ASX Announcement

29 October 2021

Quarterly report for the period ended 30 Sept 2021

- **NTI is nearing the completion of its pivotal paediatric Phase I/II open label clinical study evaluating the use of its natural medicinal cannabis containing <0.3% THC NTI164 in children with Autism Spectrum Disorder (ASD).**
- **Recently completed NTI164 preclinical Multiple Sclerosis (MS) studies showed significant suppression of expression of key MS biomarkers.**
- **NTI164 shown to be more effective than CBD alone and CBD/THC by up to 2.5 times.**
- **Continued to pursue the development and commercialization of Mente, including combination therapies with the Company's cannabis strains.**
- **NTI/Dolce lead strains plant production scale-up is underway, enabling large stock volumes for future studies and commercial opportunities.**
- **Neurotech considering opportunities to achieve early near-term cashflows via the development, production and sale of an over the counter ("OTC") full plant cannabis product.**
- **First strategic provisional patent applications filed with IP Australia to underpin future world-wide patent families over the unique NTI/Dolce medicinal cannabis strains.**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company") is pleased to present its quarterly activities report for the period ended 30 September 2021, together with its Appendix 4C Quarterly Cash Flow Report.

During the September quarter, Neurotech focused on researching the use of cannabis to treat neurological conditions such as autism, MS, epilepsy, and attention deficit hyperactivity disorder (ADHD) to complement its Mente produce program and build on its existing work in the field of autism.

The data collected via Neurotech's preclinical studies using its lead cannabis strain, NTI164, which naturally contains <0.3% THC, has allowed Neurotech to consider opportunities to achieve early near-term cashflows via the development, production and sale of an over the counter ("OTC") or consumer *full plant cannabis* product ("Registered Product").

PHASE I/II OPEN LABEL STUDY IN CHILDREN WITH AUTISM

In July 2021, the Company announced that the pivotal paediatric study in ASD was progressing as planned with extensive medical data being collected, and psychological assessments carried out throughout the program.

The Phase I/II open label clinical study of 20 children aged between 5-17 years with ASD is being conducted under the guidance and supervision of Professor Michael Fahey, Head of Paediatric Neurology Monash

Children's Hospital. The strong study attracted substantial support and interest from the hospital and clinical community. The Company is in discussions with various clinical and development groups to pave the way forward with respect to Phase III clinical trials and related product registration programs.

The Phase I/II open label clinical results are expected in November 2021. Neurotech is now in the process of mapping out Phase III – multi cohort registration studies in ASD to be conducted as a follow up study to the current Phase I/II study. The Phase III program is scheduled to commence in early calendar 2022 and, in addition to the potential formal registration of NTI164 for paediatric ASD treatment, the Company will also consider other Neuro-Orphan diseases to provide urgent medical therapy for rarer neuro-disorders and accelerate the registration and development process by working under the FDA's Orphan Disease Development Category and TGA Special Access Scheme Category B

Given the unique profile of the NTI/Dolce strains (naturally having less than 0.3% THC) and subject to successful clinical trials, the Company is actively assessing near-term cashflow opportunities via an over-the counter (OTC) neuro anti-inflammatory product (sold via pharmacy) which will target general inflammatory conditions. 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.

PRECLINICAL STUDIES IN MULTIPLE SCLEROSIS

Recently completed NTI164 preclinical studies showed significant suppression of expression of key Multiple Sclerosis biomarkers, IL-12 and TNF-alpha. In human derived microglial cells, NTI164 was shown to be more effective than CBD alone, and CBD/THC by up to 2.5 times.

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.

Neurotech's initial in vitro studies into the use of its unique NTI164 strain which were 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.

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Preclinical studies have re-confirmed that NTI164 can significantly suppress the expression of key MS biomarkers, IL-12 and TNF-alpha in human derived microglial cells. The results show NTI164 to be more effective than CBD alone and CBD/THC by up to 2.5 times.

The results provide a unique opportunity for the development and commercialization of potential human therapy for the management of MS confirmed the potent anti-inflammatory and neuro-regulatory activity of the NTI164, specifically:

- NTI164 reduced the inflammatory cytokine IL-12 by 44%, substantially outperforming CBD alone (15% reduction) and CBD/THC in combination (19% reduction).

- NTI164 reduced the inflammatory cytokine TNF-alpha by 42%, outperforming CBD alone (29% reduction) and CBD/THC in combination (25% reduction).

These studies are an expansion of the earlier findings (refer ASX Announcement 25 May 2021) in which NTI164 significantly suppressed the expression of COX-2 inhibition in human derived microglial cells.

Cytokines play an important role in neuroinflammatory responses. Cytokines regulate the body's response to disease and infection, as well as mediate normal cellular processes in our body.[1]

Immune system dysregulation is believed to be a major underlying mechanism for MS and disease progression. IL-12 and TNF-alpha are both elevated in MS patients and are thought to play a major role in the pathology.

The global MS therapies market was valued at over $40 Billion USD in 2021 and is projected to reach $48 Billion USD by 2026[2]. Current therapies in the treatment of MS include steroid based medicines, disease - modifying therapies and more recently antibody-based therapies.

Sativex™ is the only medicinal cannabis-based FDA approved product for the treatment of MS[3]. The Company has assessed similar formulations in these preclinical models, 1:1 CBD/THC mixtures. Results have shown that NTI164 is significantly more effective in suppressing key biomarkers versus CBD/THC formulation.

Recent patent filings by NTI will also allow the Company to assess combination formulation options with NTI164 and proven MS therapies to improve treatment efficacy and reduce side effects. This strong preclinical data further supports the potent anti-inflammatory properties of NTI164 and broadens the potential applications to now include MS in addition to autism spectrum disorder (ASD).

