

Quarterly Activities Report for the period ending 30 June 2022

HIGHLIGHTS

- NTI progressed a successful landmark study in Paediatric Autism Spectrum Disorder ('ASD') using NTI164.
 - Study protocol modified for the "wash out" period to be removed from the study to accommodate the ongoing treatment of study participants at the demand of parents/caretakers, the Principal Investigator and HREC at Monash Children's Hospital.
- Development with NTI164 combination therapy program – when combined with NTI164, Diclofenac's effect was significantly enhanced, showing a 93% reduction in the expression of TNF-alpha, 80% reduction in the expression of IL-6 as well as 38% - 66% reduction in other key biomarkers.
- Post quarter end, NTI received breakthrough results with 93% of patients showing symptoms improvement relating to the severity of illness after 28 days of daily treatment with NTI164.
 - Two patients recorded a Marked Therapeutic Index Score of 2 = vast improvement meaning: complete or near remission of all symptoms.
 - Ten patients recorded a Moderate Therapeutic Index Score of 5 & 6 = representing "Decided improvement" – Partial remission of symptoms.
 - The average rating for the severity of illness at baseline was 4.4 and reduced to 3.6 after treatment.
 - NTI164 was well-tolerated – No serious adverse events were recorded across all doses (5, 10, 15 and 20 mg/kg).

Neurotech International Limited (ASX: NTI) ('Neurotech', 'NTI' or 'the Company') is pleased to provide an update on its activities during the quarter ended 30 June 2022.

Landmark Paediatric ASD Study Using NTI164¹

During the quarter, NTI progressed its pivotal paediatric study in Autism Spectrum Disorder ("ASD") during the pre-clinical Phase I/II stage. The study had been designed to rigorously assess the safety and tolerability of NTI164 in a dose-escalation regime and to evaluate behaviours, focus and cognitive parameters using validated neuropsychological tools. The study was also designed to provide the foundation for follow up studies in the treatment of neurological disorders such as Multiple Sclerosis, Attention Deficit Hyperactivity Disorder (ADHD), Motor Neuron Disease, and Cerebral Palsy.

NTI164 is one of NTI's proprietary cannabis strains, exclusively licenced from Dolce Cann Global (Ltd), in respect of neurological applications and is the world's first full-spectrum medicinal cannabis product (less than 0.3% THC) to be successfully studied in children with ASD.

¹ ASX Announcement 12 May 2022 - Key Development in Current Paediatric Autism Spectrum Disorder Study

The study was conducted by Professor Michael Fahey, Head of Paediatric Neurology at Monash Children's Hospital in Melbourne.

The only drug currently approved by the FDA for children with ASD is Risperidone. Given the NTI trial results to date showed no serious adverse side effects and significant positive outcomes, the Company is positive about the potential success of a future phase II/III clinical studies in ASD.

"Wash Out Period" Removed from ASD Study Design²

In May 2022, Neurotech announced important developments relating to the study protocol assessing NTI164 in children with autism spectrum disorder (ASD). Due to the significant number of requests from patient's parents/caretakers, the Principal Investigator and Human Research Ethics Committee (HREC) at Monash Children's Hospital, the study protocol was modified to accommodate the ongoing treatment of study participants using NTI164.

The original study design was developed in line with similar study protocols whereby participants would undertake a "wash out period", where they reduce and subsequently stop taking the trial treatment. However, as a result of the positive impacts that the treatment was having on the children's 'overall functioning', patient parents and caretakers requested that the "wash out" period be removed from the study protocol. The patients remain on treatment and continue to be monitored and treated under the guidance of Prof. M. Fahey and the Neuro-psychology team at Monash Children's Hospital.

Preclinical Success with NTI164 + Diclofenac³

In June 2022, Neurotech reported positive preclinical research demonstrating that NTI164 can improve Diclofenac efficacy at low doses.

The results indicated that when NTI164 was coupled with Diclofenac, significant anti-inflammatory synergistic action was seen (at low doses). As previously stated, lowering the Diclofenac dose while increasing efficacy could alleviate many of the negative side effects that are directly tied to Diclofenac dosage. Importantly, NTI's provisional patents include the combination treatment and formulation.⁴

These findings could have far-reaching implications for the use of Diclofenac across a variety of applications and give NTI an excellent foundation on which to build strategic alliances and extend its clinical portfolio.

The Diclofenac + NTI164 combination therapy trial adds to NTI's preclinical portfolio, allowing the Company to build a strong pipeline of combination pharmaceuticals based on significant off-patent generic actives that have demonstrated efficacy and tolerability. In order to further develop and commercialise combination therapies, the Company plans to accelerate commercial negotiations with potential strategic partners.

² ASX Announcement 12 May 2022 - Key Development in Current Paediatric Autism Spectrum Disorder Study

³ ASX Announcement 9 June 2022 - Preclinical Success with Targeted Combination Therapies

⁴ ASX Announcement 14 October 2021 - Provisional Patent Lodgements

Table 1: A Summary of Results

Cytokine	Control	Inflammation only	Diclofenac	Diclofenac + NTI164	Significance Diclofenac vs Diclofenac+NTI 164	% Reduction in Inflammation Diclofenac + NTI versus Diclofenac
Cox 2 PROTEIN	0.755	1	0.565	0.350	P=0.05	38%
+/- SEM	0.046	0	0.184	0.058		
TNF-a	12.55	258.05	228.8	15.55	P<0.001	93%
+/- SEM	2.65	1.83	5.307	5.51		
IL-6	4.75	262.05	200.3	40.3	P<0.001	80%
+/- SEM	9.40	42.25	30.21	8.64		
IL-1a	31.25	79.5	70.50	34	P<0.001	52%
+/- SEM	1.02	6.95	3.674	1.62		
GM-CSF	46	356.5	477.75	164.50	P=0.001	66%
+/- SEM	2.44	57.56	43.88	36.55		

