Neurotech

30 July 2021

Quarterly Report for the period ended 30 June 2021

Highlights

- **Neurotech commenced world's first study to assess full spectrum medicinal cannabis naturally containing <0.3% THC in children with ASD.**
- **Clinical study is due to finish towards the end of calendar Q3 with final results available in calendar Q4 2021.**
- **Neurotech will use Phase I/II results to plan future Phase II/III registration studies.**
- **In separate highly successful preclinical studies, NTI/Dolce strains demonstrate potential benefits for management of Multiple Sclerosis (MS).**
- **Neurotech will complete preclinical studies next month and expects to initiate Phase I/II clinical trials in MS in Q1 CY2022.**
- **NTI is successfully building NTI/Dolce lead strain levels to maintain large stock volumes for future studies.**
- **Professor Allan Cripps AO appointed as a Non-Executive Director.**
- **Directors Bates, Cripps and Leedman purchase shares on-market.**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company") is pleased to present its quarterly report for the period ended 30 June 2021.

PHASE I/II OPEN LABEL STUDY IN CHILDREN WITH AUTISM

In May 2021, Neurotech commenced a Phase I/II open label clinical study in 20 children aged between 5-17 years with autism spectrum disorder (ASD). The study is being conducted under the guidance and supervision of Associate Professor Michael Fahey, Head of Paediatric Neurology Monash Children's Hospital. This is the first time that full spectrum <0.3% natural THC medicinal cannabis strains will be assessed in ASD.

The study involves daily administration of NTI / Dolce medicinal cannabis strains, delivered in a neutral tasting oil system and will measure standardised outcomes relating to behaviour, agitation, irritability and quality of life over 16 weeks, including a four-week washout period (no treatment).

NTI commenced discussions with the TGA and relevant regulatory agencies for the therapeutic expansion and registration of these novel full spectrum plants. Studies have been designed to assess dose escalation, efficacy and wash out period. All patients are being monitored and assessed by A/Prof Fahey and his team which is comprised of senior autism / behavioural clinical psychologists.

This study follows the successful completion of a series of in vitro studies that demonstrated that the NTI/Dolce strains, with the newly discovered rarer cannabinoids CBDP and CBDB, have powerful, unique properties that extend beyond CBD alone in results that are summarised below:

- Reduced inflammation within the brain cells;
- Improved mitochondrial viability in the presence of an external toxic insult (glutamate);
- Increased cell health and viability in the presence of an external insult;
- More potency than CBD isolate alone in all tests – between 30% to 80%;
- Increased number of mitochondrial cells without any toxic insult;
- Have no negative effects on cell health and maintain cell viability; and
- Demonstrate neuroprotective activity in the presence of insult.

In July 2021, the Company announced that the clinical study was progressing as planned with extensive medical data being collected and psychological assessments carried out throughout the program. The strong rigour and robustness of the study resulted in substantial support and interest from the hospital and clinical community. The Company is in discussion with various clinical and development groups to pave the way forward with respect to Phase III clinical trials and product registration program.

Furthermore, the data being collected by Neurotech through the trial will enable it to consider opportunities to achieve early, near-term cashflows via the development, production, and sale of an over the counter (OTC) CBD product (Registered Product). Given the unique profile of the NTI/Dolce strains (with naturally less than 0.3% THC) and subject to successful clinical trials, the Company is assessing an OTC (sold via pharmacy) neuro anti-inflammatory product which will target general health and well-being categories. Inflammation is now commonly accepted as the foundation or cause of many neurological illnesses. NTI/Dolce strains have demonstrated the ability to suppress and regulate neuro-inflammation in a range of pre-clinical studies and have been shown to be more effective than CBD alone.

Neurotech has also successfully scaled up production of NTI/Dolce lead strains with its partners Dolce Cann and CannaPacific Pty Ltd to ensure sufficient supply for the current study and enable the Company to expand its pre-clinical program to rapidly move to further human clinical studies.

POTENTIAL BENEFITS FOR MULTIPLE SCLEROSIS DISEASE MANAGEMENT

Neurotech has been undertaking a series of preclinical studies to assess the neuroprotective, anti- inflammatory and neuro-modulatory activities of the proprietary NTI/Dolce cannabis leads CBDA, CBDP, CBDB all with naturally less than 0.3% THC. These studies have been conducted at three leading independent laboratories – Monash University, University of Wollongong and RMIT University.

Multiple Sclerosis (MS) is a progressive inflammatory disease characterised by the loss of myelin sheath within the central nervous system. Typical symptoms include fatigue, walking difficulties, impaired speech and vision. Cyclooxygenase-2 (COX-2) is considered the main enzyme responsible for causing inflammation, the common mechanism of disease involved in MS. COX-2 is a powerful clinical biomarker in the assessment of disease progression and overall therapeutic management.

