

Quarterly report for the period ended 31 Dec 2021

- Pivotal paediatric Phase I/II open label clinical study evaluating the safety and efficacy of NTI164 natural medicinal cannabis containing <0.3% THC in children with Autism Spectrum Disorder (ASD) nears completion with the majority of initial patients completing dosages under the trial due to complete this quarter.
- Two strategic first provisional patent applications filed with IP Australia to underpin future worldwide families, using the NTI/Dolce low THC (<0.3%) medicinal cannabis strains which contain many of the “novel” cannabinoids - CBDA, CBG, CBDB, CBDP, CBGA, CBN, CBC.
- Completion of preclinical studies assessing the effects of NTI164 against Cytokines in Multiple Sclerosis (MS) models. The studies were performed at RMIT University and Monash University. Results confirming NTI164’s potent anti-inflammatory and neuro-regulatory activity and the increased application of NTI164 across a range of significant neurological disorders.
- Preclinical studies demonstrated that NTI164 can significantly improve the efficacy of prednisone at low doses. Significant anti-inflammatory synergistic activity observed when NTI164 was combined with prednisone (at low doses). Reducing the prednisone dose whilst achieving increased efficacy could overcome many of the unwanted and dangerous side effects that are directly related to the dosage of prednisone.
- Strategic discussions commenced with a number of parties both in Australia and overseas with respect to potential collaboration opportunities for nutraceutical, therapeutic and pharmaceutical research and drug development opportunities.
- Recent international publications confirm NTI’s research data into the effects of its novel strains and will assist in fast tracking strategic negotiations with potential development partners.

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company") is pleased to present its quarterly activities report for the period ended 31 December 2021, together with its Appendix 4C Quarterly Cash Flow Report.

During the December quarter, Neurotech continued to expand and validate its preclinical program using lead NTI164 to treat neurological conditions such as autism, MS, epilepsy, and attention deficit hyperactivity disorder (ADHD). Further pre-clinical studies demonstrated that NTI164 could be used as a complimentary medicine to reduce dosage levels of steroid based drugs and increase efficacy. Two strategic first provisional patent applications were filed in the quarter enhancing the commercial applications of NTI164. The pivotal Autism (ASD) trial is nearing completion with the majority of initial patients completing dosages. COVID-19 has caused some delays given the study is being undertaken in Melbourne which has impacted patient site visits and reduced hospital capacity to support clinical trials. The Study is due to complete in the current

quarter. The world first trial will examine 85 data collection points per patient over the course of the study as well as full blood analysis to be examined by neuropsychologists and medical biostatisticians under the guidance of Professor Michael Fahey. Key outcomes will be used to fine tune and map out the next round of studies (either NTI alone or in collaboration with strategic partners) in ASD and other indications.

NTI164 is a novel cannabis strain developed by Dolce Cann Global that contains full spectrum plant composition with high levels of minor cannabinoids (including CBDA, CBG, CBDB, CBDP, CBGA, CBN, CBC) and less than 0.3% THC. Large scale grow is underway in preparation for a number of trials planned for this year.



NTI164 – Current cloning program



NTI164 – Current grow expansion program

MULTIPLE SCLEROSIS STUDIES COMPLETED

Multiple Sclerosis (MS) is a progressive inflammatory disease characterised by the loss of myelin sheath which results in complex neuro-inflammatory symptoms, such as spasticity, loss of movement and pain. 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.

In October, NTI completed preclinical Multiple Sclerosis studies using NTI164 in collaboration with RMIT University and Monash University. The studies assessed the effects of NTI164, NTI's proprietary medical cannabis strain, against cytokines in MS models.

Results confirmed the NTI164's potent anti-inflammatory and neuro-regulatory activity, 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 (ASX announcement 25 May 2021) in which NTI164 significantly suppressed the expression of COX-2 inhibition in human derived microglial cells.

This strong preclinical data further supports the potent anti-inflammatory properties of NTI164 and broadens potential applications for the drug candidate to now include MS, in addition to Autism Spectrum Disorder (ASD). The global MS therapies market was valued at over \$48 billion USD in 2026*¹. It remains an area of major unmet need.

PRECLINICAL STUDIES SHOW IMPROVED EFFICACY WITH PREDNISONE

In December, the Company announced that the preclinical studies demonstrated that NTI164 can improve the efficacy of prednisone at low doses (i.e. 5uM and 25uM). Significant anti-inflammatory synergistic activity was observed when NTI164 was combined with prednisone (at the low doses). These findings may have significant application with regards to the use of prednisone across a variety of indications. Importantly, the combination treatment and formulation fall under NTI's recently lodged patent applications (refer ASX announcement 14 October 2021).

NTI discovered that reducing the prednisone dose whilst achieving increased efficacy (with NTI164 compared to prednisone alone) could overcome many of the adverse side effects that are directly related to the dosage of prednisone².

The results provide NTI with an ideal platform to progress strategic partnerships and further expand its clinical trial portfolio. The prednisone / NTI164 study further expands NTI's preclinical portfolio allowing the Company to develop a solid pipeline of combination products using major off-patent generic actives with proven efficacy without side effects.

