# Neurotech

3 July 2020

### Neurotech secures option to acquire global rights to cannabis strains targeting autism

#### Highlights

- Option to acquire an exclusive worldwide licence to use proprietary cannabis strains from Dolce Cann Global Pty Ltd ('Dolce') for medicinal use in treating autism, epilepsy and ADHD
- Complements NTI's existing technology which provides medical neurofeedback therapy for use in autism management
- Dolce is a uniquely positioned Australian developer of medicinal cannabis, with proprietary genetics sourced from 13 rare landrace chemovars developed over 20 years using selective targeted breeding techniques
- Genetic profiling of approximately 650 leaf cuttings from Dolce seedlings evidenced high levels of specific cannabinoids including CBG and CBDV recent published studies indicate potential for these to target specific neurological disorders
- NTI plans to commence in-vitro testing (human cell in laboratory) on 15 priority strains targeting autism and other neurological disorders in August / September 2020
- If initial testing is successful, NTI intends to partner with a leading Australian university to commence clinical trials utilising both the Dolce cannabis strains and its own proprietary Mente Autism neurofeedback device which analyses brain wave activity

**Neurotech International Limited (ASX: NTI)** ("Neurotech" or "the Company") is pleased to announce it has secured an option to acquire an exclusive worldwide licence to utilise proprietary cannabis strains from Dolce Cann Global Pty Ltd ('Dolce') for medicinal use in treating neurological disorders including autism, epilepsy and ADHD.

Australian-based Dolce has proprietary genetics sourced from 13 rare chemovars and bolstered over the past 20 years by selective breeding targeted for distinct purposes such as cultivation method, climate, yield, phytochemical content and harvested products including flower, seed, fibre or biomass.

Recent profiling of leaf cuttings from 650 seedlings of Dolce genetics evidenced high levels of cannabinoids CBG, CBC, CBN and CBDV among others. Recent studies have indicated the potential for these cannabinoids to target neurological disorders.

Neurotech Chairman Mark Davies said: "Neurotech has been researching in the field of autism and other neurological disorders for more than five years as it developed its Mente autism device. With more evidence pointing to the potential for certain cannabinoids to help treat neurological disorders, it makes

## sense for us to explore this possibility through this agreement with leading cannabis genetics breeder Dolce and we are excited to get started on this research over the coming months."

A key feature of the targeted Dolce strains is plant profiles with less than 0.3% THC (on average). Investigating cannabis research options for children with autism without the potential psychoactive effects of THC is a key component of NTI's proposed new project pathway. NTI believes that a combined approach to autism treatment, potentially combining the technology of its own Mente device with Dolce cannabis strains could lead to new treatment options becoming available as trials progress.

Dolce plans to engage Australia's leading cannabis testing laboratory, ACS Laboratories (Australia) ('ACS'), to undergo genetic profiling of some of their selected cannabis strains. ACS will also profile Dolce strains for the recently discovered cannabinoids THCp and CBDp as an Australian first.

Dolce has more than 60 elite clones undergoing validation for Plant Breeders Rights approval under the International Union for the Protection of New Varieties of Plants (UPOV) and potential utility patents in the USA. Dolce's ability to demonstrate its genetic development over the past 20 years puts the Company in a very strong position to secure worldwide IP protection regarding any cannabis strains that are ultimately successful as part of the NTI collaboration.

#### **Proposed Project Pathway**

Neurotech has designed a three-stage work program to investigate the use of Dolce's proprietary cannabis strains in treating the Neuro Disorders. The work program is proposed to be as follows;

#### 1. In vitro assay assessments - neuronal or muscle cell line assessments

Analytical assessments and validation program to be completed in collaboration with ACS labs. These studies are to assess:

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

#### 2. Small scale human clinical trials

To be conducted in conjunction with a leading Australian University on the following basis:

- Open label single group
- Compassionate use scheme to receive entry into clinic via accelerated pathway
- Collaboration with senior clinical advisors
- Submission to the TGA and relevant regulatory bodies

#### 3. Product formulation and final dose profiling

To be conducted in collaboration with Medipharm Australia;

- Entry into market
- White label or own label development

All three stages will run in accordance with all applicable Australian regulatory requirements and standards.