Results are expressed as: Average +/- SEM (standard error of mean)

Treatment groups include:

Control: PBS Buffer

Positive control: Inflammatory stimulation by Interferon gamma and Interleukin – 1B

activation Diclofenac concentration 5uM

Combination therapy: Diclofenac 5uM + NTI164 concentration 7.5ug/ml

Result Analysis:

Calculated as % reduction in inflammation, Diclofenac versus Combination therapy (Diclofenac 5uM + NTI164 concentration 7.5ug/ml).

Student's t-test was used for statistical analysis.

EVENTS AFTER THE REPORTING PERIOD

Breakthrough Results with NTI164 in Paediatric ASD⁵

Post quarter end, Neurotech announced breakthrough results from their landmark ASD study with successful outcomes relating to the safety, tolerability, and efficacy of NTI164 on key behavioural parameters that impact ASD patients.

The safety data concluded that NTI164 at 5, 10, 15 and 20mg/kg administered in two doses daily, was safe and well-tolerated in the study population. The efficacy data demonstrated statistical significance at 28 days of treatment. 93% (13 out of 14 active patients) showed symptom improvement relating to severity of illness after 28 days of daily treatment with NTI164. The results also demonstrated:

GLOBAL IMPROVEMENT

- 64% of patients had a global improvement of "much improved"
- 29% of patients had a global improvement of "minimally improved"
- 7% of patients had "no change"

THERAPEUTIC EFFECT (EFFICACY INDEX)

- Two patients recorded a Marked Therapeutic Index Score of 2, representing vast improvement meaning: complete or near remission of all symptoms.
- Ten patients recorded a Moderate Therapeutic Index Score of 5 & 6, representing "Decided improvement" meaning: partial remission of symptoms.

⁵ ASX Announcement 8 July 2022 – Breakthrough Results with NTI164 in Paediatric ASD

Importantly, parental/carer observations also indicated consistent improvement in the trial participant's 'overall functioning' when compared to baseline at the commencement of the trial. The average rating for the severity of illness at baseline was 4.4 (out of a score of 7 meaning "extremely ill" and 1 meaning, "not ill") and this score was reduced to 3.6 after 28 days of NTI164 treatment.

Specific instances of markedly improved behaviours (i.e. reduction in fear, agitation and anxiety) were observed and will be the key focus of the upcoming Phase II/III registration trials due to commence in calendar Q3 in 2022. The study has been granted HREC approval to continue for a further year due to the positive therapeutic effects of NTI164 combined with feedback from parents and clinicians and their recent request for no "washout" period. Safety and efficacy assessments will continue.

CORPORATE ACTIVITY

Commentary in relation to Appendix 4C

As at 30 June 2022, NTI had a cash balance of \$1.89 million, per the attached Appendix 4C.

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of \$1,112,000 which was comprised of research and development (\$664,000), product manufacturing (\$3,000), advertising and marketing (\$55,000), staff costs (\$77,000) and administrative and corporate costs (\$313,000). Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees (\$81,000) and corporate services, accounting and company secretarial fees (\$26,000).

Authority

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

Further Information

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About Neurotech

Neurotech International Limited (ASX:NTI) is a biopharmaceutical company focused on the development and commercialisation of neurological solutions that improve quality of life. Neurotech is currently conducting world-first clinical trials to assess the potential application of NTI164 for the treatment of Autism Spectrum Disorder (ASD). Results of Phase I/II indicated that 93% of participants had notable improvements relating to the severity of illness with no serious side effects. The next step will be initiation of Phase II/III of the trial to further assess the long-term safety and efficacy of NTI164, with the potential to lead to drug registration. The Company has also submitted key, provisional patents relating to the composition and use of NTI164 to treat various neurological disorders, including ASD.

For more information about Neurotech and Mente Autism, please visit 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")

30 June 2022

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	6	44
1.2 Payments for		
(a) research and development	(664)	(2602)
(b) product manufacturing and operating costs	(3)	(9)
(c) advertising and marketing	(55)	(112)
(d) leased assets	0	0
(e) staff costs	(77)	(197)
(f) administration and corporate costs	(313)	(1036)
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)	(4)
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives (R&D Rebate)	569	569
1.8 Other (VAT and GST Refunds)	94	399
1.9 Net cash from / (used in) operating activities	(444)	(2,948)

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	(8)
(d) investments	0	0
(e) intellectual property	0	0

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(f) other non-current assets	0	0
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	(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	0	27
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	27

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,335	4,826
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(444)	(2,948)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	(8)

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)	0	27
4.5	Effect of movement in exchange rates on cash held	0	(6)
4.6	Cash and cash equivalents at end of period	1,891	1,891

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	1,876	2,335
5.2	Call deposits	15	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)	1,891	2,335

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	107
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 (\$81,000) and corporate services, accounting and company secretarial fees (\$26,000).		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	91	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	Total financing facilities	91	0
7.5	Unused financing facilities available at quarter end		91
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 0.6589.			

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(444)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,891
8.3	Unused finance facilities available at quarter end (item 7.5)	91
8.4	Total available funding (item 8.2 + item 8.3)	1,982
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.46
<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: 29 July 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.