Table A: Summary of Results

Biomarker Analysis	Control PBS buffer	Inflammation only: Interleukin & Interferon activation	PDN 5uM concentration	PDN (5uM)+ NTI164 (7.5ug/ml)	Significance PDN vs PDN+NTI164	% Reduction in inflammation using combination therapy versus PDN alone
COX-2 Protein	0.799	1	0.888	0.586	P=0.0210 Significant	34%
+/- SEM	0.075	0	0.057	0.200		
TNF-a	20.33	45	30.17	20.33	P=0.0105 Significant	33%
+/- SEM	5.01	8.35	1.53	2.02		
IL-6	9.50	366.33	228.50	30.33	P=0.0002 Highly Significant	87%
+/- SEM	2.77	60.41	11.53	25.27		
IL-1a	77.5	154.83	144.5	69.00	P=0.0213 Significant	53%
+/- SEM	38.66	33.11	27.54	22.52		
GM-CSF	168.80	768.13	611.97	278.97	P=0.0398 Significant	54%
+/- SEM	83.29	294.36	375.14	138.58		

Prednisone belongs to a class of drugs known as Corticosteroids. Corticosteroids are drugs used in the management and treatment of almost all areas of medicine. Prednisone medication is used to treat a large variety of immune inflammatory conditions such as; autoimmune disorders, neurological disorders,

¹ <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>

² <https://www.medicalnewstoday.com/articles/prednisone-oral-tablet>

rheumatoid arthritis and multiple sclerosis. The corticosteroids market is expected to witness a CAGR of 4.3%, during the forecast period (2020-2025). Current market size is estimated at \$5Billion USD³.

FIRST PROVISIONAL PATENT APPLICATIONS FILED & COMMERCIALISATION

In October, the Company filed its first 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. The two patents lodged 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’.

The two provisional patent applications have been achieved in a little over 12 months of research and will assist with underpinning future world-wide patent families for NTI's key cannabinoid strain in respect of both composition and combination therapies with existing pharmaceutical treatments.

The applications will assist in current strategic partner discussions regarding commercialisation pathways, which include consideration of an OTC full plant cannabis product.

RECENT PUBLICATIONS SUPPORTING NTI RESEARCH AND DEVELOPMENT

Recent international publications confirm NTI's research data into the effects of its novel strains and will assist in fast tracking strategic negotiations with potential development partners.

In August 2021, the Lambert Institute published an article titled: An entourage effect⁴: new clues on how low-dose CBD products work". The findings reconfirmed NTI's results that full plant, low CBD hemp strains exhibit an entourage effect, which is more potent than CBD alone and leads to significantly greater potency. The study also validated and confirmed our findings that full extract, hemp plants (low CBD) provide a "Pharma-kinetic Entourage Effect" - Entourage effect has shown superior activity (versus CBD alone) across multiple indications: Pain, Inflammation, Epilepsy, Neuropathic Pain, Chronic Nausea, Mental Health ailments, i.e, ability to regulate depression and anxiety.

Published in the Journal of Natural Products in January 2022, the study found that the cannabinoids CBDA and CBGA can bind to the spike proteins of SARS-CoV-2, making it harder for the virus to enter cells and cause infection. The cannabis chemicals also bound well to the alpha and beta variants of Covid-19, leading the authors of the paper to claim that a combination of vaccination and CBDA/CBGA treatment could be a strategy going forward in the pandemic. CBN can help protect brain cells from oxidative damage and

³ <https://www.mordorintelligence.com/industry-reports/corticosteroids>

⁴ Jonathan C. Arnold, Assoc. Prof Pharmacology "Advancing our understanding of how full-spectrum CBD products work", August 2021.

preserve mitochondrial function – potential for treating age related neurodegenerative diseases such as Alzheimers and Parkinsons. (Salk Institute (US) – January 2022. Published in June 2021, preclinical data outlined the superior properties of CBG in reducing seizures versus CBD in various animal models. Published data in 2020 also showed that the “rare” cannabinoids such as, CBDP and CBDDB have potent (much greater than CBD) anti-inflammatory, anti-oxidant, anti-epileptic and anti-seizure activity.

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 31 December 2021, NTI had a strong cash balance of \$3.02 million, per the attached Appendix 4C.

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of \$1,117,000 which was comprised of research and development (\$814,000), product manufacturing (\$1,000), advertising and marketing (\$13,000), staff costs (\$35,000) and administrative and corporate costs (\$254,000).

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees (\$86,000) and corporate services, accounting and company secretarial fees (\$27,000).

Authority

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

Further Information

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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

73 610 205 402

Quarter ended ("current quarter")

31 December 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	14	29
1.2 Payments for		
(a) research and development	(814)	(1,430)
(b) product manufacturing and operating costs	(1)	(5)
(c) advertising and marketing	(13)	(56)
(d) leased assets	0	0
(e) staff costs	(35)	(84)
(f) administration and corporate costs	(254)	(483)
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)	(2)
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives	0	0
1.8 Other (VAT and BAS Refunds)	82	227
1.9 Net cash from / (used in) operating activities	(1,022)	(1,804)
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	(8)	(8)
(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 (6 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	(8)	(8)

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	12	12
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	12	12

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,045	4,826
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,022)	(1,804)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(8)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	12	12
4.5	Effect of movement in exchange rates on cash held	(2)	(1)
4.6	Cash and cash equivalents at end of period	3,025	3,025

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	3,025	4,045
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)	3,025	4,045

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	113
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
<p>Payments at section 6. relate to director fees (\$86,000) and corporate services, accounting and company secretarial fees (\$27,000).</p>		

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
7.1 Loan facilities	93	0
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
7.4 Total financing facilities	93	0
7.5 Unused financing facilities available at quarter end		93
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 0.6411.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,022)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,025
8.3 Unused finance facilities available at quarter end (item 7.5)	93
8.4 Total available funding (item 8.2 + item 8.3)	3,118
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.05
<i>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.</i>	
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: 31 January 2022
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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.