#### Medicinal Cannabis and Autism

Research around the world is currently examining a number of phytocannabinoids to determine their influence over the brain's CB1 and CB2 receptors. There are indicators that phytocannabinoids can stimulate the endocannabinoid system and send targeted signals throughout the body to address health conditions. Ultimately NTI believes that a combined approach to Autism treatment with its own Mente device and potentially Dolce cannabis strains could lead to new treatment options becoming available as trials progress.

Of the 120+ phytochemicals that are found in the cannabis plant, recent studies have suggested that CBDV and CBG cannabinoids, either in isolation or in a high yielding whole plant extract, may provide possible targeted relief from neurological disorders including autism. Much further research is required to translate some of the promising findings into ultimately proving the effectiveness of these compounds as treatment options but NTI believes that the combination of the Dolce cannabis strains and its proprietary Mente neurofeedback device may provide a unique research option which will be undertaken later in the year during clinical trials on the basis of in-vitro success.

While research on cannabis and autism is still in its early stages, a number of new studies are now in trial. (http://www.mammausa.org/human-clinical-trials-using-cannabis-for-autism.html) Israel (which legalised medical marijuana in 1992) is leading the way in researching the effectiveness of cannabis in reducing both seizures and behavioural challenges (https://www.freethink.com/articles/marijuana-and-autism).

In 2019, Israel's Ben Gurion University of the Negev released a study that shows a promising connection between cannabis and autism. The study followed 188 children with autism, aged 18 and under, for six months as they used cannabis oil for autism symptoms. The oil contained 30% cannabidiol oil (CBD) and 1.5% tetrahydrocannabinol (THC). According to the study, after six months of treatment more than 80% of participants reported "significant or moderate improvement".

Patients experienced various cognitive improvements including concentration and sleep. Behavioural challenges and co-morbidities often associated with autism, including seizures, restlessness, and rage attacks, were also significantly improved by the cannabis treatment according to the study. The study also found that cannabis also improved the ability to complete daily tasks such as the ability to dress and shower without help.

NTI's proposed trials are unique on a number of levels with the use of more esoteric cannabinoids (such as CBDV and CBG), lower THC and importantly, the use of the Company's Mente feedback device which can track actual brainwave responses as trials are undertaken.

#### Cannabidivarin (CBDV)

The clinical use of CBDV in epilepsy (https://pubmed.ncbi.nlm.nih.gov/28188044/) is well known and in Autism to a lesser extent to date given the timing of a number of recent studies commencing involving cannabinoids and autism.

While compounds such as THC modulate most of their physiological effects via binding with the CB1 and CB2 receptors, cannabinoids such as CBDV, which have anticonvulsant actions, use mechanisms not involving either receptor.

It is believed that CBDV's anti-epileptic activity is modulated by the cannabinoid's effects on the capsaicin receptor, TRPV1. Along with CBD, CBDV has shown an ability to dose-dependently activate and desensitise the TRPA1, TRPV1, and TRPV2 channels. By desensitizing these ion channels, these molecules cause a neuronal hyperexcitability reduction, a fact that helps reduce epileptic activity and associated seizures. This application then extends to Autism spectrum disorder (ASD) given that ASD and intractable childhood epilepsy

are closely connected.

The chemovar profiles of Dolce are unique in their properties and to NTI's knowledge, no studies have been undertaken with similar type profiles and a continued neuro feedback device. Targeted improvements in potential clinical studies would include social functioning, communication problems and repetitive behavioural issues.

#### Cannabigerol (CBG)

Unlike CBD, which has a relatively low affinity for cannabinoid receptors and acts mostly through indirect interactions with the endocannabinoid system, CBG is thought to elicit its therapeutic effects directly though interaction with the CB1 and CB2 cannabinoid receptors in the brain (https://www.crescolabs.com/cannabinoids/cbg/)

The psychoactive cannabinoid THC also produces its psychoactive effects though interactions with these receptors; CBG has been observed to work as a buffer to THC's psychactivity and can even alleviate the feelings of paranoia that sometimes come with consumption of high levels of THC.