Therapies that can inhibit COX-2 provide promise in the overall management of MS. Studies published by various international groups confirm that COX-2 plays an important role in the progression of MS and adjunct therapies such as Non-Steroidal Anti-inflammatory Drugs (NSAIDs) can reduce fatigue and improve cognitive abilities.

Recently completed initial in vitro studies conducted in collaboration with the internationally recognised Neurodevelopment in Health & Disease Laboratory at RMIT University (Melbourne) demonstrated that NTI/Dolce Strains were significantly more potent than CBD alone in supressing the production of two key inflammatory neuro-markers.

These results, summarised in the table below, reconfirm the powerful neuro-modulatory, neuro-regulatory and neuro anti-inflammatory properties of the novel NTI/Dolce Strains (which comprise rich extract of CBDA, CBGA, CBDB, CBDP and <0.3% THC) compared to CBD alone which is limited in its cellular activity. These preclinical studies will pave the way for further expansion and analysis of other neuro- markers involved in MS.

Treatment	Neuro-Markers	
	GM-CSF NTI/Dolce Strain: Mean +/- SEM: 59.2 +/- 7.3 (p<0.001)	**TNF-alpha** NTI/Dolce Strain: Mean +/- SEM: 70.1 +/- 1.75 (p<0.001)
NTI/Dolce Strain	Significant suppression on the activity of neuro-marker: GM-CSF N=8 40% reduction	Significant suppression on the activity of neuro-marker: TNF-alpha N=8 30% reduction
CBD alone	N=8 No significant effect	N=8 No significant effect

- Studies were carried out using Multiplex Quantitation System. The system allows for the accurate measurement of these neuro-markers levels. Measurements are done via fluorescence and expressed as F1 values.
- Positive controls: Interleukin and Interferon activity at 100%.
- All results are compared to positive control expressed as 100% activation.

Key neuro-markers involved in the onset and progression of MS include:

- Granulocyte Granulocyte-macrophage colony-stimulating factor (GM-CSF)
- Tumour Necrosis Factor (TNF-alpha)
- Interferon (IFN)
- Interleukins (IL-2)

NTI is committed to the development of a pipeline that expands application and use of the NTI/Dolce strains beyond autism. Further preclinical studies will determine mode of action and safety to design a Phase I/II clinical study in MS. There are several very powerful neuro-markers currently being used to assess MS disease onset and progression. Being able suppress or regulate these markers may be very beneficial in the overall disease management.

Neurotech had further success with in-vitro studies using human brain cells to assess and validate the anti-inflammatory and neuro-modulatory properties of its proprietary NTI/Dolce cannabis leads. Preclinical studies targeting potential MS treatments demonstrated that NTI/Dolce cannabis strains can suppress and inhibit the expression of COX-2 in human derived microglial cells. When compared to CBD alone, NTI/Dolce strains were up to three times more powerful in supressing COX- 2 both pre and post inflammatory insult (refer table below).

N	Control Avg	DOLCE/NTI	CBD Avg	Positive control vs DOLCE/NTI treatment	Positive control vs CBD alone treatment
Exposure 1 hour prior to inflammatory insult					
9	94.47 +/- 5.90 (SEM)	53.67 +/- 6,41 (SEM)	84.82 +/- 7.65 (SEM)	P = 0.0003	P = 0.3237
Exposure 1 hour after inflammatory insult					
9	104.26 +/- 11.08 (SEM)	21.10 +/- 6.82 (SEM)	76.32 +/- 7.95 (SEM)	P <0.0001	P = 0.0566
- NTI/Dolce is more potent than CBD alone in suppressing COX-2 expression in human microglial cells. - DAPI cell viability stain: No cell death was detected and assessed as per the DAPI cell staining method. - Cells were viable throughout these in vitro studies. - Positive control/ Inflammatory activation: Interleukin and Interferon gamma					

Next stage pre-clinical studies will compare NTI/Dolce strains against current pharmaceutical treatment options which have multiple long term use side effect implications. These studies are expected to be completed in August 2021 and initiation of Phase I/II clinical trials in Q1 next calendar year.

CORPORATE

Board Updates

Neurotech appointed Professor Allan Cripps as a Non-Executive Director, effective from 19 May 2021.

Professor Allan Cripps AO is currently a Professor Emeritus in the School of Medicine and Dentistry and the Menzies Health Institute Queensland at Griffith University, Australia. He is a member of the Infection and Immunity Research Team at the Menzies Health Institute Queensland at Griffith University, Australia. He is recognised nationally and internationally as a distinguished academic, clinical scientist and health services leader and has made significant contributions in immunology, vaccine development, diagnostics health services delivery and professional health education. The focus of Professor Cripps' research activities over the last 5 decades have been in the field of immunology and inflammation. In 2015 he was awarded an Officer of the Order of Australia (AO) in recognition of his contributions to mucosal immunization, public health and higher education.