Results Summary

Treatment	Cytokine	Results Expressed as: Average +/- Standard Deviation (SD)	Statistical Significance Reduction Compared to Control Alone
Control: Interleukin and Interferon Activation	IL-12 TNF -alpha	99.91 +/- 12.88 N=8	
NTI164	IL-12 TNF -alpha	56.30 +/-18.24 N=8 58.28 +/- 15.08 N=8	44% reduction, P=0.0001 42% reduction, P<0.0001
CBD alone	IL-12 TNF -alpha	84.40 +/- 6.54 N=8 71.13 +/- 12.81 N=8	15% reduction, P=0.008 29% reduction, P=0.0005
CBD /THC (1:1)	IL-12	80.77 +/- 12.23 N=8	19% reduction, P=0.008

[1] https://pubmed.ncbi.nlm.nih.gov/30447707/
[2] https://www.prnewswire.com/news-releases/multiple-sclerosis-drugs-market-size-worth--42-46-billion-globally-by-2028-at-6-3-cagr-verified-market-research-301352043.html
[3] https://mstrust.org.uk/a-z/sativex-nabiximols
#Impaired interleukin-12 production in multiple sclerosis patients C Rohowsky-Kochan 1, D Molinaro, A Choudhry, M Kahn, S D Cook https://pubmed.ncbi.nlm.nih.gov/10516776/

	TNF -alpha	74.49 +/- 14.30 N=8	25% reduction, P=0.01

The detailed assay results and key findings are contained in the Company's ASX announcement dated 22 October 2021. These preclinical studies have successfully paved the way forward to the further expansion of our knowledge base and the potential application of NTI's unique strains in the treatment of neuro-anti-inflammatory disorders.

CANNABIS STRAIN SUPPLY, PATENT & COMMERCIALISATION

In July 2020, the Group announced that it had secured an option to acquire an exclusive worldwide licence to use proprietary cannabis strains from Australian cannabis grower Dolce Cann Global Pty Ltd ("Dolce") for medicinal use in treating autism, epilepsy, ADHD and other complex neuro-disorders. NTI/Dolce strains are grown under a licensed and government approved facility at CannaPacific Pty Ltd in NSW.

Neurotech 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, and in order to rapidly move to further human clinical studies.

Subsequent to quarter end, NTI announced that it had filed its first strategic provisional patent applications with IP Australia to underpin future world-wide patent families in respect to research conducted into the novel neuro-regulatory and anti-inflammatory properties of the NTI/Dolce medicinal cannabis strains (Refer to ASX announcement dated 13 October 2021). The two patents have been lodged to cover:

1. Uniqueness of the NTI-164 strain – composition profile with low THC (<0.3%) and a unique combination of 'rarer' cannabinoids, and;
2. The application, formulation and use of the strain in relation to the treatment of a broad range of neuro-inflammatory disorders both on its own and in conjunction with current broadly available treatment options - 'combination treatment therapies'.

Having achieved this material milestone, NTI will now look to engage with potential commercial partners who recognise the value in the Company's provisional patent applications and explore opportunities to license its unique cannabis strains.

MENTE DEVICE

Neurotech has continued the development, and commercialisation of Mente, pursuing its business model including engaging with partners on sales and distribution, whilst also using Mente as part of its cannabis research to discover if a complimentary therapeutic benefit occurs when used in conjunction with the cannabis strains. It may also be used to monitor the progress of certain subjects.

CORPORATE

As at 30 September 2021, the Company had a strong cash at bank balance of $4.045 million, per the attached Appendix 4C.

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of $941,000 which was comprised of research and development ($616,000), product manufacturing ($4,000),

advertising and marketing ($43,000), staff costs ($49,000) and administrative and corporate costs ($229,000).

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees ($89,000) and corporate services, accounting and company secretarial fees ($37,000).

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

Further Information
Brian Leedman
Chairman
b.leedman@neurotechinternational.com
+61 (0)41 228 1780

Winton Willesee
Non-Executive Director
winton@azc.com.au
+61 (0)41 066 7844

Media:
Juliana Roadley
IR Department
juliana.roadley@irdepartment.com.au
+61 (0)41 488 9863

About Neurotech

Neurotech International Limited is a medical device and solutions company conducting clinical studies to assess the neuro-protective, anti-inflammatory and neuro-modulatory activities of our proprietary NTI/Dolce cannabis strains. 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 and Mente Autism please visit http://www.neurotechinternational.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 September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	15	15
1.2	Payments for		
	(a) research and development	(616)	(616)
	(b) product manufacturing and operating costs	(4)	(4)
	(c) advertising and marketing	(43)	(43)
	(d) leased assets	0	0
	(e) staff costs	(49)	(49)
	(f) administration and corporate costs	(229)	(229)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	0	0
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives	0	0
1.8	Other (VAT and BAS Refunds)	145	145
1.9	**Net cash from / (used in) operating activities**	**(782)**	**(782)**

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	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	0
	(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**	**0**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	0	0
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0	0
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	0	0
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**	**0**	**0**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,826	4,826
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(782)	(782)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	0

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	0	0
4.5	Effect of movement in exchange rates on cash held	1	1
4.6	**Cash and cash equivalents at end of period**	**4,045**	**4,045**

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	4,045	4,826
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,045**	**4,826**

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	126
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Payments at section 6.relate to director fees ($89,567) and corporate services, accounting and company secretarial fees ($36,645).

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	96	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	**Total financing facilities**	96	0

7.5	**Unused financing facilities available at quarter end**	96

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 0.6215.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(782)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,045
8.3	Unused finance facilities available at quarter end (item 7.5)	96
8.4	Total available funding (item 8.2 + item 8.3)	4,141
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.29

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: 29 October 2021
.....

Authorised by: The Board of Directors
.....
(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.