Research is relatively sparse regarding the therapeutic benefits of CBG, when compared to the apparent wealth of information available on THC and CBD within the cannabis science community. But there are early studies linking the compound to a whole host of potential therapeutic uses including ASD treatments as part of a whole plant "entourage" approach with higher percentages of CBG. The Dolce chemovars assayed to date have shown significant commercial yields for CBG when compared to other available strains.

#### Agreement Terms

NTI has the right to acquire an exclusive worldwide licence to utilise Dolce's proprietary cannabis strains (both existing and new variations as developed) for medicinal use in treating autism, epilepsy and ADHD ('License') on the following basis:

- (a) paying a non-refundable deposit of \$50,000 to Dolce's nominated bank account on or before 10 July 2020;
- (b) expending \$200,000 in accordance with an agreed budget;
- (c) NTI to have standard rights of pre-emption and first rights of refusal in respect of Dolce's Cannabis Strains and all Intellectual Property Rights associated with the Cannabis Strains.
- (d) In consideration of NTI acquiring the licence, Dolce or its nominees will be entitled to be issued the following securities by NTI and grant of royalty as consideration:
  - i. 33,000,000 fully paid ordinary shares in NTI and 33,000,000 unlisted options (exercisable at \$0.01 each and expiring 31 Jan 2023);
  - ii. 33,000,000 fully paid ordinary shares in NTI upon successful stage 1 in-vitro assay assessments being completed;
  - iii. 33,000,000 fully paid ordinary shares in NTI upon successful stage 1 clinical trials being completed; and
  - iv. Dolce (or nominees) will also be entitled to a 2.5% net sales royalty in respect of all sales which utilise the cannabis strains for neuro disorders.

If at any time after spending the \$200,000 and issuing any of the shares as per clause (d) above, NTI elects not to pursue the project with continued funding and support, Dolce will have the right to buy back 100% of the project and all associated intellectual property by providing NTI with the royalty set out in clause (d) (iv) above. The royalty will be capped at \$5,000,000 if NTI has not spent more than \$1,000,000 in cash on the project before

Dolce elects to buy back in accordance with this clause.

#### Placement

In conjunction with the transaction, the Company has received firm commitments for a placement of 100 million shares at 0.5c per share to raise \$500,000. The funds will be applied to the above transaction, the Company's existing Mente operations and general working capital. The placement will be in two tranches with 32.25 million shares being issued under the Company's Listing Rule 7.1 capacity with the balance being subject to shareholder approval to be sought at a general meeting of shareholders to be called shortly. A prospectus for the placement will be issued shortly.

The Company has also agreed, subject to shareholder approval, to issue 5,000,000 shares and 5,000,000 options (exercisable at \$0.01 each and expiring 31 Jan 2023) to Crown Luggers Pty Ltd, the introducer of this acquisition opportunity.

#### **Conversion of Debt to Equity**

The Company will also seek shareholder approval for the issue of shares in lieu of debts owed to directors. Approval will be sought for the issue of shares at a deemed issue price equal of 0.802c per share (being the 5 day VWAP of trading in NTI shares leading up to this announcement) in satisfaction of \$283,500 in accrued directors fees.

#### Authority

This announcement has been authorised for release by the Board of Directors of the Company.

#### **Further Information**

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#### **About Neurotech**

Neurotech International Limited is a medical device and solutions company incorporated in Australia and operating through its wholly-owned, Malta-based subsidiary AAT Research Limited. Neurotech's primary mission is to improve the lives of people with neurological conditions, with in home-use and clinical neurotechnology solutions that are both accessible and affordable. Through flagship device Mente and its associated platform, Neurotech is focused on facilitating the development and commercialisation of technological solutions for the screening and treatment of symptoms associated with conditions such as autism. Mente is 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 and Mente Autism please visit:

http://www.neurotechinternational.com. http://www.mentetech.com.

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