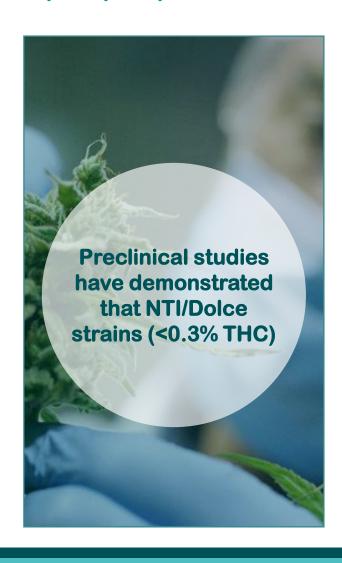
Neurotech Source: www.grandviewresearch.com

# Global drug market size for neurological disease



### NTI/Dolce strains have unique properties compared to CBD alone

- Very high levels of CBD-A (primary active) studies have confirmed that CBD-A up to 1,000 times more potent in regulating inflammation in chemotherapy patients than CBD alone.
- Recent studies have indicated that CBD-A can cross the blood-brain barrier.
- Regulate and supress inflammation by acting on Arginase1, powerful anti-inflammatory enzymes and therefore potential to be a powerful anti-inflammatory agent.
- Up-regulating and modulation of the of beta-tubulin protein, an essential protein in the maintenance and healthy survival of brain cells.
- Suppress and modulate the activity of iNOS which is directly involved in the complex cytokine pathways relating to immunity and natural defence mechanisms.



- Preclinical studies have demonstrated that NTI/Dolce strains (<0.3% THC) exhibit powerful anti-inflammatory, neuroprotective and neuro-modulatory properties – full entourage effect, which are much more powerful than CBD alone.
- NTI/DOLCE's strains have multi-functional activities across multiple pathways – to date CBD alone has only targeted one specific pathway.
- Naturally occurring low levels of THC make the NTI/DOLCE strains accessible to paediatric patients and others looking to avoid the "High" effect.
- Preclinical results to date show that NTI/DOLCE strains have unique modes of action when compared to CBD alone.

### **Results from Pre-clinical Studies**

Studies were designed to assess the neuroprotective and neuro-modulatory activities of the top DOLCE/NTI cannabis strains.

Studies were conducted in human derived brain and muscle cells – these models are internationally accepted and used to assess the efficacy and mechanism of neurological actives.

### **Key Findings**

In all studies the top DOLCE/NTI strains demonstrated superiority when compared to CBD alone.

- DOLCE/NTI strains demonstrated reduction in brain cell inflammation (up to 60%)
- DOLCE/NTI strains demonstrated an increase in overall brain cell health and viability (in the absence of toxic insult up to 80%)
- DOLCE/NTI strains demonstrated an increase in mitochondrial viability and output (in the presence of toxic insult up to 60%)
- DOLCE/NTI strains demonstrated significant suppression of neuro-markers linked to MS (GM-CSF < 40% and TNF-alpha < 30%)



Inflammation, cell and mitochondrial viability are all very important processes and outcomes in understanding, maintaining brain function and cognitive health.



Results clearly demonstrate the powerful neuroprotective and neuro-modulatory properties of the DOLCE/NTI strains and superiority when compared to current market standard: CBD isolate



Studies pave the way forward in designing the optimum clinical design program and clinical indication/s.

# Expected pathway of cannabis project

1. In vitro assay assessments

**N**euronal or muscle cell line assessments

Analytical assessments & validation program to be completed in collaboration with Monash University, RMIT University and University of Wollongong. These studies are to assess:

- Dose response studies
- Upper level of toxicity assessments
- Mechanism of action profiling
- Selection of top candidates



С

O M P

> L E T

T E D 2. Product formulation and final dose profiling

To be conducted in collaboration with Cannabis Formulation Experts and ACS Laboratories

Final product application: i.e. Spray, tincture, oil

Final specification sign off



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3. Phase I/II Human safety & efficacy clinical trials

Commenced in May 2021 in at Monash Children's Hospital a leading Australian University leading A/Prof. Michael Faye

- Open label single group
- 20 patients from 5 to 17yo
- 16 week duration including 4 week washout period
- Assess key behaviours changes
- Submission to the TGA and relevant regulatory bodies

# Why target Autism Spectrum Disorders (ASD)?

- ASD is a serious neuro inflammatory developmental disorder that impairs the ability to communicate and interact
  - > Range and severity of symptoms can vary widely
  - Common symptoms include; behavioural issues, agitation, repetitive movements, inability to focus and compulsive neurological patterns
- Huge unmet medical need patients need better treatment options without side effects
- Limited options are available to children
- \*\$4b US annual sales from market leading medications; Ritalin and Concerta (active ingredient Methylphenidate)
- Both medications have numerous side effects including:
  - > Appetite loss, dry mouth, anxiety, irritability, nausea, insomnia, abdominal pain, weight loss, dizziness and heart palpitations
  - > Parents and carers often stop using these medications due to their side effects profile
- Since 2017, studies with medicinal cannabis (CBD + THC) have shown some promise in children with ASD
- To date there have been no studies assessing medicinal cannabis with low (<0.3%) THC in the treatment of ASD</li>
- NTI is conducting the first study of its kind to assess medicinal cannabis rich extract with low THC in children with Autism

m Zmg

<sup>\*</sup>https://clincalc.com/DrugStats/Drugs/Methylphenidate

# Pathways to commercialisation

The anti-inflammatory properties NTI Dolce strains in combination with minimal presence of THC (< 0.3%) provides three clear pathways to commercialisation:

### **Prescription**

- Higher dosage than nutraceutical
- Safety data required
- GP and specialists to prescribe



#### **Nutraceutical**

- Over the counter (OTC)
- Natural product
- Fastest path to market
- Shorter regulatory process
- Limited safety and clinical data required



#### **Pharmaceutical**

- Long pathway to market
- Expensive
- Huge potential upside
- Partnering/licensing opportunities

TIME TO MARKET

# **Strategic Partners**

Monash Children's Hospital

A/Prof Michael Fahey – Head of Neurology Professor Katrina Harris – Head of Paediatrics

Victorian College of Pharmacy

Department: Centre for Medicinal Chemistry

ACS Laboratories | Melbourne Australia TGA Approved Cannabis Testing Facility

BJP Laboratories, Brisbane Australia Unit: Formulation and Development Group

RMIT | Melbourne Neurodevelopment in Health and Disease

Walter and Eliza Hall Institute | Melbourne

Department: Cellular and Molecular Biology

Canna Pacific | Australia Fully approved ODC Facility – NSW

Hemp Masonry | NSW – Growing Advisory Services

Althea Life Pharmaceuticals | Cannabis Breeding Services - Vic, Australia



















# **Expected news flow**





#### **Preclinical**

Expansion of Preclinical programme into wider neurological indications
– June 2021

#### **Further results**

Further Preclinical results in MS

– June 2021

#### Interim results

Interim results on Phase I/II clinical study in Autism – July 2021

### Final results

Final results on
Phase I/II clinical
study in Autism
– Q4 calendar 2021

### **Expansion**

Expansion of Phase II clinical study in Autism

- Q4 calendar 2021

### **Multi-cohort Phase**

Multi-cohort Phase III Registration Trials in Autism

- Q1 calendar 2022





#### **CONTACT DETAILS**

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

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