Professor Cripps has experience in the development of immunity in children and mucosal immune mechanisms, in recent years he has made a significant contribution to the field of immunology through translational research and human clinical studies. Professor Cripps is also a co-inventor on several patents in the fields of diagnostic technology and vaccine protein antigens for respiratory infection. He has published over 325 peer reviewed scientific papers and presented at many national and international scientific conferences.

In 2012 he launched the first international peer-reviewed journal exclusively focused on pneumonia as a means for bringing together knowledge related to pathogenesis, treatment and prevention of this disease and remains the Journal's Founding Editor. Pneumonia is the single largest cause of death in children globally.

Professor Cripps is a member of journal VACCINE Council of 100. This Council is made up of 100 of the world's leading vaccine researchers and clinicians and provides advice on vaccine development to both the Journal and other organisations globally. He is also a member of the Immunisation Coalition and a member of the Coalition's Scientific Advisory Committee and is currently appointed to industry advisory boards for advice on strategies related to the development of vaccines for respiratory infections in children and adults including those with chronic lung conditions.

NTI Chairman, Brian Leedman purchased shares on-market in June and Directors, Krista Bates and Allan Cripps purchased shares on-market in July.

Result of General Meeting

On 7 May 2021, Neurotech held a General Meeting of Members in Perth. All resolutions were passed via a poll.

The resolutions were, as follows:

1. Ratification of issue of Placement Shares to Placement Participants
2. Approval to issue Underwriting Options to Merchant Group Pty Ltd
3. Approval to issue Fee Options to Merchant Group Pty Ltd
4. Ratification of issue of Licensee Shares to Dolce Cann Pty Ltd
5. Approval to issue Performance Rights to Dolce Cann Pty Ltd for the Expanded Licence
6. Approval to issue Shares to CannaPacific Pty Ltd.

Operational expenditure and payments to related parties

As noted in its Appendix 4C, during the quarter the Company recorded a gross total (excluding revenue sources) of $918,000 in operational expenses. This was made up of research and development ($555,000), product manufacturing ($19,000), advertising and marketing ($23,000), staff costs ($69,000) and administrative and corporate costs ($252,000).

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate

to director fees ($63,000) and corporate services, accounting and company secretarial fees ($55,000).

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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Neurotech International Limited	
ABN	**Quarter ended ("current quarter")**
73 610 205 402	30 June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	12	42
1.2	Payments for		
	(a) research and development	(555)	(1,186)
	(b) product manufacturing and operating costs	(19)	(52)
	(c) advertising and marketing	(23)	(85)
	(d) leased assets	0	0
	(e) staff costs	(69)	(209)
	(f) administration and corporate costs	(252)	(919)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	0	0
1.5	Interest and other costs of finance paid	0	(2)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives	117	162
1.8	Other (VAT Refunds)	4	24
1.9	**Net cash from / (used in) operating activities**	**(785)**	**(2,225)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	0
	(d) investments	0	(70)
	(e) intellectual property	0	0
	(f) other non-current assets	0	0

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	23
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.3	Cash flows from loans to other entities	0	0
2.4	Dividends received (see note 3)	0	0
2.5	Other (provide details if material)	0	0
2.6	**Net cash from / (used in) investing activities**	**0**	**(47)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	5,000
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	2,172	2,621
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(116)	(478)
3.5	Proceeds from borrowings	0	100
3.6	Repayment of borrowings	0	(147)
3.7	Transaction costs related to loans and borrowings	0	0
3.8	Dividends paid	0	0
3.9	Other (provide details if material)	0	0
3.10	**Net cash from / (used in) financing activities**	**2,056**	**7,096**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,552	12
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(785)	(2,225)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	(47)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,056	7,096
4.5	Effect of movement in exchange rates on cash held	3	(10)
4.6	**Cash and cash equivalents at end of period**	**4,826**	**4,826**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	4,826	3,552
5.2	Call deposits	0	0
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,826**	**3,552**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	118
6.2	Aggregate amount of payments to related parties and their associates included in item 2	0

Payments at section 6.relate to director fees ($63,000) and corporate services, accounting and company secretarial fees ($55,000).

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	94	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	**Total financing facilities**	94	0

7.5	**Unused financing facilities available at quarter end**	94

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Overdraft facility with a limit of EUR 60,000. The lender is Bank of Valetta. The facility is unsecured. The interest rate is 5.65%.

The above values are stated in AUD, converted from EUR at an exchange rate of 0.6320.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(785)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,826
8.3	Unused finance facilities available at quarter end (item 7.5)	94
8.4	Total available funding (item 8.2 + item 8.3)	4,920
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.26

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
Answer: N/A	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30 July 2021
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Authorised by: The Board of Directors
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(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.